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# Regulating Food in the EC and in the WTO

## *A Comparative Legal Analysis*

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*A Gianfranco e Biancamaria,*
*senza il cuo incondizionato*
*sostegno e sconfinato amore*
*questa tesi mai avrebbe potuto*
*vedere la luce.*

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"**Salus populi suprema lex esto**"

Cicero, *De Legibus*, Liber Tertius

# *Introduction*

The last decade has witnessed a rise of genuine concerns for the quality and safety of the food we eat. While food safety has always been the focus of regulatory attention[1], the recent food crisis that have outraged Europe have shown that to regulate the food sector only through the economic lens of the internal market could have been inadequate to address the new challenges brought by the generally new perception of risks. As a result, the reformed European regulation of food aims at assuring "a high level of protection of human health and consumers' interests in relation to food, by taking into account in particular the diversity of supply of food including traditional products, whilst ensuring the effective functioning of the internal market"[2].

The objective of this study is to explore the evolution of the European regulation of food - from the adoption of the first directives in the matter to the establishment of the European Food Safety Authority - within the broader framework set by the WTO Agreements. After having analyzed in detail the interpretation and application of the main provisions relating to food existing in the two systems, this study offers a comparison between these two emerging food safety regimes.

In this introductory chapter defining the scope and the structure of the research (C) a justification for such an attempted comparison will be provided, together with its underlying methodology (B). But first, one may legitimately wonder why to pick up the

[1] For an overview of early food regulations, see, e.g., P. Barton Hutt and R.A. Merril, *Food & Drug Law*, Cases and Materials, II[ed.], New York, Foundation Press, 1991.

[2] Article 2 of Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, in O.J. 2002 L31 (hereinafter: the 'general food law regulation' or, merely, the 'Regulation'). Also available at http://europa. eu.int/comm/food/fs/efa

regulation of food as the main subject for writing a PhD thesis in international economic law. Several reasons may be adduced to justify this choice (A).

## A. WHY FOOD LAW?

First, this dynamic and emotive area of law does not only provide for an excellent vehicle for understanding the evolution of the European integration process, by illustrating the progressive abandonment of the original functionalist approach to integration, but it also represents a mini-history of European law. As all EC law students are aware of, an entire course of European law may successfully be taught by focusing exclusively on the European Court of Justice's case law developed on foods, such as pasta, feta or chocolate, and drinks, such as Cassis de Dijon, beer or spirits. However, no food may better explain the evolution of EC food law than British beef. In short, looking into food policy enables to retrace how, why and by whom European policies develop.

Second, over the last decade the food safety crises that have outraged Europe have invested the EC institutions with the challenge of developing an appropriate risk regulation model. For its effectiveness and speediness, this process may be seen as a model for the conception and the development of new EC policies. In less than five years, the Community managed to develop not only an institutional reform of its food policy, symbolized by the establishment of the European Food Safety Authority (EFSA), but also to combine this innovation with a profound regulatory reform paving the way for the launch of the first EC model for risk analysis, which is addressed not solely to the EC institutions but also to its Member States. In the light of the above, food law, being now an autonomous branch of EC law, provides a privileged perspective from which to examine the development of an emerging European risk analysis framework.

Third, the production and consumption of food play a crucial role to any society. On any day every European citizen requires food, and more than 10 million of them work for the Agro-Food sector[3]. The food and industry is a leading industrial sector in the European

[3] While it is estimated that more than 4 million workers are employed by the Food and drink industry, around 7 million work in the agricultural sector. See Confederation of the Food and Drink Industries (CIAA) of the EU Key Figures, 15 November 2005 available at http://www.ciaa.be/pages_en/news_events/news_list.asp?news

Union with an annual production worth almost 800 billion[4]. This amounts to almost 15 per cent of total manufacturing output in the EU. The agricultural sector has an annual production of more than 220 billion.

Fourth, being this area of EC law subject to the WTO rules, it offers the chance to analyze the WTO framework for food safety (as provided for by the Sanitary and Phytosanitary Agreement (SPS)) and, accordingly, to single out the main points of tensions existing between the reformed EC food safety regime and the WTO obligations. The Uruguay Round sketched out a set of legal obligations constraining Member States' ability to regulate the food sector, by paving the way for the development of a risk analysis model mandating the use of risk management science-based measures. This discipline has to be enforced through a strengthened dispute settlement mechanism to prevent countries from misusing their measures. During the first 10 years of WTO more than 40 disputes have arisen over food measures and, although most of them have not led to the adoption of a report, more than 20 found their origin in complaints brought against the EC[5]. This shows how the WTO represents an inescapable dimension for a full understanding of the EC food regime.

Fifth, the prescribed science-based character of food safety measures in both the EC and WTO legal systems raises one of the most difficult and unexplored aspects of the controversial relationship between law and science: the judicial review of regulations based on scientific evidence. How a judge, by definition a non scientist, may conduct an assessment on whether a measure is scientifically supported? Which is the level of intensity of the scrutiny that this judge may exert over the risk regulation being reviewed? These questions are currently sources of endlessly controversy in the international legal arena[6] and at the centre of some international trade disputes[7].

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_id=168 and A. Barthelemy, *Changes in agricultural employment*, available at http://europa.eu.int/comm/agriculture/envir/report/en/emplo_en/ report_ en.htm, respectively.

[4] See the Confederation of the Food and Drink Industries of the EU Key Figures, 15 November 2005, available at http://www.ciaa.be/ pages_en/news_events/news_list.asp?news_id=168

[5] See A.R. Young and P. Holmes, *Protection or Protectionism? EU Food Safety Rules and the WTO*, in D. Vogel and C. Ansell (eds.), *European Food Safety Regulation: The challenge of Multi-level Governance*, MIT Press, forthcoming (2006) and T. Jostling, D. Roberts and D. Orden, *Food Regulation and Trade, Toward a Safe and Open Global System*, (Institute for International Economics, Washington, D.C., 2004), at 63-68.

[6] See C.D. Ehlermann, *Six Years on the Bench of the "World Trade Court": Some Personal Experiences as Member of the Appellate Body of the World Trade Organization*, in 36 J. World Trade (2002) 605, at 612-13, who, while leaving the organ, has noted that "during the last months, the question of standard of review has thus become one of the most controversial aspects of the Appellate Body's jurisprudence".

Last, but not least, it is believed that, in what must be viewed as a delicate moment in the European project, with integration put somewhat on the back burner, the new European food safety regime and the establishment of the EFSA may contribute to regain EU's popular legitimacy, by effectively responding to citizens' concerns, thus proving a system capable of reconciling scientific expertise, traditions and free movement.

## B. WHY A COMPARISON BETWEEN THE EC AND THE WTO?

Rather than focusing on each specific piece of legislation relating to food, this study takes a comparative outlook, by making an attempt to identify the main points of tension existing between the EC food regime and the WTO law. The decision to take such a comparative perspective reflects the conviction according to which "one can no longer disregard the doctrinal developments of the WTO even if one's primary interest rests in the doctrinal market of the EU"[8]. This statement best illustrates Weiler's vision of the emergence of a nascent Common Law of International Trade. Without going so far as to unconditionally embrace this vision, which still sounds more a prediction than a tangible truth, this study relies on this emerging comparative method by applying it to the food sector[9].

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[7] In May, 2003, the US, Canada, and Argentina filed a complaint at the World Trade Organization (WTO), alleging that European restrictions (notably, the EC general moratoria, the product specific moratoria and the national bans) on the importation of genetically modified organisms (GMO) violate WTO rules, notably several SPS provisions. These violations can be divided into two groups: violations of procedural requirements (Article 8 and Annex B, Article 7 and Annex C) and violations of substantive obligations (Article 5.1 and Article 2.2). These alleged violations would entail a disguised restriction on international trade in accordance with Article 5.5 and Article 2.3 of the SPS Agreement. See Request for Consultations by Argentina, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS293/1, 2003 WL 21191302 (WTO May 21, 2003); Request for Consultations by Canada, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS292/1, 2003 WL 21180725 (WTO May 21, 2003); Request for Consultations by the United States, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/1, 2003 WL 21180726 (WTO May 20, 2003) [hereinafter *Biotech case*]. For an excellent background report on this pending case, see *U.S. vs. EC Biotech Products Case – WTO Dispute Backgrounder*, The Institute for Agriculture and Trade Policy, September 2005.

[8] J.H.H. Weiler, *Cain and Abel – Convergence and Divergence in International Trade Law*, in J.H.H. Weiler (ed.), *The EU, the WTO, and the NAFTA, Towards a Common Law of International Trade?*, (Oxford:2000).

[9] There already exists a growing number of comparative studies following this innovative EC/WTO perspective. While some of them concern either the different liberalization tools and 'constitutional dimension' of the two legal systems, others focus on some specific common substantive areas, such as environmental protection, public health, trade in services and taxation. Among the former studies see, apart from the abovementioned leading Weiler's book, e.g., G. De Burca and J. Scott (eds.), *The EU and the WTO: Legal and Constitutional Aspects* (Oxford, Hart Publishing, 2001); N. Emiliou and D. O'Keefe (eds.), *The European Union and World Trade Law: After the Uruguay Round* (London, John Wiley and Sons, 1996); J. Scott, *GATT and Community Law: Rethinking the 'Regulatory Gap'*, in Shaw and More (eds.), *New Legal Dynamics of EU*, 1995, and the

During recent years, we have assisted not only to a 'juridification' of the GATT/WTO legal framework[10], but we have also witnessed a certain degree of convergence in the substantive law areas between EC and WTO legal systems. Thus, apart from the introduction of a compulsory and automatic decision-making process settlement disputes system[11], based on a two-tier mechanism of panels of first instance and a permanent Appellate Body (AB), the WTO Agreements represent a departure from the traditional GATT-type framework, by moving beyond matters dealing with market access to deal with issues of national regulation. In particular, notwithstanding its less evolved normative framework, it will be shown that the WTO is not only going beyond non-discrimination but it is also developing some tools of positive integration whose ambitions are similar to those pursued by the EC harmonisation instruments.

Finally, being the EC a full Member of the WTO, and therefore bound by its agreements, it may be useful to analyze the WTO food safety regime (part II) in order to determine to what extent the current EC discipline, as established by general food law regulation, may be held compatible with the WTO regime (part IV). In particular, this study will emphasize some points of tensions currently existing between the two legal orders.

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more recent F. Ortino, *Basic Legal Instruments for the Liberalization of Trade* (Oxford and Portland Oregon, 2004). In particular with regard to the environmental field, see, e.g., N. Notaro, *Judicial Approaches to Trade and the Environment: The EC and the WTO, alias the Comparative Disadvantage of Dolphins and Turtles* (London, Cameron May International Law Publishers, 2003); J. Wiers, *Trade and the Environment in the EC and in the WTO: A Legal Analysis* (Groningen, Europa Law Publishing, 2002); E. Neumayer, *Greening the WTO Agreements – Can the Treaty Establishing the European Community be of Guidance?*, 35 Journal of World Trade (2001) at 145 and D. Esty and D. Geradin, *Market Access, Competitiviness, and Harmonization: Environmental Protection in Regional Trade Agreements*, 21 Harvard Environmental Law Review (1997) at 265. In the public health field, M.M. Slotboom, *Do Public Health Measures Receive Similar Treatment in European Community and World Trade Organisation Law?*, in Journal of World Trade (2003) 553 and C. Button, *The Power to protect* (Oxford and Portland, Oregon, 2004). With regard the liberalization of services, see, e.g., L. Radicati di Bronzolo, *Un primo confronto tra la liberalizzazione delle telecomunicazioni nel sistema del WTO e della Comunità europea*, in SIDI (Società Italiana di Diritto Internazionale), *Diritto ed organizzazione del commercio internazionale dopo la creazione della Organizzazione Mondiale del Commercio* (Milano, Editoriale Scientifica, 1998) and P. Eekhout, *Constitutional Concepts for Free Trade in Services*, in G. De Burca and J. Scott (eds.), *The EU and the WTO: Legal and Constitutional Aspects* (Oxford, Hart Publishing, 2001). And, finally, with regard the taxation field, see, for instance, P.J. Kuyper, *Booze and Fast Cars: Tax Discrimination Under GATT and the EC*, 23 Legal Issues of European Integration (1996) at 129.

[10] See, e.g., C. Joerges and J. Neyer, *Politics, Risk Management, World Trade Organisation Governance and the Limits of Legalisation*, in Science and Public Policy, June 2003, at 221, who argue that both politics are based on the idea according to which intergovernmental bargaining should follow legal principles and that non-partisan bodies, such as the ECJ and the WTO DSB, should adjudicate if the disputing parties are unable to compromise in accordance with those legal principles.

[11] The adoption of panel reports by the DSB cannot longer be blocked by the losing party as it was the case under the GATT system. A refusal of the report is possible only within 30 days of circulation by consensus (thus including also the highly improbable vote of the winning party). See, Articles 16.4 and 17.14 DSU. For an overview of the DSS, see G. Sacerdoti, Il sistema di soluzione delle controversie dell'Organizzazione Mondiale del Commercio a dieci anni dalla sua istituzione, in La Comunità internazionale, 3, 2005.

## C. STRUCTURE OF THE RESEARCH

Before starting off the analysis of the EC and WTO regulations of food, it is necessary to sketch out a tentative scheme for our comparative analysis of the two systems, by focusing notably on their respective regulatory frameworks, risk analysis schemes and standards of judicial review employed by their respective courts. A special attention will be given thoroughout this study to the role played by science within both food regimes.

This work is divided in four parts.

Part I is entirely devoted to an analysis of the evolution of European food safety regulation, from the adoption of the first directives in the matter to the establishment of the European Food Safety Authority.

Chapter 1 provides an account of the historical shift that has occurred in the European food policy in the wake of the food scandals. It identifies four different eras in the evolution of the EC food policy: the 'Genesis', starting from 1962 through the mid-80s; the 'New Approach', which developed between the Single European Act of 1986 and the *BSE*'s crisis of 1997 (BSE stands for Bovine Spongiform Encephalopathy and has been commonly referred to as "Mad Cow Disease"); the 'Emergency', lasting from 1997 to 2001; and, finally, the current phase: the 'Global approach' to food safety.

Chapter 2 focuses on the current new regulatory regime stemming from regulation 178/2002 laying down the general principles of EC Food law and establishing the EFSA (hereinafter the "general food law regulation" or, merely, the "Regulation").

Chapter 3 is entirely dedicated to the EFSA. After providing a detailed description of its origins and institutional structure, the analysis will shift to the EFSA's substantive powers, stressing, when necessary, its main differences with the U.S. Food and Drug Administration (FDA). This chapter, by taking a rather critical stance on the EFSA's organizational independence, looks at the composition of its organs and brings into light the "grey areas" existing in its relationship with the EC Commission. It finally offers some elements for a comparison between EFSA and its US counterpart.

Part II deals with the broader context of the multilateral regulation of food provided by the WTO/SPS Agreements. Before introducing the reader to the main obligations

imposed by the SPS Agreement, an attempt is made to illustrate the different logics governing the EC and WTO regimes for food safety.

While Chapter 1 provides for an historical background of the GATT/WTO provisions dealing with food safety, the following chapter illustrates the main obligations stemming from the EC full membership to the WTO, by analyzing their scope as defined by the relevant WTO courts' case law.

Where the previous two parts provide an in-depth analysis of the food safety regulatory disciplines existing within the EC and the WTO, Part III expands on that analysis by examining how these disciplines have been judicially reviewed by their respective courts. Chapter 1 sums up the main food safety obligations imposed by both regimes on their respective Member States, by focusing notably on the scientific justification requirement. Chapter 2, after having introduced the reader to the issue of judicial review of food safety measures, examines the standards of review developed by the EC and the WTO courts while called upon scrutinizing the legality of food safety regulations.

Finally, Part IV, by building upon the previous parts, ventures a comparison between the EC and WTO food safety regimes in order to show the main points of tension existing between them.

In particular, Chapter 1 provides for a comparison between the EC and WTO food disciplines, by looking at their respective goals and at their instruments. Chapter 2 furthers this exam by notably comparing their food safety risk analysis models thus identifying the main points of tensions existing between the two regimes: the role of "other legitimate factors" in risk analysis and the status of the "precautionary principle". Due to the lack of risk management policy within the WTO/SPS risk analysis model, the analysis expands, when appropriate, on the Codex' principles for risk analysis. Chapter 3 offers then a comparison of the standards of review applied by the EC courts and the WTO judicial bodies, by focusing notably on the respective level of scientific involvement required from them. After having analyzed the WTO expert consultation practice, it lastly formulates some proposals aimed at reorienting the role of the WTO and EC judicial bodies in order to make them less involved with science while reviewing science-based measures.

# PART I: THE EUROPEAN FOOD REGULATION

## CHAPTER I: THE EVOLUTION OF EUROPEAN FOOD LAW: ITS FOUR MAJOR ERAS OF DEVELOPMENT

For the purpose of this chapter, I identify four main periods in the evolution of the EC food policy. The first phase is the 'Genesis' stretching from 1962 to the mid-1980s. During this foundational period, the Community, animated by the goal of establishing an internal market for foodstuffs, pursued a detailed harmonization program consisting in the adoption of directives setting up compositional standards for individual foods. The second period, the 'New Approach', developed between the Single European Act of 1986 and the *BSE*'s blow of 1997. This phase is characterized by the introduction of an innovative approach to harmonization based on the mutual recognition principle combined with the use of the minimum harmonization method. The *BSE* and other food scandals triggered the development of a third phase: the 'Europeanization of food risk', lasting from 1997 to 2001. During these years the Commission transformed its policy efforts expressed in its communications into a concrete legislative proposal laying down a new food safety regime for Europe in order to avoid the balkanization of the internal market. The entry into force of Regulation 178/2002 and the establishment of the European Food Safety Authority symbolize the current phase: the 'Global approach' to food safety.

## 1. THE 'GENESIS': THE FREE MOVEMENT OF GOODS AND THE EUROPEAN "STANDARDS OF IDENTITY" (1962 - 1985)

As the Treaty of Rome[12] did not contain any expressed legal basis for the establishment of a common food policy, the existing EC food legislation has come into being as a result of both the application of the common market prohibitions and the gradual harmonization of national rules which was necessary in order to guarantee the free movement of foodstuffs and prevent distortions of competition in the establishment of the single market[13]. However, the Founding Fathers affirmed in the Preamble of the Treaty of Rome that the "essential objective of their efforts" was "the constant improvements of the living and working conditions of their peoples" and for that reasons they entrusted the Community with the task to promote a "harmonious, balanced and sustainable development of economic activities"[14]. Against this backdrop, the Community could develop, by relying on a variety of different legal basis provided in the Treaty, a European regulation in the food sector.

### 1.1 The internal market and the free movement rules

The creation of a common market lies at the heart of the EC. Article 2 says that the Community has as its task the establishment of a common market, and one of the activities of the Community listed in Article 3 is the creation of an

> "internal market characterized by the abolition, as between Member States, of obstacles to the free movement of goods, persons, services and capitals".

[12] Treaty establishing the European Community (hereinafter "ECT"), consolidated version published on the O.J. (C- 325) 24 Dec. 2002, *available at* http://europa.eu.int/eur-lex/en/treaties/dat/EC_consol.pdf

[13] On the gradual widening of Community policies to non-economic sectors, see J.H.H.Weiler, *The Transformation of Europe*, 100 Yale Law Journal, at 2403. For a reconstruction of the birth and evolution of EC food policy, see P. Deboyser, *Le droit communautaire relative aux denrées alimentaires*, Story-Scientia, Louvain-La-Neuve, 1989 and L. Azoulay, *La Sécurité alimentaire dans la législation communautaire, in J. Bourrinet & F. Snyder, La sécurité alimentaire dans l'Union européenne* 95, at 30 (Bruylant ed., 2003), at 32.

[14] Article 2 EC.

The free movement of goods is therefore only one of the EC's main instruments for achieving the creation of the internal market[15] as

> "an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured"[16].

While free trade agreements (FTA) and custom unions (CU) focus solely on the free movement of products, a common market allows for the free movement of production factors (workers and capitals) as well as products[17]. In order to achieve the objective of the creation of the internal market and to ensure the free movement of production factors two sets of rules are provided within the Treaty: "negative integration" and "positive integration" provisions[18]. While the former consists in a set of prohibitions aimed at eliminating a number of impediments to the proper operation of an integrated area, such as the internal market, the latter consists in measures allowing for the creation of new policies (*see* Diagram 1).

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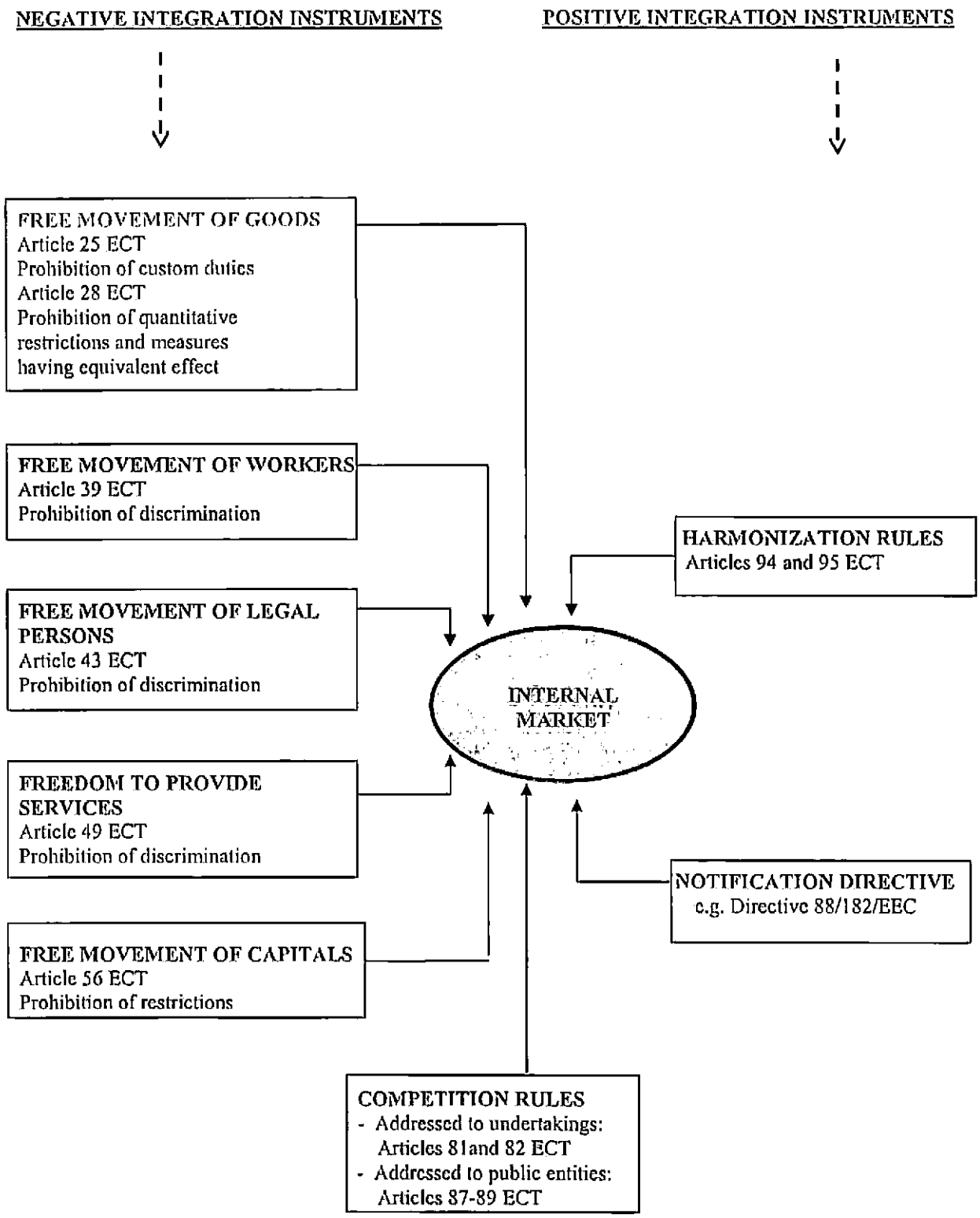
[15] On the importance of the common market in goods in European constitutionalism, see J.H.H. Weiler, *The Constitution of the Common Market Place: Text and Context in the Evolution of Free Movement of Goods*, in P. Craig and G. De Burca (eds.), *The Evolution of EU Law*, (OUP Oxford 1999), 349; M. Poiares Maduro, *We the Court*, Hart Publishing, Portland, 1999.

[16] Article 14.2 EC.

[17] According to the levels of intensity of market integration, there exist different forms of integration: a FTA is characterized by a common internal policy (free movement of goods between participating States) but different external policies (each State retains competence to regulate trade with third countries); a CU is similar to an FTA internally, but differs from an FTA externally because its States have a common commercial policy vis-à-vis non-Members). Both forms have been originally recognized by Article XXIV GATT as an exception to the MFN principle and therefore subject to several conditions of validity.

[18] The distinction between negative and positive integration was originally formulated by Jan Tinbergen, *International Economic Integration* 76 (2d ed. 1965).

**Diagram 1.** The structure and the main provisions of the internal market according to Tinbergen's dichotomial view of integration.



Foodstuffs, being goods within the meaning of the ECT, are subject to both the "negative integration" provisions of Articles 28-30 prohibiting quantitative restrictions on imports and exports or measures having an equivalent effect, and to the "positive integration" Articles 94-95 of the ECT, which allow the EC institutions "to adopt the measures for the approximations of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market".

### A. Negative integration: the scope and application of Article 28 EC

Article 28 enjoins Member States from imposing quantitative restrictions (QRs) on imports or measures having an equivalent effect (MEE)[19]. According to this general principle of Community law[20], Member States are prohibited from hindering the entry of goods from other Member States into their territories, unless their measures can be saved by one of the grounds of derogation listed in Article 30.

Similarly, Articles 39, 43, 49 and 56 limit the Member States' ability to adopt measures capable of restricting intra-Community trade in order to allow for the free movement not only of goods, but also of natural and legal persons, services and capitals. As the Court put it in *Gaston Schul*, the aim of the negative integration provisions is to eliminate

> "all obstacles to intra-community trade in order to merge the national markets into a single market bringing about conditions as close as possible for those of a genuine internal market"[21].

While quantitative restrictions have been easily defined by the ECJ as those "rules restricting the importation (or exportation) of one or more product according to quantitative norms"[22], the interpretation of "measures having an equivalent effect" has

[19] Similarly, Article 29 requires that any restrictions on exports and measures having an equivalent effect should be abolished.
[20] Case 240/83 Association de défense des brûleurs d'huiles usagées (ADBHU) [1985] E.C.R. 531, at 584. All EC Courts judgments are available at http://www.curia.eu.int
[21] Case 15/81 Gaston Schul Douane Expediteur BV v. Inspecteur der Invoerrechten en Accijnzen, Roosendaal [1982] ECR 1409, para 33.

proved more difficult. Accordingly, being the scope of Article 28 at stake, a vast ECJ's case law has developed on this notion.

Before moving to illustrate this case law, the next paragraph introduces to Article 30, which allows Member States, under specific severely restricted conditions, to make exceptions to the prohibition of quantitative restrictions.

*1. The exceptions: Article 30 EC*

The prohibition established in Article 28 EC suffers the exceptions laid down in Article 30, enumerating the grounds which justify trade barriers:

- public morality;
- public policy or public security:
- *the protection of health and life of humans*, animals or plants;
- the protection of national treasures possessing artistic, historic or archaeological value or the protection of industrial and commercial property.

Thus, Member States are allowed to maintain national measures aimed at protecting the health and life of humans.

The generous wording of this article clearly showed that large sectors of non-economic regulation, such as public health and food policy, were regarded as a matter remaining in the hands of the Member States. Thus, domestic trade-restrictive measures which by themselves infringe Article 28 EC may nevertheless be lawful if they are justified on grounds of public health. However, the second sentence of Article 30 EC, similarly to the chapeau of Article XX GATT[23], adds that those restrictive measures "shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States". The interpretation of this requirement has given rise to the

[22] Case 2/73 Geddo [1973] ECR 865.

[23] Note, however, that: a) in Article 30, contrary to Article XX, there is no reference to the notion of "unjustifiable discrimination"; b) the list of Article XX GATT covers a larger sets of non-economic interests; c) Article XX requires that trade restrictive measures be either "necessary, essential or related" to one of the justifications rather that merely "justified on grounds of " (however, this textual difference has been overcome by the introduction of the proportionality principle).

"proportionality principle", according to which a national regulation grounded on public health will only be considered lawful under Article 30 EC if it is restricted to what is actually necessary to secure this protective goal. Thus, this principle limits the availability of the public policy exceptions by imposing a Member State that has a choice between various measures to attain the same objective to choose the measure that least restricts the free movement of goods.

### *2. Case law developed on Article 28*

*Dassonville*

In the 1974 *Dassonville* case[24], the ECJ gave a broad definition of the notion of "measure having an equivalent effect to a quantitative restriction" concept by holding that:

> "all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having an equivalent effect to quantitative restrictions".

This case concerned parallel imports of Scotch whisky into Belgium. Belgium legislation required all whisky sold within its territory to be accompanied by a certificate of origin. Mr Dassonville, who bought Scotch whisky in France for re-importation into Belgium, was accused of fraud as he could not obtain the British certificates of origin in France. The Belgian court, being asked to condemn him for fraud, submitted the question to the ECJ. The Belgian measure was found as falling within the scope of Article 28 and thus prohibited. In particular, the Court stated that this provision could not been applied to Scotch whisky which had been lawfully imported and put into free circulation in France and re-exported to Belgium, because it was much more difficult to obtain the certificate of origin for whisky imported in Belgium by way of a third country than for direct imports from Scotland. The ECJ ruled that the Belgian legislation in fact was a hindrance to trade.

[24] Case 8/74 Dassonville [1974] ECR 837.

The wide interpretation given by the Court in this landmark case amounts to saying that even rules which are not designed to restrict cross-border transactions may hinder the free movement of goods. Any sovereign measure, likely even only indirectly or potentially[25], to negatively affect the flow of goods between States is, in principle, a prohibited measure having equivalent effect.

As such, these measures come under the Court's scrutiny ex Article 28, thus restraining MS's regulatory capacity[26]. The consequence of this ruling was that overnight, thousands of national laws and regulations relating to imported products fell within the scope of the provisions contained in Articles 28-30 EC.

This basic rule has been repeated by the Court in a large numbers of later judgments, and continues to be the ritual starting point for the Court's analysis of national measures under Article 28[27].

*Cassis de Dijon*

After having developed such a "broad, catch-all criterion", the Court faced a dilemma if it did not want to subject the Member States' power to regulate to the complete control of Article 28. Either it could have restricted the notion of measure having an equivalent effect or it could have extended the list of justification contained in Article 30.

With the well-known judgment in the 'Cassis de Dijon' case of 1979[28], the Court did essentially the latter, thereby laying the foundations for a new approach to the harmonization policy in the area of free movement of good[29].

This case involved a German law which prohibited the marketing of liqueurs with alcohol strength of less than 25%. Rewe-Central AG introduced an authorization before the German authorities to import from France a liqueur, Cassis de Dijon[30]. As Cassis contains only 15-20% by volume of alcohol, the authorities informed the importer that the liqueur could not be sold in Germany. Although there were some exceptions to the German

[25] Thus, the ECJ, by relying on the Dassonville formula, has held that a French rule on the composition of foie gras breached Article 28 altough very little foie gras was produced in other Member States (the national measure was found to be "capable of hindering, at least potentially, inter-State trade"). Case C-184/96 Commission v. France (foie gras) [1998] ECR-I-6197, para. 17.

[26] Case 178/84, Commission v. Germany [1987] ECR 1227.

[27] Among the last judgements, see, e.g., Case C-20/03, Burmanjer, [2005] not yet reported.

[28] Case 120/78, Rewe-Zentrale AG v. Bundesmonopolverwaltung fur Brantwein, [1979] E.C.R. 649.

[29] See infra paragraph 3, The New Approach.

[30] Crème de Cassis is a blackcurrant liqueur.

minimum alcohol content regulations, the company was told that Cassis was not one of them.

A German national court referred the question to the ECJ as to whether the national legislation was consistent with Article 28 EC. The Court found that the German legislation produced a restrictive effect, regardless of the fact it was not discriminatory, to the extent it amounted to a *de facto* prohibition of Cassis in the German market. In particular, facing for the first time a measure applicable without distinction to domestic and imported products, the Court stated that:

> - first, in the absence of Community regulations in manufacture and marketing, it is up to Member States to enact the relevant regulations for their territory; and
> - second, that barriers to community internal trade arising from these (inevitably) different national regulations must be accepted as long as these provisions are necessary in order to meet binding requirements, notably the requirements of effective tax control, public health protection, the integrity of trade and consumer protection.

In the light of the above, it concluded by stating that

> "the requirements relating to the minimum content of alcohol beverages do not serve a purpose which is in the general interest such as to take precedence over the requirements of free movement of goods, which constitutes one of the fundamental rules of the Community".

In view of an increasing number of obstacles to the free movement of goods stemming for regulatory divergence, the Commission took *Cassis* as a basis for developing the principle of mutual recognition and explained it to Member States, the European Parliament and the Council in its well-known 1980 communication[31].

It was there established that

> "The principles deduced by the Court imply that a Member State may not in principle prohibit the sale in its territory of a product lawfully produced and marketed

[31] Communication on the mutual recognition principle, OJ C256, 3 October 1980, at 2-3.

in another Member State even if the product is produced according to technical or quality requirements which differ from those imposed on its domestic products. Where a product fulfills the legitimate objectives of a Member State's own rules (public safety, protection of the consumer or the environment, etc.), the importing country cannot justify prohibiting its sale in its territory by claiming that the way it fulfills the objectives is different from that imposed on domestic products".

These "legitimate objectives" are the so-called mandatory requirements.
At the same time, the Court in Cassis also gave some clarification to the exceptions recognized by Article 30 EC. The German government tried to justify its measure under the public health ground by arguing that a limitless authorization for liqueurs of different alcoholic strengths would have led to an increase in consumption of alcohol as a whole and, accordingly, to increase the dangers of alcoholism in the population. The Court held that such considerations could not be

"decisive since the consumer can obtain on the market an extremely wide range of weakly or moderately alcoholic products and furthermore a large proportion of alcoholic beverages with a high alcoholic content freely sold on the German market is generally consumed in a diluted form"[32].

In the absence of Community harmonization with regard to a certain product, Member States are at liberty, in principle, to choose the level of protection of public health they intend to assure within their own territory. They may, for instance, establish a procedure under which prior authorization is required for the marketing of foodstuffs authorised in other Member States. This freedom is, however, restricted by Article 28 governing the free movement of goods within the EC. That means that, in our example, recourse to a system of pre-market approval is compatible with the requirements of the free movement of goods only if it is justified by the aim of protecting public health and proportionate to the objective envisaged[33]. In other words, the Member State should invoke Article 30 and

[32] Case 120/78, Rewe-Zentrale AG [1979] ECR para 11.
[33] This case law has originally developed in the pesticides sector (Case 272/80, Frans-Nederlandse Maatschappij Voor Biologische Producten [1981] ECR 3277, para 12), but it has been extended to vitamines (Case 174/82, Sandoz [1983] ECR 2445, para 18) and to the additives (Case 247/84 Motte [1985] ECR 3887, para 20). For a most recent application of this principle, see Case C-443/02, Schreiber [2004] not yet reported, where a national

to show that the objective of protecting health cannot be achieved by having recourse to a less trade-restrictive procedure.

*Keck*

The *Keck* judgment represents the last of the three landmarks decisions defining the scope of Article 28 EC[34]. After having given a broad intepretation of this prohibition, by including within its scope also indistinctly applicable measures, if they could not be explained by mandatory requirements, the ECJ felt the need to limit this broad approach by stating that "certain selling arrangements" (that is, measures concerning the circumstances of selling the goods) are not covered by Article 28 EC.

The opportunity for this historical *revirement* came in a case involving the prosecution of Mr Keck and Mr Mithouart for having resold products at a price lower than their actual purchase price. The question referred to the Court was whether the French legislation prohibiting "resale at loss" was compatible with Article 28 EC.

"[C]ontrary to what has previously been decided", the Court held that

> "the application to products from other Member States of national provisions restricting or prohibiting certain selling arrangements is not such as to hinder directly or indirectly, actually or potentially, trade between Member States within the meaning of the Dassonville judgment [...], so long as those provisions apply to all relevant traders operating within the national territory and so long as they affect in the same manner, in law and in fact, the marketing of domestic products and of those from other Member States".

Moreover, the Court held that

> "[p]rovided that those conditions are fulfilled, the application of such rules to the sale of products from another Member State meeting the requirements laid down by that State is not by nature such as to prevent their access to the market or to impede access any more than it impedes the access of domestic products. Such rules therefore fall outside the scope of Article 30 of the Treaty"[35].

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measure introducing a market authorization procedure for the marketing of blocks of red cedar wood having natural anti-moth properties has been held to comply with EC law.

[34] Joined Cases C-267 and 268/91 Keck and Mithouard [1993] ECR I-6097.

[35] *Ibid.*, paras 16-17.

These two paragraphs of the *Keck* judgment have indisputably been the most commented ever in the ECJ's case law and they still are the subject of discussion. What it sure is that this judgment represents a severe constraint to the *Dassonville* catch-all formula, by ruling out from the scope of Article 28 all indistinctly applicable selling arrangements. What is not clear is whether the market access criterion developed as an obiter dictum in paragraph 17 of the Keck judgment is presently the test applied by the Court[36].

### B. Positive integration rules: Articles 94 and 95 EC

As previously stated, to ensure the establishment of an internal market and the realization of the free movement of goods the Treaty also provides for positive integration rules. This on the assumption that Treaty prohibitions, being by definition limited to an ex-post application, do not suffice *per se* to attain this goal[37].

Since the divergence existing among national food provisions appeared to be the main obstacles to achieve a single marketplace for foodstuffs, it was necessary to proceed to the harmonization of these legislations. To take but an example, it became apparent that, in the absence of any coordination, a given food would need to meet the standards set by the different national product safety rules in order to enter their markets. More specifically, as these food safety provisions were likely to constitute justified barriers to trade under Article 30, the only manner to remove such obstacles was by means of Community harmonized rules. One of the main avenues for Community intervention was Article 100 (current Article 94) of the original Treaty of Rome, allowing the EC institutions to adopt directives aimed at harmonizing national provisions that "directly affect the establishment or functioning of the common market" (notably this Article reads: "The Council shall, acting *unanimously* on a proposal from the Commission and after consulting the European Parliament and the Economic and Social Committee, issue directives for the approximation of such laws, regulations or administrative provisions of

[36] For an innovative reading of the Keck jurisprudence see Case C-20/03, Burmanjer, not yet reported, as commented by A. Alemanno, *Libre circulation des marchandises: arrêt Burmanjer*, in Revue du droit de l'Union européenne, 02/05, at 392.

[37] This proved to be true even after the ECJ gave a broad interpretation to Article 28 of the EEC Treaty, thus limiting the Member States' room for manoeuvre.

the Member States as directly affect the establishment or functioning of the common market").

In the words of the ECJ, while

> "the purpose of Article 28 is, save for certain specific exceptions, to abolish in the immediate future all quantitative restrictions on the imports of goods and all measures having an equivalent effect", " [...] the general purpose of Article 100 is, by approximating the laws, regulations and administrative provisions of the Member States, to enable obstacles of whatever kind arising from disparities between them to be reduced"[38].

The Community could also relied on Article 235 (current Article 308) EC that, by providing a legal basis for measures which could not prove a direct link to the establishment or functioning of the internal market, allows the EC institutions to intervene when the Community's action is necessary to attain one of the objectives for which the Treaty has not provided a necessary power. Unlike Article 100, it requires a looser link with the common market and allows the adoption of "all appropriate measures".

Although the original EEC Treaty had envisaged to set up such positive integration rules, the legal bases provided (notably Articles 100 and 235) required unanimous voting in Council, thus weakening their utility. Only in 1987, the Single European Act incorporated, in line with the Community's "New Approach on Technical Harmonization and Standards", Article 100A (current Article 95) into the Treaty[39]. This new 'harmonization provision', by requiring a qualified majority in the legislative process instead of unanimity, paved the way to a smoother harmonization process. However, the price to be paid for the introduction of a qualified majority voting in the Treaty was the insertion of an expressed provision (current paragraph 4 of this article) allowing Member

[38] Case 193/80, Commission v. Italy, ECR [1980] 3019.

[39] For an overview on the safeguard clauses of Article 95 EC and the related interpretative problems, see, e.g., P. Oliver, *Free Movement of Goods in the European Community*, 2003, p. 466 ; N. De Sadeleer, *Les clauses de sauvegarde prévues à l'article 95 du Traité CE*, *Revue trimestrielle de droit européen*, 38, 2002, 63; R. Verheyen, *The Environmental Guarantee in European Law and the New Article 95 EC in practice – A Critique*, *RECIEL*, 1/2000, p. 180-187; H. G. Sevenster, *The Environmental Guarantee after Amsterdam: Does the Emperor have New Clothes ?*, *Yearbook of European Environmental Law*, 2000, vol. I, p. 236. For an analysis of the conditions of application of Article 95, paragraph 4, see Opinion by AG Tizzano in Case C-3/00, [2003] *Denmark v. Commission*. For a critical comment on this opinion and the final judgement, see A. Alemanno, Case C-3/00, [2003] *Denmark v. Commission*, in *Revue du Droit de l'Union Européenne*, 02/03.

States to derogate from a measure adopted under Article 100A (current Article 95) in specific circumstances[40]. In the words of AG Saggio (Case C-319/97, Aklagaren v Antoine Kortas [1999]), the introduction of such a safeguard clause

> "essentially serves to offset the mechanism requiring a qualified majority, which, although it has led to a notable increase in the efficiency of the decision-making process for establishing the internal market, has on the other hand entailed a sacrifice of national interests which merit protection".

Although initially this derogation was confined to national measures existing at the time when the harmonized directive was adopted, the Amsterdam Treaty extended the possibility to derogate from harmonized measures also to national regulations adopted after the enactment of the Community measure[41]. Hence, current Article 95(5) allows Member States "to introduce national provisions based on new scientific evidence [...] on grounds of problem specific to that Member State arising after the adoption of the harmonization measure". Despite some alarming reactions by some commentators[42], Article 95(4) and (5) have not often been invoked by Member States[43].

In particular, Article 95(8) states that where a problem relating to public health is raised by a Member State in a field which has been the subject of prior harmonization measures,

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[40] While the safeguard clause contained in paragraph 4 had been introduced by the 1987 Single European Act, the one expressed within paragraph 5 has been inserted ten years later by the Amsterdam Treaty, which has redesigned the whole provision. Paragraph 4, on the one hand, retains the same invocability conditions (the protection of the interests mentioned in Article 30 EC and and the protection of the environment or working enviornment), paragraph 5, on the other hand, imposes stricter limitations on the introduction of national measures after harmonization. These measures must be "based on nes scientific evidence relating to the protection of the environment or the working environment", on the grounds of a problem specific to that Member State which has arisen after the adoption of a Community measure.

[41] However, according to AG Tizzano, the original paragraph 4 of Article 95 "ne se limitait pas du tput à l'hypothèse du "maintien" de règles nationales par dérogation à l'harmonization; au contraire, il se référait plus généralement au cas où un Etat membre entendrait « appliquer » lesdits règles, se sorte que cette disposition avait déjà un caractère englobant par rapport à l'une et à l'autre hypothèses considérées : à savoir tant le maintien de règles préexistantes que l'introduction de règles nouvelles' (Opinion in Case C-3/00, [2003] *Denmark v. Commission*). For a critical comment on this opinion and the final judgement, see A. Alemanno, Case C-3/00, [2003] *Denmark v. Commission*, supra note 39.

[42] See, e.g., P. Pescatore, *Some Critical Remarks on the European Single Act*, in 9 Common Market Law Review 1987.

[43] See, on this point, A. Alemanno, supra note 39. For a detailed analysis of the safeguard clauses contained in Article 95, focusing on their origin, functioning and their current practice, see N. de Sadeleer, *Les clauses de sauvegarde prévues à l'article 95 du Traité CE – L'efficacité du marché intérieur en porte-à-faux avec les intérets nationaux dignes de protection*, in Revue trimestrielle du droit européenne, 38 (1), 2002. For a more recent analysis of the Commission practice developed on Article 95(4) and (5), see J. Scott and E. Vos, *The Juridification of Uncertainity: Observations of the Ambivalence of the Precautionary Principle within the EU and the WTO*, in Joerges C. and Dehousse, Good Governance in Europe's Integrated Market, 2002, footonote 63.

it needs to bring this matter to the attention of the Commission which should immediately examine whether it is necessary to propose appropriate measures aimed at tackling the newly emerged problem. A combined reading of paragraphs 5 and 8 would seem to exclude the possibility of introducing new unilateral measures in the public health field.

*Other positive integration rules*

Although under the original Treaty of Rome the Community largely relied on Articles 100 and 235, rules applicable to foodstuffs have developed from a variety of different legal bases provided in the Treaty, in order to serve different policy objectives[44]. Among the most common legal basis for the adoption of EC food legislation: Article 152, for the adoption of measures in the veterinary and phytosanitary fields whose direct objective is to protect public health[45]; Article 153 relating to consumer protection measures[46] and Article 37, for the replacement of national market organizations by common organizations and the adoption of legislative when agricultural aspects predominate.

The EC Treaty contains a separate title on agriculture, Articles 32-38, which constitute the Common Agricultural Policy (CAP). The CAP's main objectives differ from the Community's food law objectives as they focus mainly on promoting the increase of agricultural productivity and on ensuring a fair living for the agricultural community. However, although consumer and public health protection is not mentioned explicitly as one of the CAP's objectives, the Community has enacted a great deal of legislation for common market organizations covering nearly all agricultural products, for instance, eggs, bananas and wine[47]. Delimitation between food law in a strict sense and CAP can be recognized by means of the Treaty basis of legislative instruments. While food law legislation is based on Article 100A (94) and 100 (95) EC Treaty, CAP legislation is

[44] The EC food legislation is also based on a complex division of responsibilities between the Commission and the Member States. It is therefore no surprise that the Community lacked for more than 40 years of a coherent policy towards the foodstuffs sector as a whole, and approached the different aspects of food safety in an uncoordinated fashion. See, *e.g.*, M. Lugt, *Enforcing European and National Food Law in the Netherlands and England*, at 254 (Koninklijke Vermande ed., 1999).

[45] These measures may derogate from the Common Agricultural Policy and fall under the co-decision procedure. Possible examples of such measures are legislation involving zoonoses, BSE or resues of veterinary medicines or pesticides.

[46] This article, as reformulated after Amsterdam, improves the protection of consumers because it obliges the Community to contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organize themselves in order to safeguard their interests.

[47] Regulation 2771/75 of the Council of 29 October 1975 on the common organization of the market of eggs, OJ L282/49; Council Regulation 822/87 of 16 March 1987 on the Common organization of the market of wine, OJ L84/1; Council Regulation 404/93 on the Common organization of the market in bananas, OJ L47/1.

based on Article 43 EC. Some legislations show that the Council and the Commission choose to use Article 43 EC when the legislative measure involves agricultural products, these being agro-food and foodstuffs in a strict sense, as well as agricultural products only. However, more and more often, measures based on Article 43 do not solely involve CAP objectives, but also other objectives such as consumer protection.

Due to the introduction of Article 95 (formerly Article 100A) in the EC Treaty, there are no longer any differences in the decision procedures between Article 43 and 95. The only remaining difference involves the European Parliament (EP): while Article 43 only requires consultation with the EP, according to Article 95 the cooperation of the EP is required.

### C. Conclusions on the genesis

The Community has stepped in the regulation of food safety by pursuing, primarily, the goal of eliminating the trade barriers arising from diverging food national measures and, secondly, the aim of laying down a proper food policy throughout Europe. Thus, the EC food law has traditionally been conceived as a set of rules prompted mainly by the desire to eliminate trade obstacles within the European internal market[48] and having the force of law in all Member States. Like several other European policies, the legislative framework of food law has been primarily designed to answer economic rather than safety or societal concerns. In fact, apart from the health and life exceptions to the prohibition laid down in Article 30, the Treaty did not provide for a specific power of the Community in this area until the adoption of the Single European Act (1986) and the Maastricht Treaty (1992)[49].

We have seen that the Community involvement in health and consumer protection, notably in the food area, found its roots not only in the combined use of both negative and positive integration measures, but also in other sources. To determine the correct legal basis for health and consumer regulation, notably for food safety legislation, is of great importance in light of the principle of enumerated powers contained in the Treaty.

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[48] The original Treaty of Rome, signed by Belgium, France, Germany, Italy, Luxembourg and the Netherlands in 1957, provided that in order to establish a common market Member States should eliminate customs duties and quantitative restrictions applied between them and approximate their legislations to the extent required for the functioning of the common market. See Article 2 ECT.

[49] Following the entry into force of the Maastricht Treaty (1992), the Community has acquired new responsibilities to contribute to the attainment of high level of human health protection (Article 129), of protection of consumers (Article 129a) and of the environment (Article 130r).

According to this principle, every binding Community act must rely on a direct or indirect legal basis in the provisions of the Treaty itself. This requirement pursues two main functions: an instrumental and a guarantee function. EC institutions must refer to a legal basis first to show that they are performing their tasks in accordance with the Community objectives set forth in Article 2 EC, but also to demonstrate that no decisions are taken where the Community lacks competence[50].

We will see that for almost three decades the EC maintained this "economic" approach to food law, by using Article 100 (current Article 94) of the EC Treaty to harmonize a few specific areas of national food legislation. Because the different national provisions on food appeared the main obstacles to achieve a single marketplace for foodstuffs, it was necessary to proceed to the harmonization of this legislation. The task was not self-evident because national regulations of foodstuffs were not only profoundly diverse, but they also embodied different administrative traditions. Quite surprisingly, one of the very first ever adopted by the Community is the directive relating to the use of colorings in foodstuffs[51].

*The Genesis of food law on the other side of the Atlantic: the first steps of US Food law*

Similarly, in the U.S., before Congress enacted the 1906 Federal Food and Drugs Act (which became the Federal Food, Drug and Cosmetic Act in 1938)[52], the governmental involvement in food regulation was based on the Commerce Clause[53]. At that time the

[50] See R. Barents, *The Internal Market Unlimited: Some observations on the Legal Basis of Community Legislation* (1993) 30 CMLRev, 85-86.

[51] *See* O.J. 1962 (L 115) 2645. The directive has no number because at that time a numbering system was not established yet. O'Rourke has ironically observed that "this was not an auspicious start for the establishment of EU Food law as major concern of EU legislators". See R. O'Rourke, *EC Food Law* 185 (1st ed., 1998), at 3. See also P. Gray, *Food Law and the Internal Market. Taking Stock*, Food Policy, 1990, p. 111.

[52] For a comment on the evolution of the Federal Food and Drug Legislation, *see* P. Barton Hutt & R.A. Merrill, Food and Drug Law, supra note 1, at 6-15. The text of the Act is reproduced in P. Barton Hutt & R.A. Merrill, Food and Drug Law, Cases and Materials – 2ed., 1996 Statutory Supplement, at 1-269 and it is also *available at* http://www.fda.gov/opacom/ laws/fdcact/fdctoc.htm

[53] G.C. Shaffer and M.A. Pollack, *Les différentes approches de la sécurité alimentaire*, in J. Bourrinet and F. Snyder, *La sécurité alimentaire dans l'Union européenne*, at 134 (Bruylant ed., 2003).

regulator's main purpose was "to protect against fraud in the market place"[54] rather than to pursue a free trade objective in contrast to the situation within the EC Community. However, throughout the time, the economic purpose has found its way also in the U.S. As it has been stated,

> "Regulators in both jurisdictions ultimately derive their legal authority to define and control food safety risks from their constitutional power over the free or interState movement of goods and both share some aspects of that authority with their constituent States"[55].

## 2. THE "TRADITIONAL" APPROACH TO FOODSTUFFS: THE "EUROPRODUCTS" (1969-1985)

Recognizing that there were substantial trade barriers caused by differences in legislation, in 1969 the Commission drew up the General Program for the Elimination of the technical obstacles to Trade, thus launching the so-called "traditional approach"[56] to harmonization.

The second part of the Program addressed notably the technical obstacles to the free movement of foodstuffs stemming from the different legislative, regulatory and administrative measures existing among Member States. Thus, the Community made an attempt to speed up its harmonization efforts by setting out 43 areas for harmonizing legislation including butter, cacao, pasta, ice-cream, jam, sugar, soft drinks, beer, cheese, etc., but also additives. Being these areas divided within 5 different phases, the program provided different deadlines for the presentation of harmonization proposals to the Council according to each phase.

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[54] P. Barton Hutt, *Government Regulation of the Integrity of the Food Supply*, 4 Annual Review of Nutrition 1 (1984).
[55] M.A. Echols, *Food Safety Regulation in the European Union and the United States : different cultures, different laws*, *in* Columb. J. Eur. L. 525, at 530 (1998).
[56] As adopted by the Council in its Resolution [1969] OJ C 76/1. See, on this document, Azoulay, supra note 13, at 33.

The idea behind this harmonization program was that every national product in principle required a Community measure in order to ensure the free circulation of goods. All restrictions to the intra-Community trade of foodstuffs due to different national legislation could only be solved when a similar provision was issued at Community level, thus each national provision had to be replaced by a European measure.

This explains why the harmonization took place in areas that were predominantly 'vertical', leading to the drafting of very detailed directives (so-called: recipe legislation)[57]. These legislations introduced obligatory designations for foodstuffs whose use was made subject to a clearly described composition of the foodstuff in question, for example, on chocolate, honey and fruit juices[58]. Although the program was due to be completed within about two years, only 4 measures had been agreed by 1973.

This program was then replaced by the 1973 "Industrial Policy Programme"[59], which replaced the deadlines previously decided on by the Council for the adoption of around thirty-five "vertical" directives aimed at establishing compositional standards for individual food, the so-called 'recipe laws'[60]. The first "europroduct" conceived by the EC legislator was chocolate[61].

These standards dictating permissible ingredients and prohibiting products which do not satisfy these requirements from using a designated trade description were highly detailed and inclusive. It is clear that the common goal pursued by these directives was to facilitate the free movement of foodstuffs within the European Common market, rather than promoting health and consumer protection goals. The latter were tackled only to the

[57] They apply only to one foodstuff or to a group of foodstuffs. Vertical legislation can be distinguished from horizontal legislation, which applies to all foodstuffs, for instance, provisions on additives or hygiene.
[58] See infra note 55.
[59] Council Resolution of 17 December 1973 on industrial policy, JO C 117, p. 1-14. See notably Annex 1, timetable for the removal of technical barriers to trade in foodstuffs, setting out different deadlines for the adoption of the Commission's proposal by the Council.
[60] Much of this food legislation was developed by the Internal Market Directorate General (former DGIII, today DG MARKT). These directives lay down detailed specifications for certain sugars intended for human consumption, 73/437/EEC, 1973 O.J. (L 356) 71; Coca and chocolate products, 73/241/EEC, 1973 O.J. (L 228) 23; honey, 74/409/EEC, 1974 O.J. (L 221) 10; fruit juices and certain similar products, 75/726/EEC, codified by 93/77/EEC, 1993 O.J. (L244) 23; partly or wholly dehydrated preserved milk, 76/118/EEC, 1976 O.J. (L 24) 49; coffee extracts and chicory extracts, 77/436/EEC, 1977 O.J. (L 172) 20; fruit jams, jellies and marmalades, and chestnut puree, 79/639/EEC, 1979 O.J. (L 205) 5.
[61] Council directive 73/241/EEC, 1973 O.J. (L 228) 23.

extent that it was necessary to ensure regular intra-Community trade and were mainly left to the choice of the Member States[62].

This total harmonization approach to food law was not limited to Europe at that time. These EC food recipes laws recall to some degree the food standards of identity promulgated by the U.S. FDA until the 1970s[63]. However, unlike the EC standards, the U.S. recipe laws were primarily aimed at preventing "economic adulteration, by which less expensive ingredients were substituted so as to make the product inferior to that which the consumer expected to receive when purchasing a product with the name under which it was sold"[64]. In short, the U.S. standards were not conceived as promoting trade but rather as a tool of consumer protection. However, while the FDA abandoned this strategy by the FDA in the 70s, the Community realized the failure of its traditional approach to harmonization at the beginning of the 80s. Two factors paved the way to the failure of recipe laws[65]. First, Article 94 of the Treaty, requiring unanimity for the adoption of the directives, turned out to be inadequate in promoting the creation of the internal market because it enabled Member States to block any Commission action with which they did not agree upon and, when the consensus was reached, it contributed to slowing down considerably the adoption of directives[66]. Second, sensitive questions of culinary cultures and traditions[67] combined with the rigidity of the total harmonization instruments[68] contributed to render the decision-making procedure extremely

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[62] In this line of thought, Ellen Vos affirms that the Community involvement in health and safety regulation may be considered as an accidental consequence of the market integration objective (spill-over)". See E. Vos, *Institutional Frameworks of the Community Health and Safety Regulation. Committees, Agencies and Private Bodies* (1999), at 9.

[63] The FDA has promulgated approximately 300 standards of identity, covering – at their maximum reach – about 45% of the American food supply shipped in interState commerce, excluding fresh fruits. *See* 44 *Fed. Reg.* 75990, as reported by Hutt, *supra* note 1, at 107. For an historical presentation of the introduction of these standards in the US, see R.A. Merril & E.M. Coller, *"Like Mother used to Make": an Analysis of FDA Food Standards of Identity*, 74 Columbia L. Rev. 561 (1974).

[64] See P. Burton Hutt & R.A. Merril, *supra* note 1, at 99.

[65] For an analysis of the factors leading to the failure of the Old Approach see R.H. Lauwaars, *The Model Directive on Technical Harmonization and Standardisation*, in R. Bieber, R. Dehousse, J. Pinder, J.H.H. Weiler (eds.), *1992: One European Market? A Critical Analysis of the Commission's Internal Market Strategy*, Nomos, Baden-Baden, 1988, p. 155.

[66] J. Pelkmans, *The New Approach to Technical Harmonisation and Standardization, Journal of Common Market Studies*, 1987, p. 249 ss. and L. Costato, *Dal mutuo riconoscimento al sistema europeo di diritto alimentare: il regolamento 178/2002 come regola e come programma*, in Rivista di diritto agrario, 3/2003, p. 290.

[67] Gray, *supra* note 51, at 112.

[68] According to Mattera: "on est en présence d'une harmonization totale lorsqu'une directive impose des règles qui se substituent entièrement aux règles nationales existantes en la matière ... L'effet d'une telle méthode est de dessaisir les Etats membres de leurs competences dans les secteurs specifiquement reglementes au niveau communautaire ». See A. Mattera, *Le marché unique européen* (Jupiter ed., 1990), at 180.

cumbersome and provided a shelter by which to protect home trade [69]. In 1985, directives have been adopted only in 14 of the 50 sectors identified by the general harmonization program[70]. These difficulties for harmonizing food quality requirements for all foodstuffs led the Commission to rethink its traditional approach, leading to a 'new strategy' of harmonization.

### 3. THE 'NEW APPROACH': MUTUAL RECOGNITION PRINCIPLE AND MINIMUM HARMONIZATION STANDARDS (1985 - 1997)

In 1985, the EC Commission decided to abandon its titanic effort to introduce universally applicable "recipe laws" for all European-made foodstuffs, and launched the "New Approach to Harmonization of national legislations"[71], in particular to those related to foodstuffs[72]. In doing so, the Commission relied on the mutual recognition principle formulated by the European Court of Justice in the 1979 *Cassis de Dijon* judgment[73]. According to this principle a Member State should allow the free circulation in its territory goods produced or marketed in conformity with the rules, tests or standards found in another Member State which offer an equivalent level of protection to its own rules, tests or standards[74]. Suddenly, it appeared that there was no longer a need to

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[69] See D. Welch, *From 'Euro Beer' to 'Newcastle Brown', A Review of European Community Action to Dismantle Divergent 'Food Laws'* (1983-4) 22 JCMS 57 and M. Lugt, supra note 44, at 17.

[70] COM(85)603 final, 3.

[71] Communication on the completion of the internal market "New Approach to Technical Harmonisation and Standards", COM(85) 19 final then adopted by the Council Resolution on a New Approach to Technical Harmonisation and Standards [1985] OJ C136/1. For a detailed description of the "New Approach", see A. Mattera, *L'article 30 du Traité CE, la jurisprudence Cassis et le principe de la reconnaissance mutuelle*, in *Revue du Marché Unique Européen*, fasc. 4, 1992, at 35-36. Since the beginning of the 1980s the Commission has began using the tool of Communications, acts designed to show intentions and to set up guidelines to direct operators without however creating obligations. See A. Mattera, *Le Marché Unique Européen*, supra note 68.

[72] More precisely, the Commission extended the "New Approach" to foodstuffs by publishing the communication to the Council on the completion for the internal market: Community legislation on foodstuffs, COM(85) 603 final, also called in Brussels's jargon the "Mini White Paper" or "White Paper-bis".

[73] Case 120/78, Rewe-Zentrale AG v. Bundesmonopolverwaltung fur Brantwein, 1979 E.C.R. 649. In this case the Court stated that Member States could not refuse entry to products (in this case a French blackcurrant liqueur, the Cassis de Dijon) even if their national legislation prohibited the sale of the product.

[74] This formulation of the principle was developed for the first time by the Communication of the Commission concerning the consequences of the judgment given by the Court on 20 February 1979 in Case 120/78 (*Cassis de Dijon*), O.J. 1980 (C 256) 2, where it is stated that: "The Court's interpretation has induced the Commission to set out a number of guidelines. The principles deduced by the Court imply that a Member State may not in principle prohibit the sale in its territory of a product lawfully produced and marketed in another Member State even if the product is produced according to technical or quality requirements which differ from those imposed on its domestic products. Where a product "suitably and satisfactorily" fulfils the legitimate objective of a Member State's own rules (public safety, protection of the consumer or the environment, etc.), the importing

harmonize all the food legislation of Member States by agreeing on common food quality requirements for "Euro Bread", "Euro Chocolate", "Euro Beer", etc[75]. As it has been said by one of the most prominent supporters of the "New Approach":

> "Il ne s'agissait plus de créer un ensemble d'europroduits - une bière européenne, un pain européen, un jouet européen ... - mais d'instaurer une plus grande liberté d'échange de « produits légalement fabriqués dans la Communauté » et d'arriver ainsi a l'acceptation, par chaque Etat membre, des diversités nationales des autres pays" [76].

The European Court of Justice endorsed this interpretation of the *Cassis* judgment by continually holding that the protection of consumers cannot be a legitimate ground upon which a Member State may prohibit the marketing in its territory of foodstuffs that are compositionally different from those generally sold there. According to the Court, the consumer protection objective could be achieved by the inclusion of additional information on the labeling of products indicating differences in compositional and production methods existing in the exporting Member. This measure allowed individuals to make informed choices.

The principle of mutual recognition, while preserving all traditions, richness and diversity existing among the different national culinary traditions, allowed the Community to

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country cannot justify prohibiting its sale in its territory by claiming that the way it fulfils the objective is different from that imposed on domestic products. In such a case, an absolute prohibition of sale could not be considered "necessary" to satisfy a "mandatory requirement" because it would not be an "essential guarantee" in the sense defined in the Court's judgment. The Commission will therefore have to tackle a whole body of commercial rules which lay down that products manufactured and marketed in one Member State must fulfil technical or qualitative conditions in order to be admitted to the market of another and specifically in all cases where the trade barriers occasioned by such rules are inadmissible according to the very strict criteria set out by theCourt.

The Commission is referring in particular to rules covering the composition, designation, presentation and packaging of products as well as rules requiring compliance with certain technical standards. The Commission's work of harmonization will henceforth have to be directed mainly at national laws having an impact on the functioning of the common market where barriers to trade to be removed arise from national provisions, which are admissible under the criteria set by the Court. The Commission will be concentrating on sectors deserving priority because of their economic relevance to the creation of a single internal market. To forestall later difficulties, the Commission will be informing Member States of potential objections, under the terms of Community law, to provisions they may be considering introducing which come to the attention of the Commission. It will be producing suggestions soon on the procedures to be followed in such cases". For a review of this communication *see, e.g.*, Vos, supra note 62, at 56.

[75] See S.M. Stephenson, *Mutual Recognition and its Role in Trade Facilitation*, in Journal of World Trade, 1999, p. 141 ss., according to whom the New Approach "served to remove the largest stumbling block from the creation of the EU, as progress on integration had been held up for years by the impossibility of harmonising 'en bloc' all of the differing national standards".

[76] A. Mattera, *L'article 30 du Traité CE, la jurisprudence Cassis et le principe de la reconnaissance mutuelle*, supra note 71, p. 35.

realize an internal market without having to adopt hundreds of "vertical" directives[77]. However, even among the European relatively homogeneous Member States national regulations cannot always be equivalent in their level of protection. This stems from the different approaches to regulation adopted in each Member State, reflecting differences in culture, the peculiar functioning of their political institutions and also their different attitudes towards the management of risk. As a consequence of the resulting differences in regulation, the goals of free circulation could have not been achieved without some form of 'positive integration', by agreeing common rules in order to overcome the obstacles that could not have been tackled solely by the mutual recognition principle.

In accordance with the new strategy, Community food legislation would henceforth be limited to the harmonization of national rules justified on four grounds:

- the need to protect public health;
- the need to protect other consumer interests, notably consumers' need for information;
- the necessity to ensure fair trading and
- to necessity to provide appropriate official controls[78].

The idea was that the EC could lay down harmonized rules only on a horizontal basis to set forth the "essential requirements" necessary for the free circulation of foodstuffs[79]. The mutual recognition principle combined with a reinforced labeling regime guaranteeing consumer information would realize an internal market for foodstuffs.

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[77] This new approach to harmonization was definitely launched by the Commission in its White Paper on the Completion of the Internal Market, COM (85) 603,¶ 7, published in June 1985, becoming eventually the cornerstone of the "1992 Programme". See A. Mattera, *Le marché unique européen*, supra note 68.

[78] The Commission in its 1985 "MiniWhite Paper" stated that "[I]n the absence of harmonised Community rules, the Member States have the power to lay down, in respect of their own production, rules governing the manufacture, composition, packaging and presentation of foodstuffs. However, in line with the mutual recognition principle, they are required to admit to their territory foodstuffs lawfully produced and marketed in another Member State unless it can be demonstrated that a restrictive measure is: a) necessary in order to satisfy mandatory requirements (public health, protection of consumers, fairness of commercial transactions, environmental protection); b) proportionate to the desired objective; and is the means of achieving that objective which least hinders trade. See supra note 72.

[79] Under the New Strategy, the EC institutions apart from legislating only "essential requirements", they would have also delegated the determination of more-detailed standards to quasi-public European Standards organizations and then coordinated quasi-public national bodies in charge of assessing the conformity of products produced in any one Member State for sale throughout the EC market. See G. Shaffer, *Reconciling Trade and Regulatory Goals: The Prospects and Limits of New Approaches to Transatlantic Governance Through Mutual Recognition and Safe Harbor Agreements*, 9 Columbia Journal of European Law 33 (2002).

Although the Council would always adopt the "essential requirements" of food law, there would be delegated to the Commission the task of implementing these rules under the conditions provided by the Council.

However, it turned out quite soon that the *Cassis de Dijon* doctrine combined with a reinforced labeling regime guaranteeing consumer information would have not been a sustainable strategy. First, there was the fear that the application of the mutual recognition principle would have led to a 'race to the bottom' situation, where Member States would have given up higher quality standards in favor of adaptation to the lowest common denominator[80]. Second, the functioning of the mutual recognition principle could be hindered by its operational requirement, which is the functional equivalence (or parallelism) of national legislations. In fact, as there are many products presenting genuine differences in their regulatory regimes, their nature may require a single Pan European standard, which involves harmonization. Third, the elimination of barriers to trade through the mutual recognition principle presupposes, unless Member States voluntary refrain from asserting specific domestic standards for the imported products, an initiative by economic operators (manufacturers or importers) or the Commission and can come about only reactively and case by case[81].

Only law approximation could respond to these three problems. However, it would have been inconceivable to go back to the traditional approach to harmonization, especially because Article 94 ECT still required unanimity. The new intervention should have relied on new premises. The 1986 Single European Act provided the answer by introducing a new legal basis, Article 100A (current 95), which modified voting rule for the enactment of EC internal market legislation. This article requires a qualified majority in the legislative process instead of unanimity as required under Article 100 EC. It thereby

[80] The original formulation of this argument can be found in the Cassis case, where the Federal Republic of Germany affirmed that: "Ultimately, the regulation binding in all Member States would be that of the country setting the lowest requirements; since this legal conclusion would be based on the directly applicable provision of Article 30, these legal changes will have to have been effected already, at latest by 1 January 1970. Because of the automatic effect of Article 30, in the future further amendments to national legal provisions could be adopted continually as soon as only one Member State adopted a new regulation with lower requirements. In the extreme case, then, one Member State could, without any co-operation or information of other Member States, determine legislation for the whole Community. The outcome would be that the minimum requirements would, without the harmonization provided for in Article 100 EEC, requiring consensus by Member States, be reduced to the lowest level to be found in the regulations of any one of the Member States".

[81] One should also bear in mind that the ECJ's judgments can only act by abolishing without substitution the national measures. They never replace them by new requirements.

eliminated Member States veto rights in the Council, thus speeding up the harmonization process [82].

As a part of this approach, the EC Community adopted a wide-ranging set of framework (horizontal) directives, the so-called 'New Approach directives'[83], dealing with "essential requirements" in the fields of additives[84], extraction solvents[85], flavoring agents[86],

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[82] Article 100A (current Article 95) ECT read: "1. By way of derogation from Article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 14. The Council shall, acting in accordance with the procedure referred to in Article 251 (qualified majority vote) and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market. 2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons. 3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective. 4. If, after the adoption by the Council or by the Commission of a harmonization measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them. 5. Moreover, without prejudice to paragraph 4, if, after the adoption by the Council or by the Commission of a harmonization measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonization measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them. 6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market. In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved. When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months. 7. When, pursuant to paragraph 6, a Member State is authorized to maintain or introduce national provisions derogating from a harmonization measure, the Commission shall immediately examine whether to propose an adaptation to that measure. 8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonization measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council. 9. By way of derogation from the procedure laid down in Articles 226 and 227, the Commission and any Member State may bring the matter directly before the Court of Justice if it considers that another Member State is making improper use of the powers provided for in this Article. 10. The harmonization measures referred to above shall, in appropriate cases, include a safeguard clause authorizing the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure".

[83] For an overview of the results obtained by the New Approach, see M. Egan, *Constructing a European Market: Standards, Regulation, and Governance*, at 166-167 (2001) and G. Majone, *State, Market, and Regulatory Competition in the European Union: Lessons for the Integrating World Economy*, in (A. Moravcsik, ed. 1998), *Centralizing or Fragmentation? Europe Facing the Challenges of Deepening, Diversity and Democracy* 94, 107-8.

[84] Council Directive 89/107/EEC [1989] OJ L40/27. After much discussion, this framework directive was agreed in December 1988 and published in early 1989. Following problems in developing the specific directives for the additives, it was necessary to amend the framework directive in 1994.

[85] Council Directive 88/344/EEC [1988] OJ L157/28.

[86] Council Directive 88/388/EEC [1988] OJ L184/61.

colors[87], sweeteners[88], food additives other than colors and sweeteners (i.e. preservatives, antioxidants, emulsifiers, etc.)[89], labeling foods for particular nutritional needs, hygiene and official controls[90] in order to establish basic standards and guiding Member States in the development of more detailed rules[91]. These directives contained positive lists of authorized substances to be used in the food sectors, but, being framework directives, they need to be supplemented by implementing measures by the Commission, in accordance with a regulatory committee procedure.

National food legislations, constrained by the respect of the framework directives, would have been accepted within the Community by virtue of the mutual recognition principle. The existing vertical directives would have remained in place and the Community would still have been in charge of periodically updating and replacing their texts[92]. However, in principle, the Community was not to issue new vertical harmonization legislation, not only in order to preserve the culinary richness of Member States, but also to avoid the introduction of legislative rigidity that would prevent innovation and commercial flexibility[93]. Yet, the vertical approach is still partly pursued by the Community, who regularly updates and replaces several directives concerning specific foodstuffs adopted in the 70s[94].

Moreover, in order to reduce the negative impact stemming from the creation of new national provisions on food, the Community extended the scope of the "Informative directives" to foodstuffs, by requiring Member States to notify their draft food-related regulations to the Commission's services[95]. This initiative appears to be of great

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[87] European Parliament and Council Directive 94/36/EC [1994] OJ L237/13.
[88] European Parliament and Council Directive 94/35/EC [1994] OJ L237/3, then amended by 96/83/EC OJ L/18/4.
[89] European Parliament and Council Directive 95/2/EC [1995] OJ L61/1, then amended by 96/85/EC, OJ L86/1.
[90] Council Directive 89/397/EEC [1989] OJ L186/23.
[91] Deboyser, Patrick, Le marché unique des produits alimentaires, Revue du Marché Unique Européen, 1991, p. 65 ss.
[92] *See supra* note 29. See also L. Azoulay, supra note 13, p. 36.
[93] "Mini-white" paper, *see supra* note 72, at 16-17.
[94] See Vos, supra note 62, p. 135 (several examples are offered).
[95] Council Directive 88/182/EEC, 1988 O.J. L 81/75 amending Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations (then amended by European Parliament and Council Directive 94/10/EC, 1994, OJ L100/30). Each year the services of the Commission consider some 60-80 new national measures relating to the foodstuffs sector under the procedure laid down by the 'Informative directives'. This procedure enables the Commission to comment on draft legislation and to ask Member States to re-shape their drafts in order to bring them into conformity with EC law thus minimising the impact on the intra-community trade. For an analysis of the 'informative directives', *see* Mattera, *supra* note 68.

important to the extent the food sector is one of the regulatory area where various new national measures continued to be proposed.

Although the Community tried in these years to re-orient the EC food policy toward the achievement of new goals, such as the protection of public health or consumer protection, these aspects of EC food law were still neglected at the time and implemented in a way functional to the economic requirements of the internal market[96]. The only priority was the completion of the internal market widely-publicized by the 1992 single-market program. Even though much national food legislation had already been harmonized at the Community level, European food law continued to develop in a fragmented fashion[97]. Thus, for instance, there was no unifying text that clearly defined the responsibilities of the parties concerned.

There is therefore no doubt that, before 1992, following more than thirty years of legislative activity, Community action in the area of food policy remained largely conditioned by the Community's emphasis on the removal of barriers to trade, rather than on safety issues[98]. And this even though in 1992 the aim to attain "a high level of health protection" was given the status of a general objective of the EC Treaty[99].

Although a significant number of EC legislative texts were adopted and the same Treaty had been modified to achieve a high level of health protection, one could not properly speak of a "common food policy"[100].

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[96] For instance, in the 1985 Communication it is stated that EC food legislation should be limited to provisions justified by the need to provide consumers with information not exclusively related to the health and fair trade and to provide for adequate and necessary official controls of foodstuffs. See supra note 72.

[97] Vos E., *EU Food Safety Regulation in the Aftermath of the BSE Crisis*, 23 Journal of Consumer Policy 233 (2000); Lafond F.D., *The Creation of the European Food Authority. Institutional Implications of Risk Regulation*, 10 European Issues 4 (November 2001).

[98] Dehousse speaks of the "dual subsidiarity" of social regulation in the structure of the Treaty of Rome: "subsidiarity with respect to the Community's main reason d'être, namely market integration, and subsidiarity with respect to national regulatory policies". See R. Dehousse, *Integration v. Regulation? On the Dynamics of Regulation in the European Community*, Journal of Common Market Studies, vol. XXX, n. 4, 1992, at 388.

[99] This amendment of the Treaty brought about the "scientific factor" into EC law. This is because the aim to attain a high level of protection was given the status of general objective of the Treaty, Article 100a (current Article 95) was amended as to expressly require the Commission, "in its proposal [...] concerning health, safety, environmental protection" to take into account "any new development based on scientific facts".

[100] C. Lister, in 1992, identified the following deficits in the Community food law: absence of substantive regulatory goals, tendency toward rigidity (recipe directives), tendency toward ambiguity, tendency toward new trade barriers by means of rigid rules, tendency towards double standards (for the EU and for third countries), tendency toward uncoordinated policy-making, particularly between food law and the common agricultural policy, and tendency toward non-transparent rule-making expressed by a lack of public discussion common in democratic societies. See C. Lister, *Regulation of Food Products by the European Community*, 285, (Butterworths, 1992), at 285-292.

## 4. THE 'EMERGENCY': TOWARD THE 'EUROPEANIZATION' OF FOOD RISK (1997-2002)

In the mid-1990s, in the wake of several food outbreaks and food scares[101], it became clear that the free movement of foodstuffs could no longer be the overriding principle of EC food law. Food safety was not only a consumer's concern, but also a condition *sine qua non* for a proper functioning of the internal market. It was therefore necessary to figure out how to re-shape this European policy.

The *BSE* crisis heavily contributed to spreading this awareness among citizens and institutions by showing the inadequacy of the existing regulatory regime in ensuring a high level of protection of public health and consumer protection[102]. As Chalmers notes:

> "The BSE crisis marked a Year Zero for the European Union food regime by forcing both Member States and the Community to acknowledge the shortcomings of the existing European approach to food safety issues"[103].

Facing a motion of censure from the European Parliament for alleged mismanagement of the *BSE* crisis[104], the *Santer* Commission promised to radically revise its internal

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[101] In the long list of food safety crises and scandals of that time appear olive oil, contaminated wine, Perrier water, E.coli listeria, salmonella, polluted drinking water, BSE, dioxin sludge, animal feed, pesticides etc.

[102] For further analysis of the impact of the BSE crisis on the evolution of the European Food regulatory system, see A. Alemanno, *The Evolution of Food Safety in the EU*, in D. Vogel and C. Ansell (eds.), *European Food Safety Regulation: The challenge of Multi-level Governance*, MIT Press (2006); E. Vos, *EU Food Safety Regulation in the Aftermath of the BSE Crisis*, supra note 97, at 227-255 (2000); Lafond, supra note 97; M. Hagenmeyer, *Modern Food Safety Requirements – according to EC Regulation* 178/2002, 4 ZLR 443 (2002); E. Millstone, *Recent developments in EU food policy: institutional adjustments or fundamental reforms?*, 6 ZLR 815 (2000); L. Buonanno et al., *Politics Versus Science in the Making of a New Regulatory Regime for Food in Europe*, 5 EIPoP (2001); S. Krapohl, *Risk Regulation in the EU between interests and expertise – The case of BSE*, 10 Journal of European Public Policy 189 (April 2003); P. Shears, F.E. Zollers and S.N. Hurd, *The European Food Safety Authority. Towards coherence in food safety policy and practice*, 106 British Food Journal 336-352 (2004) and K. Vincent, *Mad Cows and Eurocrats – Community Responses to the BSE Crisis*, 10 European Law Journal 517, 2004.

[103] D. Chalmers, *"Food for thought": reconciling European risks and traditional ways of life*", 66 The Modern Law Review 532, 534 (2003).

[104] In the European Parliament's debate on the report by the Temporary Committee of Inquiry into BSE on the 18 February 1997, the Parliament called on the Commission to bring together all the activities spread out among the various directorates-general within a single DG, to set up a framework directive on food law, to ensure the safety of the foodstuffs which circulate freely within the Community, to change the way in which scientific committees work, etc. See Debate in plenary session of the EP, 18 Feb. 1997, 1-2 EU Bulletin 163-6 (1997). The Temporary Committee of Inquiry into BSE was set up by the European Parliament in July 1996, on the alleged contraventions or maladministration in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and the national courts of 7 February 1997, A4-0020/97/A, PE 220.544/fin/A.

organization and to establish a new EC food regulatory regime and also made reference, for the first time, to the idea of establishing an independent European Food Agency (EFA)[105].

## 4.1 The New Approach to Food Safety after the BSE crisis

### A. Green Paper on the General principles of Food Law and New Approach to Consumer health and Safety

The first highly symbolic step along the Santer's *manifesto* was the adoption, on 30 April 1997, of a long-awaited[106] Green Paper on the General Principles of Food Law in the EC (hereinafter: the Green Paper) aimed at launching a public debate on how the European Community should best regulate the area of food law[107]. The Community seriously envisaged the possibility of adopting a 'general Directive on food law'[108], containing definitions of the fundamental terms of food law, particularly the term "food" itself[109]. Such an EC-wide definition was considered essential to determining the scope of the EC food laws.

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[105] In his speech to the EC Parliament, the President of the Commission, Jacques Santer, after conceding that "mistakes and errors have been made, some by the Commission", he appealed for "the gradual introduction of a genuine food policy which places particular emphasis on the protection of consumer health". See speech by President Santer, 19 Feb. 1997, 1-2 EU Bulletin 163-6 (1997).

[106] For several years there has been a call for a European regulatory framework for food. The most significant initiative was the 1993 publication, at the request of the EC Commission, of draft texts for a framework food directive by three food experts (C. Castang, A. Cleary, D. Eckert). The Commission's introduction to these proposals for a 'first draft directive' setting out a general approach to food law explains this initiative by saying that '[...] a "European framework law" might allow more effective systematic consistency and integration of the directives and regulations currently in force (both vertical and horizontal)'. For a collection of these documents, *see* F. Snyder, *A Regulatory Framework for Foodstuffs in the Internal Market*, Report on the Conference 6-7 May 1993, European University Institute, Department of Law, Florence, EUI Working Papers in Law No 94/4. Among the other voices pleading for the creation of a general community framework for foodstuffs, see e.g. R. O'Rourke, supra note 51; Lugt, supra note 44, at 256; Mettke, *Uber die Notwendigkeit eines europaischen Rahmengesetzes fur das Lebensmittelrecht*, EFLR 1/91, 5, at 19.

[107] The General Principles of Food Law in the European Union - Commission Green Paper. COM (97) 176, 30 Apr. 1997 *available at* http://europa.eu.int/scadplus/leg/en/lvb/l21220.htm. Green Papers are texts of 'soft law' by which the Commission raises many issues relating to a certain area of regulation and ask opinions thereon of all interested parties but without presenting its own point of view on the issues debated.

[108] This idea was not completely new. For several years there had been a call for a European regulatory framework for food. Already in 1993 the Commission entrusted three food experts (Charles Castang, Amanda Cleary, Dieter Eeckert) to published draft texts for a framework food directive. Because the final conclusions of the three experts were too different to be summed up in a unique document, they had each prepared their own draft. To know more about this initiative, see Snyder, supra note 106.

[109] Green Paper, supra note 107, at 3.

In this text, although not putting into questions the fundamental goals of EC Food law[110], the Commission stressed that

> "The *BSE* crisis has highlighted the need for a European food policy centered on the requirement that *only foodstuffs which are safe*, wholesome and fit for consumption be placed on the market. Health protection in relation with consumption of foodstuffs is to be an absolute priority at any time and not only something to be looked at in emergency situations"[111].

The protection of public health was gradually entering the EC food law policy as a goal deserving inasmuch coverage as the other economic goals related to the CAP and the free movement[112]. In order to ensure the development of a "true food policy which attaches fundamental importance to the protection of the consumer and his health", the Commission proposed that

- the most recent and complete scientific evidence be considered when adopting new legislative measures[113];
- the precautionary principle approach be the rule in case of lack or incomplete scientific evidence;
- there is a clear responsibility for the safety of food at all stages of the food chain (primary production, processing, transport, handling and distribution, display at final point of sale);

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[110] More precisely, these are: the need to ensure a high level of protection of public health and safety, and of consumer protection; the need to ensure the free circulation of goods within the single market; the need for legislation to be based primarily on scientific evidence and risk assessment, in respect of our international obligations; the need to ensure the competitiveness of the European industry, allowing for flexible adaptation of the legislation to incorporate new technical developments as well as to enhance Community export prospects; the need to place the primary responsibility for safe food with industry, producers and suppliers, including imports from third countries, through self-checking provisions (so-called Hazard Analysis Critical Control Points systems or HACCP) backed up by official controls and appropriate enforcement; the need for legislation to be coherent, rational, consistent, simpler, user-friendly and developed in full consultation with all interested parties.

[111] Green Paper, supra note 107, at 11.

[112] This shift of objectives stems clearly also from the ECJ's judgment in the *BSE* case: Case 180/96 R United Kingdom v. Commission [1996] E.C.R. 3903, paras 90-93 where the Court recognized that in the application of emergency measures, such as those adopted by UK after the 1996 *BSE* scare, paramount importance must be accorded to the protection of public health, even at the expense of serious and possibly irreparable damage to commercial interests. See O'Rourke, supra note 51, at 93-94 and Lugt, supra note 44, at 254.

[113] By referring to the scientific requirement (The Community will increasingly be required to provide scientific justification for its measures at international level), the green paper was the first document to underline the need for EC food law to comply with the Community's WTO obligations, thus echoing the programmatic idea of the SPS. See Green paper, supra note 107, at 62, para 2.3.1.

- control and inspection measures are taken at all critical points throughout the food chain. The same rule applies to imported foodstuffs;

- appropriate measures are taken to inform consumers about the nature and content of the food;

- the responsibilities of the various controlling agents (producers, Member States' authorities, the Commission, etc.) are clearly established[114].

The Green Paper also began considering a possible involvement of the Community with nutrition and health issues without, however, providing any definitive answers.

From a policy perspective, the aim of the Green Paper was to examine the extent to which current legislation was meeting the needs and expectations of consumers, producers, manufacturers, and traders; to consider whether official control and inspection systems were operating effectively; and to determine future food law developments. The ultimate objective was to provide legislation which takes a harmonized approach to control and inspection for each part of the food production chain. The Community role in the field of control was not to replace the Member States, but to verify that the necessary controls are carried out in an effective and equivalent manner throughout the internal market. Steps should have been taken to reinforce administrative and scientific cooperation between Member States and with the Commission in order to ensure equivalence of enforcement throughout the Community. While recognizing it is impossible to offer a zero-risk system, the legal framework should cover all potential risks at all stages to the greatest extent possible.

According to the Green Paper, simplification and rationalization of the existing food legislation should not result in a reduction of the level of protection of public health or consumer protection. It should rather strike the balance between general provisions and more detailed prescriptive legislation, between the use of binding legislation and recourse to voluntary instruments, and between horizontal approaches and specific rules applicable to particular categories of foodstuffs.

[114] Green paper, supra note 107, at 11-12.

In November 1997, the European Commission and the European Parliament organized a conference to discuss the Green Paper and the 140 reactions to this document made by all parties interested, but it did not lead to a proposal for Community legislation[115].

Along these lines, the Amsterdam Treaty, agreed by the European Union's political leaders on 17 June and signed on 2 October 1997, fully acknowledged public health protection and consumer protection as objectives of the European integration process and, accordingly, conferred on the Commission new responsibilities to the their attainment[116].

The following step in reshaping the EC food law was the Commission's publication of the "Communication on Consumer Health and Safety" in May 1997[117]. This text, almost simultaneous with the Green Paper, laid down the foundations for a new EC food regime as announced by the Commission's President, Jacques Santer, before the European Parliament on 18 February 1997[118]. In particular, the Commission set out the action which it was taking to reinforce the manner in which it obtains and makes use of scientific advice, and operates its control and inspection services, in the interests of consumer health and food safety. The new approach, laying down a new political departure, was based on three general principles:

- separation of legislative responsibilities (risk management) and those relating to scientific advice (risk assessment)[119];
- separation of legislative responsibilities and those relating to controls and inspections;
- enhanced transparency and dissemination of information throughout the decision-making process and monitoring activities[120].

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[115] A summary of the Green Paper's reactions are available at http://europe.eu.int/comm/dg03/publicat/consumer/ foodcom.pdf. For a report of the conference, see G.H. Schipper, *Herstel consumentenvertrouwen en niet de interne markt stond centraal*, VMT 18 Dec. 1997, No. 26-27.

[116] The Amsterdam Treaty is *available at* http://europa.eu.int/abc/obj/amst/en/

[117] Communication from the Commission on consumer health and food safety, COM(97) 183 final.

[118] Speech by Jacques Santer, President of the European Commission, to Parliament on 18 February 1997 *available at* http://europa.eu.int/abc/doc/off/bull/en/9701/p203001.htm

[119] Although laying down this crucial conceptual framework to be used in the analysis of risk, the Commission did not provided yet a theoretical design to realize a distinction between risk assessment and risk management.

[120] Communication on Consumer health, see supra note 117, at 9-10.

In order to better satisfy these objectives and to enhance consumer health protection, the Directorate-General (DG) XXIV of the European Commission was reorganized.

The division between "responsibility for legislation" and "scientific consultation" was realized by entrusting the latter to DG XXIV, renamed DG on Consumer Policy and Consumer Health Protection (DG SANCO)[121], which thus became responsible for the scientific assessment system. The Commission had in particular placed the management of all the Scientific Committees working in the field of foodstuffs[122] and responsibility for inspection and control under the authority of this DG and had reorganized the relevant Directorate General to have the particular responsibility for consumer health[123]. Thus, the scientific committees were distanced from the legislative wing of the Commission services, being subjected to the exclusive control of a DG totally oriented to the consumer. At the same time they were removed from direct industrial pressures[124]. In particular, the committees were regrouped and coordinated by a Scientific Steering Committee (SSC) in order to achieve greater synergy and effective coordination[125].

The proper functioning of these Committees was to be based on three main principles: excellence, independence and transparency. To satisfy the principle of excellence, scientific evaluation had to be undertaken by eminent scientists[126]. The principle of

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[121] DG SANCO stands for *Direction générale de la Santé et de la Protection des consommateurs.*

[122] Since 1974, the European Commission has established several scientific committees, such as the Scientific Committee on Food, the Scientific Committee on Veterinary Medicine, the Scientific Committee on Pesticides and the Scientific Committee on Animal Nutrition. These committees were located in different Directorates General and were in charge of "critically examining risk assessments made by scientists belonging to Member State organisations" and advising the Commission on any scientific problem related to their specific competence. After being heavily criticised for lack of coordination and for being to close to the needs of industry in the wake of the *BSE* outbreak, the European Parliament urged the Commission to revise the structures of the scientific committees. This led to two commission decisions, one establishing a Scientific Steering Committee (SSC), regrouping all the chairpersons of the Committees in the field of consumer health and food safety, and the other to establish eight Scientific Committees. See, respectively Commission decision 97/03/EC and Commission decision 97/579/ EC.

[123] However, some areas of food law remained outside DG of Health and Consumer Policy (now DG-SANCO), falling within the competence of DG AGRI.

[124] Communication on Consumer health, see supra note 117, at 9-10

[125] Commission Decision 97/404/EC of 10 June 1997 setting up a Scientific Steering Committee (SSC), O.J. 1997 (L 169) 85, and Commission Decision 97/579/EC setting up Scientific Committees in the Field of Consumer Health and Food Safety, O.J.1997 (L 237) 18. The SSC was set up to coordinate the work of the individual Scientific Committees and to address scientific issues that cut across two or more of the Committees and scientific issues outside all of their remits.

[126] In accordance with directive 97/404/EC, setting up a Scientific Steering Committee, the Commission has established the selection criteria for the appointment of the committee Member in the "Call for expressions of interest for the post of Member of one of the Scientific Committees" (available at http://europe.eu.int/comm/dg24/health/dc/call_en.html). In accordance with these criteria, the Commission gives preference to those scientists with: professional experience in the field of consumer health and more specifically in the areas covered by the field of competence of the committee concerned; experience in risk

independence required scientists serving in the scientific committees to be free from interests which might be in conflict with the requirement of providing independent advice. Lastly, to improve openness and transparency, all documents, minutes, pre-opinions and opinions were to be available on the Internet for easy access by all interested parties (individuals and associations, EC institutions and national authorities).

The Community response to the new regulatory challenge was based on the assumption that good management would have helped in solving the difficulties that had arisen from the possible ways of dealing with scientific advice.

In particular, the Communication introduced its official doctrine of "risk analysis", composed by three distinct components: risk assessment[127], risk management[128] and risk communication[129]. This crucial conceptual distinction would subsequently be reiterated in all Community documents and legislative texts relating to scientific expertise. This distinction aimed at enabling decision-makers to act with the best knowledge of the scientific data relating to a certain phenomenon. Only once the risk assessment is carried out by an independent body of experts, it is possible to act at the risk management stage by deciding whether to authorize a certain activity or substance on the market. Risk communication should then be entrusted with the task of exchanging information with all parties concerned in a manner as transparent as possible.

As for control and inspections, the new approach aimed at providing a harmonized system of control for all parts of the food production chain, following three main orientations. Firstly, in view of the broad range of areas covered by the legislation, control and inspection were to follow a scheme of priorities established by risk assessment procedures and, secondly, they were to ensure that the whole of the food production chain is covered (from 'plough to plate'). Thirdly, the control activities were to be exercised through the introduction of formal audit procedures enabling the

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assessment; experience in delivering scientific opinion at national or international level; professional experience in a multidisciplinary and international environment; attested scientific excellence; experience in scientific management. See directive 97/404/EC, 1997 O.J. (L 169) 85.

[127] According to the definition provided by the *Codex Alimentarius*, risk assessment is a scientifically based process consisting of the identification and characterization of hazards, the assessment of exposure and the characterization of the risk.

[128] Risk management may be defined as the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

[129] Risk communication consists in the exchange of information with all parties concerned.

Community to assess the control systems operated by the national authorities. This new regime had to be implemented through the Food and Veterinary Office (hereinafter: "FVO"). The 150 FVO inspectors, situated in Dublin, Ireland, are in charge of monitoring the observance of food hygiene, veterinary and plant health legislation within the European Union[130].

Although that communication only represented a first Community rough reaction to the new challenges of food safety, these efforts to protect consumer health by focusing on scientific advice, risk analysis, and control and inspection heralded the future European Food Authority and the newly-established regulatory food safety regime.

Two years after the changes undertaken in 1997, the then Director General of DGXXIV (now termed SANCO), H. Reichenbach, mandated three scientists – Philip James, Fritz Kemper and Gerard Pascal – to assess the existing system of scientific advice and, eventually, to conceive a better system in terms of independency (to ensure that the scientists are free from conflicting interests), transparency (easy access to information on the activities of the committees and their advice) and excellence (risk evaluation is undertaken by eminent scientists)[131].

Their report, submitted to the newly appointed Commission in December 1999, sketched out the blueprint for a European Food Authority and was immediately endorsed by the new Commission President Prodi in its first speech before the European Parliament as one of the priorities of his mandate[132].

### B. The White Paper on Food Safety: toward a comprehensive and integrated approach to EC food policy

In the meanwhile, several events contributed to speeding up the food safety policy reform, by decidedly counteracting the Member States resistance to the establishment of

[130] For a detailed reconstruction of the history of the FVO, see Lugt, supra note 44, at 33-35. It must be observed that all FVO inspections reports are published on the Internet so that the cases in which Member States are acting in an insufficient way are brought to the public.

[131] The full text of the mandate given to them has been made public at http://europa.eu.int/comm/food/fs/sc/future _mandate _en.html. See infra chapter II, paragraph 1: The origins.

[132] Speech of Romano Prodi to European Parliament, Plenary Session, 3 October 2000 (SPEECH 00/352).

an independent European Food Authority. One may recall the on-going *BSE* crisis, growing consumer concerns upon the safety of GM foods and, lastly, the dioxin contamination outbreak in Belgium.

In the wake of these food emergencies and consumer scares, the European Commission proposed to combine the envisaged radical reform of the EC food regulatory framework with an innovative institutional reform by publishing the White Paper on Food Safety on 12 January 2000[133].

By launching a debate and involving the governments and all other parties affected by the new regime, this text expressed the need of a major structural change in the food safety regime to assure the twin objectives of assuring the highest standard of food safety and restoring consumer confidence. In order to achieve these goals, it proposed the establishment of a European Food Authority within the framework of a broader EC food safety legal reform mainly driven by the need to guarantee a high level of food safety throughout the Community.

The guiding and somewhat 'revolutionary' principle of the White Paper was that food safety policy must be based on a "comprehensive, integrated approach" throughout the food chain; across all food sectors; between the Member States; at the EC external frontier and within the EC; in international and EC decision-making for and at all stages of the policy-making process. The assumption was that a comprehensive, integrated, approach would lead to a more coherent, effective and dynamic food policy.

More precisely, the strategic priorities of the White Paper were:

- to create as soon as possible a "European FDA"[134]: the European Food Authority;

- to propose a new legal framework laying down the general principles of Food law such as:

    - responsibility of feed manufacturers, farmers and food operators;

[133] White Paper on Food Safety COM (99) 719, 12 Jan. 2000 *available at* http://europa.eu.int/comm/dgs/health/consumer /library/pub/pub06_en.pdf

[134] The US's Food and Drug Administration (FDA), together with the EU's Medecines Evaluation Agency (EMEA), represent the two main models the EC Commission relied on in conceiving the European Food Authority (EFSA). The EFSA has then inspired the creation of two other agencies, the European Maritime Safety Agency and the European Aviation Safety Agency. See Chalmers, *supra* note 103, at 532.

- traceability of feed, food and its ingredients;
- proper risk analysis through
  - risk assessment (scientific advice and information analysis),
  - risk management (regulation and control) and
  - risk communication, and
  - the application of the precautionary principle if appropriate

- to consistently implement a 'farm to table' approach in food legislation;
- to establish the following principles:
  - that the information for consumers should include that the Commission shall test the performance of Member States' control capacities and capabilities through audits and inspections;
  - all the instructions needed by way of an appropriate labeling to allow consumers to make more informed choices;
  - that Member States need to ensure surveillance and control of the economic operators.

Following the two 1997 Communications, the Green Paper and the Consumer Health, the Commission confirmed the central role of risk analysis as "the foundation on which food safety policy is based"[135] and described its three components: risk assessment (scientific advice and information analysis), risk management (regulation and control) and risk communication.

Relying on this conceptual framework, the White Paper proposed to entrust the Authority with particular responsibilities for both risk assessment and communication on food safety issues, while denying it any role in risk management activities. Thus, the scope of the mandate to be given to the Authority reflected the "generally accepted need to

[135] *See* White paper, supra note 133, para 12.

functionally separate risk assessment and risk management"[136] already sketched out by the Commission in its Communication on Consumer Health. The EFA was envisaged as being: 'guided by the best science'; 'independent of industrial and political interests"; 'open to rigorous public scrutiny'; 'scientifically authoritative' and closely intertwined 'with national scientific bodies'[137]. As such, the EFA was designed to become the 'automatic port of call' when scientific information on food safety and nutritional issues were sought.

Moreover, the White Paper advocated the adoption of eighty-four distinct measures (involving around thirty directives and regulations) forming a complete and coherent corpus of legislation covering all aspects of food products from "farm to table". The new legal framework should have virtually covered the whole of food chain, including animal feedstuffs, the animal health and welfare, hygiene, contaminants and residues, new types of food, food additives and flavors, packaging materials and ionizing radiation.

As for food safety controls, in light of the wide variations in the manner in which Community legislation is being implemented and enforced at national level[138], the Commission proposed that, in cooperation with the Member States, a Community framework for the development and operation of national control systems would be developed. Along these lines, the White Paper revamped the Rapid Alert System[139], whereby there is a coordinated exchange of information between the Commission and Member States regarding potential threats to the health and safety of consumers, by extending obligations of economic operators to notify food safety emergencies and ensure appropriate information of consumers and trade organizations. The EFA would be entrusted of its operation.

[136] See White paper, supra note 133, para 29.
[137] See White paper, supra note 133, para 38.
[138] Under the EC Treaty, the main responsibility for food control and the enforcement of EC food law lies with the national authorities of the Member States while the EC Commission monitors how these competent authorities exercise their powers.
[139] The Rapid Alert System has been established by Directive 92/59/EEC and it is a network of national authorities managed by the European Commission that exchanges information on measures taken to address potential health risks in the area of food and feed. Recent food crises have showed the inadequacies of the Rapid alert system. See infra

## 5. THE 'GLOBAL APPROACH': THE NEW FOOD SAFETY REGIME AND THE EFSA (2003-PRESENT)

It took more than two years for the Commission to transform the White Paper into a proposal for a regulation "laying down the general principles of food law, establishing the European Food Authority, and providing for urgency measures in matters of food safety"[140]. This proposal, published in March 2001, contained all the main features originally sketched out by the White Paper and was subsequently adopted, with few amendments[141], as Regulation (EC) No 178/2002 on the 28th of January 2002 with a title only slightly modified[142]. Its legal basis can be found in Articles 37, 95, 133 and 152 (4) b of the ECT.

This regulation represents the first attempt to address all aspects of food safety at EC level by laying down a comprehensive EC food policy covering horizontally all stages of production, processing and distribution of food and feed (from 'farm to fork'), thus encompassing raw materials, intermediate products and finished food products as well as feedstuffs (Article 3.3)[143]. Being addressed to not only to the EC institutions, but also to the Member States, the scope *ratione personae* of this policy is unusually broad[144].

The overriding principles of the new EC food regime are that food law, enacted either by the Community or by its Member States, should seek to achieve a high level of protection of human health and consumers' interest whilst ensuring the effective functioning of the internal market.

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[140] Proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food, COM/2000/0716 final, O. J. 2001 (C 96 E), 247-268 then modified by Amended Proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety (presented by the Commission pursuant to Article 250 (2) of the EC Treaty), COM/2001/0475 final, O.J. 2001 (C 304 E), 273-326.

[141] For a detailed an analysis of the differences between the two proposals, see L. Gonzalez Vaqué, *Objetivo: la seguridad alimentaria en la Union Europea*, in 223 Gaceta Juridica de la UE 59 (2003), at 61-71.

[142] For some comments on the new EC Food Regulatory framework, see L. Gonzalez Vaqué, *Objetivo: la seguridad alimentaria en la Union Europea*, supra note 141; M. Hagenmeyer, *Modern food safety requirements – according to EC Regulation 178/2002*, supra note 102, at 443-459 (2002); F. Aubry-Caillaud, *La sécurité alimentaire au sein de l'Union Européenne: les apports de l'approche globale*, in 4 Europe 4-7 (2003).

[143] See Artt. 1.3. and 4 defining the scope *ratione materiae* of the Regulation. According to Article 1.3 this Regulation does not apply to "primary production from private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption".

[144] L. Gonzalez Vaqué, *Objetivo: la seguridad alimentaria en la Union Europea*, supra note 141, at 62.

The Regulation seeks to achieve these twin principles in two main ways:

a) It establishes a comprehensive EC-wide food policy, addressed to both the Community and its Member States, by setting forth:

i. general principles (Articles 5-10);

ii. obligations and requirements of Food Law (Articles 10-21); and also

iii. some procedures in matters of food safety (Articles 50-57).

b) It creates a new independent agency:

the European Food Safety Authority (Articles 21-49).

These aspects will constitute the object of the two following chapters. While the general food law part of the regulation (a) will be discussed within Chapter 2, the new institutional configuration of the EC food policy (b), the European Food Safety Authority, will be the main focus of chapter 3.

# CHAPTER II: THE EUROPEAN REGULATORY REGIME FOR FOOD SAFETY

## 1. THE NEW REGULATORY REGIME FOR FOOD SAFETY IN EUROPE: A BRIEF ANALYSIS

This chapter aims at exploring the philosophical rationale underpinning the first comprehensive EC food regime, by analyzing its main principles and obligations and focusing notably on the risk analysis scheme set forth by the new regulation.

The risk analysis' scheme, building upon the distinction between risk assessment and risk management, represents the conceptual frame within which the new food safety must operate. Indeed, the dichotomy between risk assessment and risk assessment not only dictates the procedural dimension to be followed by both the EC institutions and the Member States while adopting food safety legislation but is also determines the institutional framework of the new regime by imposing a clear cut separation between the risk assessors (EFSA) and the risk managers (EC Institutions).

Before setting forth the regulatory and institutional framework of the new food policy, the regulation provides for the first time common definitions in the food area, thus injecting legal certainty into an area which has hitherto been extremely empirical, being left to the legislative autonomy of Member State. Although EC food law has been enacted since the beginning of the 1960s, a uniform Community definition of foodstuff has never been introduced. It goes without saying that the formulation of a clear-cut definition of food turns out particularly useful in defining the scope of the new regime[145].

### 1. 1. Definitions

The provision that better exemplifies the 'global approach' pursued by this regulation is represented by Article 2, providing for the first time a common definition of 'food' throughout the Community[146]:

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[145] *Ibid.*.

[146] In the past, each vertical directive contained a specific definition of the food concerned. See R. Rossolini, *Libera circolazione degli alimenti e tutela della salute nel diritto comunitario*, Padova, 2004, p. 1.

"(For the purpose of this Regulation), 'food' (or 'foodstuffs') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans".

In accordance with the notion of "foodstuffs" contained in the *Codex Alimentarius*[147] and in the majority of Member States' legislations[148], this definition is deliberately wide in scope, including – by virtue of the 2 paragraph of Article 2 – drinks, chewing gum and any substance, "intentionally incorporated into the food during its manufacture, preparation or treatment". It therefore includes all the food chain.

The concept of ingestion seems to suggest that it is intended to cover all products which may be assumed by mouth or nose or administered by gastric intubation. Moreover, it might also been inferred that it would not cover products administered directly into the blood stream.

However, the ingestion criterion should not be overestimated in determining whether a product should be classified as food. After having asked whether the method of ingesting a product is significant for its classification as medicinal product or as a foodstuff, the Court has held in case *HLH Warenvertirebs GmbH* that

"the competent authority must decide on *case-by-case*, taking into account of all the characteristics of the product, in particular its composition, its pharmacological

[147] The *Codex Alimentarius* Commission is an intergovernmental body jointly sponsored – since 1962 - by the World Health Organisation and the Food and Agriculture Organisation (WHO/FAO, both United Nations bodies) to develop international food standards. Over 160 countries are Member, including all fifteen EU Member States. It functions through two types of committees: Codex Committees, which prepare the norm proposals, and the coordination committees, which intervene when groups of countries are involved and can propose norms for the geographical area involved. The Food Standards Agency represents the UK in *Codex*. All Member countries participate equally in Codex and have one vote each. Recognised international Non-Governmental Organisations (*e.g.* consumer, industry and academic bodies) are also free to attend as observers, and are able to speak, but not vote. The European Community, represented by the Commission, currently has observer status in Codex. The European Community is already a Member of FAO (but not of WHO). This provides the Community with the legal entitlement to apply for Membership of Codex, but does not require it to do so. It also sets a precedent for the way the EU as a Regional Economic Integration Organisation participates in UN inter-governmental organisations. EU Member States are constrained by European Treaty obligations to support an application for full Membership of Codex. EU countries already co-ordinate their positions in a Council Working Group before each *Codex* Commission meeting. This is because most of the subject matter in *Codex* is in areas of harmonised EC Food Law and Member States must agree a Community approach. Where a consolidated Community line is agreed, this is usually presented at Codex meetings by the Presidency. EU Member States are free to speak in Codex, mindful of their responsibilities under the European Treaties, to support and develop the Community position. These arrangements are flexible and have worked very successfully, with the Community and the Commission having sixteen powerful and influential voices in the debate, and a wide range of experience and expertise to call upon.

[148] See Gonzalez Vaqué, supra note 141, at 62.

properties, to the extent to which they can be established in the present State of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail"[149].

Yet, the ingestion criterion plays a crucial role in delimiting the scope of regulation 258/97 on novel foods. To distinguish between food, within the meaning of regulation 178/2002, and novel food, as falling within the abovementioned directive, it has to be verified whether the food or the food ingredient in question has been consumed to a significant degree by humans before the reference date. As stated by the Court, "that condition refers to consumption, in the sense of ingestion by humans"[150].

Moreover, the reference to "partly processed" and "unprocessed food" solves the long-standing question whether EC food laws also covered primary products, which may either be for human consumption or for industrial use. Their clear inclusion within the scope of the definition means that producers are subject to all relevant obligations arising under EC Food legislation for all substances used in food.

The insertion of a definition of food must be welcomed for several reasons. As shown above, it introduces legal certainty in determining the scope of the different EC food laws, by solving several interpretative questions arisen throughout the time. Lacking a common definition of food, the scope of several horizontal legislation, such as those concerning additives or hygiene, was determined case by case the interested Member State. Moreover, it lays down the fundamental premise for a broad scope of the new EC food regime, virtually covering the whole "farm to fork" distribution chain. To avoid possible interpretation problems, the last paragraph of Article 2, clearly lists those items that do not fall within the food definition: feedingstuffs, live animals (unless prepared for human consumption), plants (prior harvesting), medicinal, cosmetics, tobacco and tobacco products, narcotics, residues and contaminants.

In particular, although the wide definition of the word 'foodstuff' provided in the regulation may (seem to) include medicinal products, it is apparent from point (d) of the

[149] Cases C-211/03, C-299/03 and C-316/03 to C-318/03, HLH Warenvertriebs GmbH [2005] not yet published, points 89 – 94. See L. González Vaqué, *Novedades en la jurisprudencia del Tribunal de Justicia de las Comunidades Europeas relativa a las nociones de medicamento y alimento?: una primera valoración de la sentencia "HLH Warenvertriebs"*, in Revista de Derecho Alimentario, Julio 2005, p. 21.
[150] HLH, supra note 149, para 83.

third paragraph of that article that 'food' does not cover medicinal products within the meaning of Directive 2001/83. Likewise, Article 1(2) of Directive 2002/46 relating to food supplements provides that that directive is not to apply to medicinal products as defined by Directive 2001/83.

However, *quid* when a product satisfies equally well the conditions for classification as a food stuff and the conditions for classification as a medicinal product? One may wonder which provisions of EC law may be applicable to this particular product. In case *HLH Warenvertirebs GmbH* the ECJ has held that only the provisions of Community law specific to medicinal products may apply to this particular product. This interpretation is supported by Article 2, paragraph 2, of directive 2004/27/EC amending Directive 2001/83/EC, which is worded as follow:

> "In case of doubt, where taking into account all its characteristics, a product may fall within the definition of a "medicinal product" and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply"[151].

Finally, Article 3 provides definitions for many other expressions such as "food law", "food business", "food business operator", "feedingstuff", "placing on the market", "risk analysis" and its three components, and also "traceability", "hazard", "final consumer", "so that they form a "common basis for measures governing food taken in the Member States and at Community level"[152].

### 1.2. General principles and requirements of food law

Chapter II of the Regulation, listing the general principles of food law, principles of transparency, general obligations of food trade and general requirements of food law, forms "a general framework of a horizontal nature to be followed when measures are taken" by both the Community and its Member States. Finally, the EC food law disposes of a central unifying text setting out the fundamental principles of Community food law.

[151] Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136 p.34.
[152] See Preamble n. (4) of the Regulation.

### A. General objectives

Article 5 provides that EC food law must pursue one or more of the general objectives as sketched out in the preamble:

- high level of protection of human life and health:
- protection of consumers' interests, including
    - fair practices in food trade
    - the protection of animal health and welfare, plant health and the environment
- the free movement in the Community of food and feed.

Furthermore, the same provision, showing the EC's willingness in honoring fully the obligations stemming from the WTO TBT and SPS Agreements[153], establishes the duty to take into consideration in the development of the food policy, the existing international standards, unless where such standards would not be an effective mean to achieve for the fulfillment of the food policy's legitimate objectives, where there is a scientific justification or when they would result in a different level of protection from the one pursued by the Community[154]. In accordance with Article 4 of the SPS Agreement, the

[153] These two agreements were concluded at the end of the Uruguay Round to prevent technical legislation which is intended for the protection of the human health or safety, the protection of health or life of humans, animals or plants, consumer protection against deceptive practices resulting in unjustified barriers to international trade. In particular the Agreements encourage WTO Member to participate actively in the development of harmonised international standards in order to reduce the obstacles to trade arising from conflicting national rules. Measures adopted in conformity with these standards are presumed to comply with the provisions of the Agreements. However, WTO Member are free to adopt measures that provide a higher level of protection than that ensured by the relevant international standard, provided that these measures do not result in unjustifiable restrictions on international trade. The basic aim of these two Agreements is to maintain the sovereign right of any Member to establish the level of health protection it deems appropriate, but to make sure that this right is not misused for protectionist purposes. By imposing on Member the duty to implement international standards in their legislation, these Agreements introduce for the first time a form of positive integration within the WTO: not only measures do not have to discriminate, but they also have to be adapted to international standards in order to reduce their divergence. See infra Part II, chapter I, The SPS Agreements and its Main Obligations.

[154] Article 13 lett. a) encourages the EC not only to adopt legislation in conformity with international standards but also to contribute to their development within international organizations and non-governmental organizations.

regulation (Article 13, let c) ) also encourages the development of bilateral agreements on recognition of equivalence (MRAs) of specific food and feed-related measures[155].

## B. Risk Analysis: the EC 'specificity' in assessing risk

### *1. The principles of Risk Analysis*

The risk analysis' scheme, set forth by Article 6, represents the foundation (*Grundnorm*) of the new EC food policy. This is the main tool upon which the regulation relies on to seek to achieve its primary two-fold objectives: a high level of protection of human health and life and the free movement of foodstuffs[156]. Lacking an expressed definition within the Regulation, risk analysis may be defined a process for controlling situations where an organism, system or population could be exposed to a hazard[157].

Both the Community and the national food laws should be based on a risk analysis scheme as structured on the following three different components:

- risk assessment,
- risk management and
- risk communication.

These three interconnected components of risk analysis provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health. This structured approach incorporating the three distinct but closely linked components of risk analysis was firstly developed and popularized by

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[155] For an analysis of the Mutual Recognition Agreements (MRAs) concluded by the EC, see A. Alemanno, *Gli Accordi di Reciproco Riconoscimento di Conformita' dei prodotti tra regole OMC ed Esperienza Europea*, 2-3 Diritto del Commercio Internazionale 379-406; A. Alemanno, *Le principe de la reconnaissance mutuelle au delà du marché intérieur. Diversité règlementaire ou 'colonialisme' règlementaire ?*, in Revue du droit de l'Union européenne, forthcoming (2006) and O'Rourke, supra note 51, at 196-97.

[156] Article 5 (1).

[157] See, Descriptions of selected key generic terms used in chemical hazard/risk assessment; OECD/IPCS, October 2003, available at http://www.oecd.org

the US National Research Council[158] and to day finds support in the main guidelines developed by national and international organizations dealing with risk analysis[159].

Although, as we will see below, a clear-cut distinction between risk assessment and risk management is not unproblematic, its main rationale is to provide decision-makers with scientifically-grounded data on which to base regulatory choices. According to A.G. Mischo this distinction meets a dual goal: it ensures a rational technocratic dimension to the decision-making process while enabling the political process to be independent from the results of scientific assessments[160].

While not clearly expressed by Article 6 of the Regulation ("food law shall be based on risk analysis"), the duty to conduct a risk analysis while adopting food law bears not only on the EC institutions but also on Member States. Therefore this obligation exists within the entire area of food legislation regardless of whether it falls within the EC – exclusive or shared – competence or the Member States'. This may be inferred from the fourth and fifth recitals in the preamble of the regulation where it is stated that since there are important differences in relation to concepts, principles and procedures between the food laws of the Member States, "it is necessary to approximate these concepts, principles and

[158] For decades the National Research Council (NRC) has been called on to consider how to improve decisions about risks to public health, safety and environmental quality. The NRC has conducted a series of studies on how society can understand and cope with those risks. In particular, the distinction between risk assessment and risk management has been originally conceived in *Risk Assessment in the Federal Government: Managing the Process* (also called the Red Book), a study that sought "institutional mechanisms that best foster a constructive partnership between science and government". Subsequently, this distinction played a crucial role in the development of an organizational separation of risk assessment and risk management in many US regulatory agencies. However, as we will see further, later publications of the NRC recognized the difficulties of maintaining a sharp dividing line between the two processes and emphasized the importance of ensuring interaction and communication between risk assessors and risk managers. See P. Stern and H. Fineberg (eds), *Understanding Risk: Informing Decisions in a Democratic Society* (National Academy Press, Washington DC, 1996) and for a brief account of this development also I. Suczenauer, M. Tamplin, B. Buchanan, S. Dennis, L. Tollefson, A. Hart, *Briefing Paper: US Experience*", European Workshop on the interface between Risk Assessment and Risk Management, 2003 *available at* http://www.ra-rm.com

[159] See, within the U.S., *National Research Council Report on Science and Judgment*, National Academy Press, 1994 Washington, D.C. 1994, at 4 (prepared by a Committee of the National Research Council/National Academy of Science in response to a U.S. Environmental Protection Agency request mandated by the Clean Air Act Amendments of 1990); see, within the OECD, Descriptions of selected key generic terms used in chemical hazard/risk assessment; OECD/IPCS, October 2003, available at http://www.oecd.org; see within FAO and WHO, Joint FAO/WHO Expert Consultation, Application of Risk Analysis to Food Standards Issues (WHO/FNU/FOS/95.3, 13-17 March, 1995, Geneva 1995), p. 6; Joint FAO/WHO Expert Consultation, Risk Management and Food Safety, (27-31 January, 1997), FAO Food and Nutrition Paper 65, 1997; Joint FAO/WHO Expert Consultation, The Application of Risk Communication to Food Standards and Safety Matters, Rome, 2-6 February 1998, FAO Food and Nutrition Paper 70, 1999.

[160] Opinion in Case 192/01 Commission v Denmark [2003] ECR 9693.

procedures so as to form *a common basis for measures governing food and feed taken in the Member States and at Community level*".

However, the duty to entail a risk analysis procedure before adopting a piece of legislation regarding food law may suffer an exception. Article 6 explicitly recognizes that food law shall not be based on risk analysis where this is not appropriate to the circumstances or the nature of the measure. There are good reasons to believe that this derogation refers to crisis or emergency situations and therefore, though apparently open-textured, such a provision is closely framed.

One may wonder if this obligation to conduct a risk analysis implies a duty to consult a particular organism. As we will see below, there is no general obligation to request a scientific opinion to EFSA, unless it is expressly provided in EC secondary legislation as, for example, within a pre-market approval mechanism.

Furthermore, the risk analysis' duty exists only to the extent a particular measure aims at achieving the general objective of a high level of protection of human health and life. To the contrary, according to Article 7, the precautionary principle applies in order to ensure a high level of health protection regardless of whether it is human, animal or plant health put at stake. It follows that the risk analysis scheme does not have to be followed when a measure to be adopted in the food sector does not put at stake public health or when it may potentially endanger solely animal or plant health.

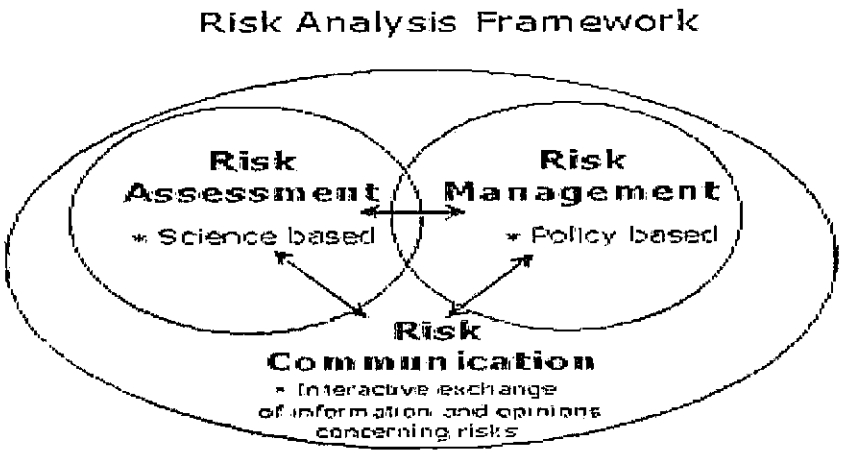
However, according to Article 152, paragraph 4 (b), the duty to entail a risk analysis within the Common Agricultural Policy may exist regarding measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health.

It might be interesting to observe that this duty seemed to have been generalized to all science-based measures by the CFI who has stated that

> "when a scientific process is at issue, the competent public authority must, in compliance with the relevant provisions, entrust a scientific risk assessment to experts who, once the scientific process is completed, will provide it with scientific advice"[161].

[161] Case T-13/99 Pfizer Animal Health v. Council, 2002 E.C.R. II-3305, para 157.

**Diagram 2.** This diagram illustrates the relationship between the three components of risk analysis.




*1.1. Risk Assessment (RA)*

Risk assessment is defined by Article 3 of the Regulation as "a scientifically based process" consisting of four steps:

- hazard identification;
- hazard characterization;
- exposure assessment;
- risk characterization[162].

It shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

Risk assessment is typically seen as a method for organizing and analyzing scientific information. According to its most notorious definition it may be described as a

[162] The identification of these 4 scientific stages in risk assessment was originally sketched out by the National Research Council (NRC) in *Risk Assessment in the Federal Government: Managing the Process* (Washington, D.C.: National Academy Press, 1983), supra note 158. Note that although the NRC talks about dose-response assessment instead of hazard characterization, this different wording does not seem to hide any conceptual difference for present purposes. The same steps within risk assessment may be found in Descriptions of selected key generic terms used in chemical hazard/risk assessment; OECD/IPCS, October 2003, available at http://www.oecd.org

"systematic approach to organizing and analyzing scientific knowledge and information for potentially dangerous activities or for substances that might pose risks under specified conditions"[163].

The first step of RA, the so-called hazard identification, is meant to guarantee a risk analysis which focuses on the descriptive elements of the potential risks by entailing the identification of known or potential inherent health hazards. Hazard is the potential of an identified source, biological, chemical or physical agent, to cause an adverse legal effect[164]. The next stage, the heart of RA, is generally expected to offer a more structured overview of the probabilities of certain phenomena or events. It aims at providing a qualitative and, wherever possible, quantitative description of the inherent properties of an agent or situation having the potential to cause adverse effect. Finally, there is an intermediary phase in which the exposure of an organism, system or population to an agent is evaluated, before leading the way to the final risk management stage: risk characterization. This is the stage of risk assessment in which the balance between confidence and uncertainty in the assessment is characterized and in which the risk assessment results are expressed in a form which is useful to decision-makers and risk managers. It may be defined as the qualitative or quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system or population, under defined exposure conditions[165].

EFSA's role in relation to risk assessment is defined in paragraph 34 of the preamble to the Regulation: "the Authority should take on the role of an independent scientific point of reference in risk assessment". A separation of responsibilities for risk assessment and risk management is implied later in the same paragraph where it is stated that EFSA "may be called upon to give opinions on contentious scientific issues, thereby enabling the Community institutions and Member States to take informed risk management decisions".

[163] NRC Science and Judgment, supra note 159, at 4.
[164] Article 3 (14).
[165] See Descriptions of selected key generic terms used in chemical hazard/risk assessment; OECD/IPCS, October 2003, available at http://www.oecd.org, reflecting the most up-to-date and harmonised descriptions of risk analysis terms adopted by OECD/IPCS, October 2003.

The definition of risk assessment in the Food Regulation as a "scientifically based process" implies a dependence on scientific research, both in the establishment of general procedures and in the production of data for particular assessment. The regulation requires EFSA to commission scientific studies necessary for the performance of its mission and to cooperate and avoid duplication with Member State or Community research Programs. Thus, many projects in the Commission's 5th and 6th Framework programs are providing basic knowledge for risk assessment.

Although this risk analysis' framework would seem to be presented as a harmonized model to be followed by virtually all bodies carrying out scientific opinions throughout the Community, it is limited to the food sector. For this reason, a Working party is currently developing a harmonized approach to risk assessment procedures among the Scientific Committees advising the European Commission in the area of human, animal and plant health and on the environment[166].

### *1.2. Risk Management (RM)*

Risk management is defined by Article 3 of the Regulation as a process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and if need be, selecting appropriate prevention and control option[167].

This definition contains a clear recognition that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should

[166] Notably, it has been established a Working Party on "Harmonization of Risk Assessment Procedures" to address specifically the general principles of risk assessment and its application to broad consumer health issues, with a particular reference to measures that would enhance compatibility of approaches between the Scientific Advisory Committees. See the Updated Opinion of the Scientific Steering Committee on Harmonization of Risk Assessment Procedures, adopted on 10-11 April 2003. A full Second Report on the Harmonization of Risk Assessment Procedures is expected by the end of the year.

[167] Similarly, risk management is defined within the OECD as a decision-making process involving considerations of political, social, economic, and technical factors with relevant risk assessment information relating to hazard so as to develop, analyse, and compare regulatory and non-regulatory options and to select and implement appropriate regulatory response to that hazard. See Descriptions of selected key generic terms used in chemical hazard/risk assessment; OECD/IPCS, October 2003, available at http://www.oecd.org. For a more cautious definition of risk assessment see Joint FAO/WHO Consultation Risk Management and Food Safety, p. 9, where it is defined as the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

legitimately be taken into account. Recital 20 of the Preamble, containing a list of such factors, mentions societal, economic, traditional, ethical and environmental factors and the feasibility of controls[168].

Therefore, while risk assessment is seen as a technical or scientific phase in which experts analyze information, risk management is conceived as the political or value-laden stage in which risk managers consider scientific, political, economic and social information in order to determine what the acceptable level of risk is and how it should be attained.

The risk management of a decision does not consist solely of a selection of both the facts and the methods of assessment, but it also implies a complex decision on whether to accept the risks in question or not.

As it has been stated, according to this risk analysis frame: "the decision is no longer to be regarded as the final point of a linear process of decision-making, but it, instead, to be regarded as a decision which is meant to bind uncertainty while, at the same time, allowing for a re-entry of uncertainty, because it uses the decision and proposed decision process for the generation of new knowledge which can, in the future, be used for the revision of the assumptions on which the decision was based"[169].

According to the risk analysis' scheme provided by Article 6 of the Regulation, whilst risk assessment must be based on the available scientific evidence and carried out independently, risk management must take into account its results. In other words, the scientific assessment of risk to the consumer from a product forms the basis for risk managers to develop risk reduction or containment measures. Once the risk has been identified, it is the decision-maker's responsibility to decided if it is acceptable, which may mean adopting an attitude of zero tolerance.

In particular, risk managers (EC institutions and the Member States' authorities) have to take into account:

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[168] The inclusion of "other legitimate factors" in food risk assessment is confirmed by Article 7(1) of Regulation 1829/2003 on Genetically Modified Food and Feed [2003] OJ L287.

[169] K.H. Ladeur, *The Introduction of the Precautionary Principle into EU law: A Phyrric Victory for Environmental and Public Health Law? Decision-making Under Conditions of Complexity in Multi-Level Political Systems*, in 40 Common Market Law Review, 1465.

a) the results of risk assessment, in particular the "opinions" of the EFSA;

b) "other factors legitimate to the matter under consideration" (the 'social factor'[170]), and

c) the "precautionary principle" within the limits laid down in Article 7

in order to achieve the general objectives of food law.

Article 5, paragraph 3, adds to this list:

d) "international standards [...] except where such standards or relevant parts would be:

a. an ineffective or inappropriate means for the fulfillment of the legitimate objectives of food law, or

b. Where there is a scientific justification, or

c. Where there would result in a different level of protection from the one determined as appropriate in the Community".

While the role of precautionary principle and of EFSA's scientific opinions will be discussed in the further chapters, the next paragraph focuses on the "other factors" to be considered within risk management.

### *1.3. Role of non scientific factors*

Although science plays the major role at the risk management stage, the Regulation reserves the right of risk assessors to take other factors into consideration when reaching a final decision[171]. This is because "it is recognized that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decisions should be based"[172]. These factors relevant for the health protection of consumers may consist, for instance, of societal, economic, traditional, ethical and environmental

[170] Echols, supra note 55, at 530.
[171] The regulation states several times that risk management decisions may consider not only risk assessment but also "other legitimate factors". See preamble (19), Article 3 (12) and Article 6 (3). See also Article 7(1) of Regulation 1829/2003 on Genetically Modified Food and Feed [2003] OJ L287
[172] See Regulation, preamble (19).

factors[173]. In line with the Communication on the precautionary principle, in case of scientific uncertainty

> "judging what is an "acceptable" risk for society is an eminently political responsibility. Decision-makers faced with an unacceptable risk, scientific uncertainty and public concerns have a duty to find answers".

The perceived need to consider also non science-based factors within the decision-making process characterizes the European approach to risk analysis by differentiating it greatly from the one adopted by the U.S. and by the WTO/SPS legal frameworks.[174].

The former EC Health and Consumer Protection Commissioner D. Byrne has recently confirmed that the Commission will take into consideration not "only science, but also many other matters for example economic, societal, traditional, ethical or environmental factors, as well as the feasibility of controls"[175].

The EC approach to risk analysis has been effectively described as a system in which "scientific knowledge is authoritative, but not exclusively so"[176].

Which are the consequences stemming from such a European non-exclusively science-based approach to risk analysis?

The well-know *Hormones* dispute between the EC and the US exemplifies the impact that the EC analysis of risk may have not only upon its external trade relations[177], but also

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[173] The list of examples provided by the Preamble of the Regulation seems slightly narrower that the one contained within the White Paper (see supra note 133, para 4), which mentions "environmental considerations, animal welfare, sustainable agriculture, consumers' expectation regarding product quality, fair information and definition of the essential characteristics of products and their process and production methods". However, containing both lists mere examples, their differences do not carry any particular value and should not be overemphasised.

[174] *See infra* part IV, chapter II.

[175] D. Byrne, "EFSA: Excellence, integrity and openness", Inaugural meeting of the Management Board of the European Food Safety Authority, Brussels, 18 December 2002, *available at* http://www.europa.eu.int/rapid /start/ cgi/guesten.ksh?p_action.gettxt=gt&doc=SPEECH/02/405/0/RAPID&lg=EN&display=

[176] G. Skogstad, *The WTO and Food Safety Regulatory Policy Innovation in the European Union*, *in* 39 Journal of Common Market Studies 485, 490 (2001).

[177] *See* Appellate Body Report, *European Communities--Measures Concerning Meat and Meat Products*, WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998) (*adopted* Feb. 13, 1998; Panel Report, *European Communities - Measures Concerning Meat and Meat Products*, WT/DS26/R/USA (Aug. 18, 1997) (hereinafter: *EC-Hormones*). For a detailed reconstruction and insightful analysis of the dispute, see T. Christoforou, *Science, Law and Precaution in Dispute Resolution on Health and Environmental Protection: What Role for Scientific Experts?*, in J. Bourrinet et S. Maljean-Dubois (eds.), *Le Commerce International des Organismes Génétiquement Modifiés* (2003), at 239 and D. Wüger, *The Implementation Phase in the Dispute Between the EC and the United States on Hormone-Treated Beef*, 33 Law & Pol'y Int'l Bus. 777 (2002).

on its internal market dimension. The EC decision to ban the production and importation of meat derived from animals treated with non-therapeutic growth hormones was adopted by the EC institutions notwithstanding the advice of the Scientific Working group proving that the outlawed growth-hormones were harmless to human health. The ban triggered not only the US and the Canadian reactions but also some internal resistance[178]. Member States were split up over that decision: while France, Germany, Italy and the Netherlands supported the total prohibition, UK and EIRE opposed it so seriously as to bring the controversial legislation before the European Court of Justice[179].

The EC ban turned out to be motivated by a complex mix of political, social, economic and conflicting scientific factors that, as we have seen, may now formally enter into the EC food decision-making process directed to the adoption of safety measures.[180]

Notwithstanding the existence of a scientific consensus concerning a certain substance, the possibility to take "other legitimate factors" into consideration may lead to divisions across Member States over controversial food safety measures while at the same time bringing the EC measures at odd with the WTO framework.

Although comprehensible in terms of policy *realpolitik*, this opening to non-science-based factors may increase the divide existing between Member States in assessing the level of protection to be provided to their citizens. At the same time, it puts the EC regulatory framework in conflict with the WTO SPS Agreement. As we will see below, this Agreement subjects all sanitary and phytosanitary measures to scientific evidence and risk assessment procedures by imposing on Member States the duty to demonstrate that their measures are necessary to protect human health. Under the existing SPS

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[178] Thus, for instance, an association of pharmaceutical manufacturers sought the annulment of the Directive prohibiting the use of certain hormonal growth promoters for the purpose of fattening cattle. See Case 160/88 Fedesa v. Council [1988] ECR 6399.

[179] Case C-180/96, United Kingdom v. Commission, [1998] supra note 107. See also Case C-157/96, The Queen v. Ministry of Agriculture, Fisheries and Food, ex parte National Farmers' Union et al. [1998] ECR I-2211. Contrary to the former case, the latter was not a direct action for annulment of the EC ban, but rather a preliminary ruling pursuant to a question about the validity of the EC measure from the UK High Court.

[180] On this case, see, e.g, J. Scott, *Of Kith and Kine (and Crustaceans): Trade and Environment in the EU and WTO* in J.H.H. Weiler (ed.), *The EU, NAFTA and the WTO: Towards a Common Law of International Trade* (Oxford: OUP, 2000); S. Pardo Quintillán, *Free Trade, Public Health Protection and Consumer Information in the European and WTO Context*, 33 Journal of World Trade 147 (1999) and R. Howse, *Democracy, science and Free Trade: Risk Regulation on Trial at the WTO*, (2000) 98 Mich.L.R. 2329.

Agreement, scientific evidence is, at least textually, the only legitimate criterion upon which to base SPS measures. Yet, during the Uruguay Round negotiations, the EC tried hard to introduce other criteria besides scientific evidence among those upon which to base measures under the SPS Agreement. It is curious to observe that although the EC failed in its attempt, the WTO AB report in the *Hormones* case stated that

> " [...] there is nothing to indicate that the listing of factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a closed list. It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but *also risk in human societies as they actually exist*, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die"[181].

In other words, the EC style in food safety regulatory policy would seem to find support in this reading of the SPS Agreement. However, the same ruling has been described as a demonstration that "the SPS Agreement exalts the role of science far beyond the point it is appropriate, attempting to eliminate all 'non-science' factors from standard setting"[182].

Chapter 2 of Part IV offers a comparison of the role played by "other legitimate factors" in the EC and the WTO, by looking at Codex's risk management policies as well.

The next paragraphs explore further the EC risk analysis model by focusing on the relationship between risk assessment and risk management.

### *1.4. The relationship between RA vs RM*

The relationship between risk assessment and risk management, which has found both a normative and an institutional application within the European regime, has been a subject of discussion since at least early 1980s, when a Report by the US National Research Council recommended that a clear conceptual distinction be made between them[183].

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[181] *EC-Measures Concerning Meat Products* Appellate Body Report WT/DS26/AB/R, WT/DS48/AB/R adopted on 13 February 1998, para 187.
[182] J. Cameron, *The Precautionary Principle, in Trade, Environment and the Millenium* (G.P. Sampson – W.B. Chambers, eds.) 1999, p. 261.
[183] National Research Council, 1983. *Risk Assessment in the federal government: managing the process*, supra note 159.

Article 6 of the Regulation gives for the first time a normative expression to the "functional separation" of risk assessment (RA) and risk management (RM), originally introduced by the 1997 Communication on Consumer Health and Safety and subsequently confirmed by the Green Paper on food law and the White Paper on food safety[184]. The primary reason given for distinction or separation is a desire to ensure independency and objectivity of the scientific process or risk assessment. As seen above, following the publication of such documents, several steps have been taken within the Commission to institutionally implement this approach to risk analysis by functionally separating those responsible for production, or the promotion of the market, from those responsible for the assessment of food safety. Thus, for instance, the management of the scientific committees was firstly transferred into what is now under the Directorate General for Health and Consumer Protection (DG SANCO), and secondly to the EFSA, a supposedly independent scientific body lacking any decision-making task.

Since the beginning of the "Emergency" period, a watertight separation between the risk assessment stage and risk management in the field of food has been increasingly seen as essential not only to ensure independence and objectivity of the scientific process[185], but also as means to enhancing the democratic legitimacy of the decision-making process by ensuring that that decisions are ultimately taken by those who are accountable vis-à-vis the public[186]. The current regulatory regime, establishing an EC comprehensive food policy and the EFSA, is built upon this conceptual scheme, turning it into a regulatory and institutional reality.

The underlying rationale is self-evident: it is assumed that the separation between risk assessors and risk managers will make it clear who is responsible for what is decided. Therefore this "functional separation" has been advocated not only for assuring the purity of scientific assessment, but also, at the time of the establishment of EFSA, for enhancing the democratic legitimacy of the decision making-process.

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[184] White paper, supra note 133, para 32.

[185] Among the major drivers for this separation we might mention: a desire to remove value judgments from risk assessment, to prevent risk assessors from being unduly influenced by risk managers, to insulate scientific activity from political pressure and to maintain the analytical distinction between the magnitude of a risk and the cost of coping with it.

[186] According to the Commission's White Paper, the EFSA should not be entrusted with risk management tasks because this would reduce democratic accountability within the Union, supra note 133, para 32.

However, this distinction between the purely technical assessment of risks by scientists within EFSA and the management of these risks by the EC Commission seems to be questioned today[187]. In particular, although this "functional separation" reflects the legitimate attempt to depoliticize the heavily scientific stage of risk assessment, and it is supported by Codex[188], it overlooks the growing phenomenon of "science policies" in risk assessment[189]

*(a) Science Policies and the structural limitations of scientific knowledge*

If risk assessment is virtually an objective and neutral stage of risk analysis, its purely scientific nature may be reduced (put at stake) by the extensive use of science policies and assumptions by scientists. While, in principle, scientists provide their scientific assessment within various scenarios and risk-mangers decide what the acceptable level of risk is, it might happen that uncertainties are such that any scientific method does allow the presentation of any factual conclusion because a proper scientific study cannot be conducted. In the presence of such scientific uncertainty, which is inherent in scientific judgements under each of the four elements of risk assessment, scientists rely on a number of assumptions and techniques to overcome such uncertainties. Scientists do so because of the pragmatic goal of risk assessment: to provide risk managers with a faithful description of the scientific status quo with reference to a specific substance.

These assumptions and techniques form part of a mainstream scientific method called 'science policies'[190]. These may be defined as "decision rules about the way in which risk assessment scientists should proceed when they encounter specified types of

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[187] This distinction has been criticised for being artificial and difficult to realize in reality. See A. Alemanno, *Le principe de précaution en droit communautaire: stratégie de gestion des risques ou risque d'atteinte au marché intérieur?*, in Revue du droit de l'Union européenne, 4/2001; C. Noiville and N. De Sadeleer, *La gestion des risques écologiques et sanitaires à l'épreuve des chiffres – Le droit entre enjeux scientifique et politiques, in Revue du droit de l'Union européenne*, 2/2001, at 406-7; and, more, recently, Ladeur, supra note 169. NRC has also questioned the wisdom and the opportunity of the separation between risk assessment and risk management for excluding other sources of information which are necessary for good decision-making from the risk characterisation, see *NRC Understanding Risk*, 1996, supra note 158, at 33-35

[188] Decision of the 24th CAC Session, 2001, *Criteria for Consideration of the Other Factors Referred to in the Second Statement of Principle*, at 32.

[189] On the role of science policies in risk analysis, see V. R. Walker, *The Myth of Science as a "Neutral Arbiter" for triggering Precautions*, 26 Boston College International and Comparative Law Review 197, at 198 ss.

[190] Because these policies usually specify which assumptions to use to bridge gaps in scientific knowledge, they are also called "inference guidelines" or "default assumptions". See NRC 1983, 28-37.

uncertainties", which are established at political level[191]. Thus, for example, one of the most common science policies is the presumption that a certain agent that can cause disease in laboratory animals can equally cause disease in humans. Other examples include the use of a linear dose-response model, the assumption that absorption in animals and humans is approximately the same or the use of body weight scaling for interspecies comparisons[192].

Such polices are commonly used by US regulatory agencies in risk assessment as a way of improving the consistency and transparency of risk assessment undertaken in situations of scientific uncertainties.

As a Joint FAO/WHO Report has found, science policies are necessary since there are inevitable gaps in the science of risk assessment that need to be filled with default assumptions in order to be able to conduct a risk assessment. Each of these represent "scientific value judgments", and inevitably the assumptions embodied in them can significantly influence the outcome of risk assessment. Each also represents a choice among a number of plausible alternatives. In fact, although substantially grounded on scientific data, these policies inevitably represent the outcome of a political selective process. In fact, the need for science policy arises notably because of the limited scientific knowledge allowing multiple accounts that are scientifically plausible. In other words, while dealing with decisions involving technical and scientific aspects, scientific expertise and political decision become so intertwined as to become impossible to separate them. In fact, the elaboration of these policies and assumptions boil down into a risk management activity[193]. As it has been stated,

> "when normal science does not indicate definitely which data, models, or assumptions will, if used, provide a positive and verifiable risk assessment outcome, it is primarily

[191] V.R. Walker, *The Myth of Science as a "Neutral Arbiter" for triggering Precautions*, supra note 189, at 214.
[192] For an illustration of the most common risk assessment policies used by the Codex's bodies in charge of conducting many of the risk assessment leading to the adoption of the Codex standards (JECFA and JMPR), see Joint FAO/WHO Consultation Risk Management and Food Safety, (FAO Food and Nutrition Paper 65, Rome1997), p. 7-9. See also S. Breyer, *Breaking the Vicious Circle* (Harvard University Press ed., 1993) at 43-44.
[193] Walker, supra note 189, at 263.

the task of the risk managers to provide risk assessors with precise and binding guidance on the science policy to apply in such risk assessments"[194].

In these particular circumstances, decision-makers are confronted by a situation where decisions about what is an acceptable risk have already been taken. In the EC food context, this shows how the Authority is never simply conveying information, but it is inevitably endorsing a particular ideological model of politics[195]. Against this backdrop, although many (both normative and institutional) efforts have been made to separate risk assessment and risk management's activities within the new regulatory regime, it would seem impossible to avoid some overlaps between the two.

In these circumstances, one may legitimately wonder whether the use of these policies and assumptions may jeopardize risk assessment as an objective and neutral basis for regulatory action. In other words, how to ensure that science retains is central role in the decision-making process, whilst taking appropriate account of the structural limitations of science?

And finally, which is, *de iure condito*, the utility to separate between risk assessment and risk management?

Although a uniform and explicit use of science policies in scientific risk assessment may ensure consistency in approach[196], it inevitably leads to strip the "functional separation" between risk assessment and risk management of its original goals: purity of scientific assessment and accountability of risk managers.

In order to avoid this, it is crucial to frame the growing use of science policies in risk analysis by injecting some transparency. As "science policies" are pervading risk analysis and are crucial to completing most risk assessments today, it is imperative to become aware of the exact role they play within risk assessment. Notably, it may be important to understand the origin and the methods and principles upon which science policies' underlying assumptions and techniques are developed as well as developing a harmonized approach to risk assessment. The need to inject some transparency into the

[194] T. Christoforou, *The Precautionary Principle and democratizing expertise: a European legal perspective*, in 30 Science and Public Policy 3, June 2003, p.207.
[195] Along these lines of thought, see Chalmers, supra note 103, at 543.
[196] Walker, supra note 189, at 261; C. Button, *The Power to protect* (Oxford and Portland, Oregon, 2004), at 99.

scope of science policies is particularly important to the extent, as we have seen above, their use by risk managers is capable of determining the outcome of risk assessment, thus dramatically blurring the separation between risk assessment and risk management. In particular, this need is strengthened by the fact that science policies' assumptions may contain different biases. Thus, some authors have argued that existing risk-assessment methods and protocols are inherently biased in favor of avoiding too stringent regulatory measures, for fear of imposing undue costs on innovation and technological progress and ultimately on society (progressive risk estimations)[197]. To the contrary, others affirmed that such assumptions and policies tend to be chosen in order to arrive at the most conservative risk estimations[198]. The latter refer to the *Hormones* case, where the scientific experts advising the panel showed repeated references to the way in which ADI (acceptable daily intake) figures were established using very sensitive end point from human primates, with the vulnerability of sensitive Members of the population taken into account when establishing safety factors[199].

Notwithstanding the growing phenomenon of science policy, the distinction between risk assessment and risk management may be maintained today within the EC context mainly because the former, contrary to the latter, may rely solely on science, or on science combined with explicit science policies, while the latter may build upon "other factors"[200]. However, to maintain the original goals pursued by this separation, it is absolutely necessary to render science policies explicit and harmonized.

Unless the assumptions and policies that have been employed to overcome scientific uncertainties in risk assessment are made explicit, courts may struggle in reviewing the legality of a science-based measure. This is because, lacking a transparent science policy, courts will not be able to analyze a measure by establishing to what extent it is science-based and whether 'other factors' have already been included within the risk assessment stage. As we have seen above, this is mainly because adopted science polices tend to be based either on conservative or on progressive risk estimations.

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[197] Breyer, supra note 192; C.F. Cranor, *Regulating Toxic Substances – A Philosophy of Science and the Law*, 1993.
[198] Button, supra note 196, at 98.
[199] Button, supra note 196, at 98, refers to the *Hormones* Panel Report, Annex: Transcript of the joint meeting with Experts, para 65. See also, S. Breyer, supra note 192, at 46; Walker, supra note 189, at 166.
[200] Walker, supra note 189, at 166.

At the same time, it may be advisable to carry on the current EC Commission's efforts aimed at harmonizing risk assessment procedures within the Community. In its attempt to develop a harmonized common methodology for the Scientific Committee's activities, the Commission should improve consistency in application of science policies and risk assessment techniques by developing some robust assessment practices[201]. The Scientific Steering Committee advised the Commission to establish a Working Party on "Harmonisation of Risk Assessment Procedures" to address specifically the general principles of risk assessment and its application to broad consumer health issues, with particular reference to measures that would enhance compatibility of approaches within the Scientific Committees. Although it is has been recognized that complete common methodology for the activities of the Commission Scientific Committees may not be achievable, it is imperative to avoid that the same chemical, biological or physical agent may be dealt with quite independently by the EFSA Committees and the other Scientific Committees in different contexts resulting in potential inconsistency in the assessment and confusion in its application[202].

This is not solely the only way in which risk assessment could remain scientifically "objective", by maintaining consistency and transparency in the face of scientific uncertainty, but also the only manner ensuring that the "functional separation" may still have a meaning in the current risk analysis scheme, by allowing the judiciary to accomplish its task of reviewing the legality of science-based measures. In conclusion, in light of the above, it is argued that the introduction of common scientific procedures to inform risk assessment would be the most appropriate mechanism for achieving a transparent interface between risk assessment and risk management

*(b) Links between risk assessors and risk managers*

Showing some sensitiveness to this trend questioning the opportunity to draw a clear-cut distinction between the purely technical assessment of risks by scientists and the management of these risks, the same Regulation expresses the need, not without some

[201] A recent initiative has been launched by the European Consumer Safety Association (ECOSA) in the occasion of the Edinburgh Risk Assessment Conference. A working party has been established with the aim of developing a common nomenclature for risk assessors and a more standardised framework for the actual risk assessment process.

[202] Updated Opinion of the Scientific Steering Committee on Harmonisation of Risk Assessment Procedures, adopted on 10 April 2003, at 2.

ambiguity, to strengthen the "link between risk assessors and risk managers" in order to promote coherence and transparency between the risk assessment, risk management and risk communication functions[203]. Several other parts of the Regulation emphasize the need for EFSA's independence to be combined with effective interaction, notably Article 40 emphasizes the need for close collaboration in relation to risk communication. This attempt to move towards a more fluid model of risk analysis which eschews formal conceptual distinctions and focuses on multiple inputs to the decision-making process, communication and public participation follows the trend launched by the same National Research Council in its 1996 Report Understanding Risk[204].

The main reasons justifying the need for such an interaction is to ensure that risk assessment addresses the right questions and that the answers are properly interpreted in risk management. Recently, the former EU Commissioner Byrne emphasized the importance of this interaction:

> "We must ensure productive interaction between risk assessors and risk managers. The process of objectively establishing, analyzing and scientifically interpreting the facts has to be done independently but not in a vacuum. This calls for close collaboration, interaction and exchanges between the Authority and those charged with the responsibility of managing risk"[205].

There is therefore within the Community a growing belief that it is essential that risk assessment and risk management interact in an efficient manner, and that public perceptions and values are included in decision-making. What is needed is an interface between assessment and management that achieves an appropriate balance between these goals. In other words, there is the need to find ways for risk assessment and risk management to interact efficiently, while maintaining appropriate functional separation. In the EFSA's annual report[206], we read that Commission's officials have attended all scientific panels' meetings to "ensure a seamless interface between the scientific advisor

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[203] Preamble (35).

[204] NRC *Understanding Risk – Informing Decisions in a Democratic Society*, supra note 158. The mandate ("letter") given to the NRC called on the committee for "guidance [...] to improve the dialogue between risk assessors and risk managers prior and during the development of a comprehensive assessment so that policy and management concerns are understood by all parties". See Preface, p. xi.

[205] Speech by David Byrne, European Commissioner for Health and Consumer Protection. Inaugural meeting of the Management Board of EFSA, Brussels, 18 September 2002.

[206] EFSA Annual Report 2003, at 17.

and the decision makers". According to the Commission, the main reasons justifying the need for such an interaction is to ensure that risk assessment addresses the right questions and that the answers are properly interpreted in risk management. We will see below that, notwithstanding this noble intention, the Commission's officials attendance of the scientific panels raises serious doubts about scientists' independency by jeopardizing the main goal pursued by the strict separation between risk assessors and risk managers.

As the EFSA's role is to provide a "an independent scientific point of reference in risk assessment [...] enabling the Community institutions and Member States to take informed risk management decisions", it is crucial for its functioning to find an appropriate interfacing between risk assessment and risk management in decision-making. A clear understanding of this interface is also crucial for the Scientific Committee and Panels of independent experts, which have been established to provide the EFSA's scientific opinions.

It is worth noticing that even before the spreading of concerns about independence of risk assessment that were stimulated by food crises, many Community Directives and Regulations specified procedures for risk assessment and risk management, for a wide range of issues. However, none of these pieces of legislation specify the distinction between these two instances as clearly as the Food Regulation. Thus, for instance, both the procedures for the control of new and existing chemicals, as laid down in Council Directive 92/32/EEC and Council Regulation 793/93, and procedures for biocides, as laid down in Directive 98/98, imply that both the acceptability of risk and the measures necessary to reduce risk in these sectors are decided as part of risk assessment, rather than risk management.

The issue of the relationship between risk assessment and risk management has recently been discussed thoroughly by a European workshop convened to consider ways of improving the interface between these instances, especially in the food safety area. The conclusion of this workshop identified six key principles:

1. There is a need for functional separation of risk assessment and risk management, to ensure the independency of risk assessment;

2. Efficient interaction between risk assessors and risk mangers is essential, to ensure that risk assessment is relevant to the needs of risk management and to optimize regulatory decision-making;

3. Risk management should take into account all relevant factors including the social, economic and cultural consequences of alternative decisions, as well as their effects on health and the environment;

4. It is important to involve all stakeholders (interested parties) in the risk analysis process;

5. Openness and effective communication are essential throughout the risk analysis process, and should facilitate increased trust between all those involved;

6. Clear policies and appropriate expertise are essential for efficient risk analysis.

A number of different approaches has been developed that could be considered when implementing each principle. Thus, for instance, it has been proposed that in order to achieve a functional separation, there is no need to introduce a structural separation between the two instances, but rather there should be a clear definition of roles, responsibilities and authorities of risk managers and risk assessors including the responsibilities of different scientific committees or bodies.

### *1.5. Conclusions*

Regulation 178/2002 represents the first piece of EC legislation formally laying down a risk analysis model for Europe. This model is largely inspired by the scheme originally developed on the other side of the Atlantic by NRC, and builds upon the three distinct aspects of risk analysis: risk assessment, risk management and risk communication. However, it also presents some particular features giving it some specificity.

The risk regulation model has not solely found normative expression within the EC, but it has also largely inspired its food safety institutional framework, by providing the conceptual basis underpinning the current European food safety architecture. It relies on the assumption according to which scientific risk assessment delivers the facts to risk

managers who then consider which regulatory action to undertake in light of "other (non-scientific) factors".

However, notwithstanding the tremendous efforts to maintain a strict separation between risk assessment and risk management, the current practice of scientific risk assessment involving science policies questions its validity. Under "science policies", risk managers set up assumptions and techniques guiding scientists among the multiple accounts that are scientifically plausible in situation of scientific uncertainties, thus inevitably influencing the outcomes of their scientific assessments. If it is true that science policies may blur the distinction existing between risk assessment and risk management, it is equally true such a phenomenon does not necessarily strip this "functional separation" of its meaning. This is because even if it is illusory to believe that all policy factors are confined to risk management, we know that, contrary to risk management, risk assessment is limited to drawing inferences based on science, science alone or on science combined with science policies or inferences guides. In other words, according to this model of risk regulation, risk assessors may follow science policy guidelines, but they should not take on the role reserved for risk managers, by, for example, making decisions on the acceptability of a certain risk level for protecting public health or selecting procedures for reducing risks. However, to ensure that this separation will maintain its original meaning, it is crucial to render science policies explicit. This is the only manner in which risk assessment could remain scientifically "objective" by maintaining consistency and transparency in the face of scientific uncertainty, thus allowing the judiciary to accomplish its task of reviewing the legality of science-based measures.

### C. The precautionary principle (PP): from scientific uncertainty to legal certainty

Another important factor risk managers have to take into account when devising new food legislation is the controversial precautionary principle[207], allowing the adoption of protective measures in situations of scientific uncertainty[208].

Because it focuses on situations with significant scientific uncertainty, the precautionary principle should be distinguished from the principle of prevention, which addresses cases where the threat or possible damage is certain. Recourse to the precautionary principle presupposes that scientific evaluation does not allow the risk to be determined with sufficient certainty. In line with the "other factors' philosophy" enlightening the EU decision-makers, it assumes that, in instances of scientific uncertainty, the results of risk assessments cannot monopolize the policy decision[209]. As we will see further, the conduct of a scientific study is the first requirement to satisfy in order to invoke the principle. In order to reduce the risk of abuses stemming from its invocation, several other requirements have been formulated, throughout the time, by both the Community courts' jurisprudence and by the EC legislation to constrain its invocation. This set of

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[207] For a wide-ranging review of this principle in Community and International law, *see* A. Alemanno, *Le principe de précaution en droit communautaire: stratégie de gestion des risques ou risque d'atteinte au marché intérieur?*, supra note 187; L. Gonzalez Vaqué, L. Ehring, C. Jacquet, *Le principe de précaution dans la législation communautaire et nationale relative a la protection de la santé*, *in* Revue du Marché Unique Européenne 1, 79 (1999); T. Christoforou, *The Origins, Content and Role of the Precautionary Principle in European Community Law*, *in* C. Leben & J. Verhoeven, *Le Principe de Précaution : Aspects de droit international et communautaire* (LGDJ : Éd. Panthéon-Assas, 2002); T. Christoforou, *The Precautionary Principle, Risk Assessment, and the Comparative Role of Science in the European Community and the US Legal Systems*, in N.J. Vig and M.G. Faure, eds., *Green Giants? Environmental Policies of the United States and the European Union* (Cambridge: MIT Press, 2004), 17-51; T. Christoforou, *Science, Law and Precaution in Dispute Settlement Resolution on Health and Environmental Protection: What Role for Scientific Experts ?*, supra note 177, at 79-120; Wiener J.B., Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems, (2003) 13 Duke Journal of Comparative and International Law 207 ; J. Cameron, The Precautionary Principle, in Trade, Environment and the Millenium, supra note 182 and L. Marini, *Il principio di precauzione nel diritto internazionale e comunitario, Disciplina del commercio di organismi geneticamente modificati e profili di sicurezza alimentare*, Padova, 2004.

[208] In the preamble (21), the principle is defined as "a mechanism for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community".

[209] C. Noiville, *EU Food Safety Pattern and the WTO*, in Ansell C. and Vogel D. (eds.), *Why the Beef? The Contested Governance of European Food Safety*, in European Food Safety Regulation: The challenge of Multi-level Governance, (MIT Press, forthcoming 2006).

requirements aims at turning the scientific uncertainity triggering precautionary action into legal certainty.

The principle may be relied upon not only by the Community institutions but also by the Member States[210]. However, different consequences ensue from recourse to the principle by the former or the latter. Although all precautionary-based measures, whether of national or Community origin, inevitably lead to a partitioning of the single market, and this regardless of whether their adoption is guided by protectionist consideration, only national measures lead to such a result without having taken into due account the view of other Member States. It will be shown how this circumstance may explain the more stringent requirements imposed on the invocation of the precautionary principle by the Member States.

### *1. Origin at International and Community level*

Since public concern associated with decision-making in the face of scientific uncertainty has grown considerably in recent years, it has been felt the need to develop a principle capable of restoring public confidence by requiring public authorities to take action or adopt measures to reduce risk, even in the absence of scientific evidence. In other words, acknowledgement of the limits of science in providing conclusive evidence has led to the development of this principle. The precautionary principle permits actions aimed at preventing uncertain risks. Uncertain risks are those for which scientific data on the likelihood of the beginning of a hazard and the nature or the importance of the hazard are insufficient or impossible to identify.

References to the principle in domestic legal systems and international treaties have grown incessantly over the years. Increasing international consensus on the principle culminated in 1992 with its formulation into the Rio Declaration, which, being continuously quoted, undoubtedly still represents the most famous definition of the principle:

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[210] After the ECJ *Artegodan* judgments, it would seem more appropriate to indicate that the precautionary principle, as a general principle of Community law, *requires* the competent authorities to take appropriate measures to prevent specific potential risks to public health, safety and the environment. See infra 253, para 184.

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are *threats of serious or irreversible damage*, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation"[211].

### *1.1. Origin of the PP in the ECJ's case law*

At EC level, the precautionary principle was originally introduced by the Treaty of Maastricht in Article 130r(2) (now Article 174(2)) of the EC Treaty as one of the guiding principles of the EC environment policy[212].

Yet, at the moment of its incorporation within the Treaty, the principle not only lacked a definition but its scope seemed to be limited to the environmental field. However, as anticipated by some commentators[213], the precautionary principle could validly be invoked beyond the field of environment because of the horizontal nature of Article 6 EC, which provides that

"environmental protection requirements must be integrated into the definition and implementation of the Community policies and activities"[214].

On this basis, the Commission widened the scope of this principle so as to apply to other fields of EC law, by quoting it in the general policy guidelines set out in the Green Paper on the General principles of Food Safety and in the Consumer Health Communication before finally declaring, in its 2000 Communication on the precautionary principle, "that the precautionary principle is a general one which should in particular be taken into consideration in the fields of environment protection and human, animal and plant health". A justification for extending the principle beyond environmental protection can be found in the same Communication where it is said:

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[211] Article 15 of the 1992 UN Conference on the Environment and Development (UNCED) in Rio de Janeiro (Rio Declaration).

[212] Article 174 EC provides that the Community's policy on the environment "shall be based on the precautionary principle and on the principles that preventive actions should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay".

[213] Gonzalez Vaqué, Ehring, Jacquet, supra note 207 and Alemanno, *Le principe de precaution en droit communautaire*, supra note 187.

[214] It must also be observed that Article 3(p) EC, also inserted by the Treaty of Maastricht, provides that the Community "contributes to achieve a high consumer protection level" among the policies and activities of the Community. Similarly, Article 153 EC refers to a high level of consumer protection.

"Although the precautionary principle is not explicitly mentioned in the Treaty except in the environmental field, its scope is wider and covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications of through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection"[215]

Further, also the Council, in its Resolution of 4 December 2000 on the use of the precautionary principle, welcomed the Commission's communication by endorsing its main guidelines[216].

*(a) The PP as an obiter dictum*

The European Court of justice had to deal with some issues related to a precautionary approach well before the start of the above described process of formal integration of the principle within the EC legal order.

This is because, back in the 80s, more and more Member States began invoking public health reasons, in situation of alleged scientific uncertainty, to prohibit specified substance contained in foodstuffs thus preventing the importation of those foodstuffs to their own territories. From an analysis of this line of cases it emerges, notably from the judgments concerning additives and pesticides[217], an embryonic form of the precautionary principle.

Most of these cases fit into the following scenario:

1. A Member State prohibits the importing of or the placing on the market of foodstuffs containing either additives or pesticides which are not allowed by the importing State legislations.

2. The rejected foodstuff was legally produced and marketed in another Member State.

[215] Commission Communication on the precautionary principle, COM (2000) 1, 2 Feb. 2000.
[216] Council Resolution of 4 December 2000 on use of the precautionary principle, (Doc. Council 14328/00).
[217] For an excellent review of this line of cases related to additives, see L. Gonzales Vaqué, *La Législation communautaire relative aux additives alimentaires*, in Revue du Droit de l'Union Européenne, 3/1993, at 119.

3. Criminal proceedings are instituted against the importer due to a violation of the individual State prescription.

4. Regularly, the relevant criminal court referred the case to the ECJ for a preliminary ruling aimed at determining whether the national prohibition infringed Article 28 EC or whether this infringement could be justified according to Article 30 EC.

According to the ECJ case law, Member State may successfully invoke public health under Article 30 EC to justify a prohibition on the free movement of goods only if they prove the existence of a "serious risk to public health"[218]. But *quid* when the current state of research does not offer any clear result about the existence of a health risk?

The ECJ had to face this critical situation in the *Kaasfabriek Eyssen* case. The Court had to consider whether a Dutch prohibition on the use of an antibiotic, nisin, as a preservative in processed cheese was justified on the ground of health protection. Here the evaluation of health risks for the additive in question could not reach any clear result[219]. As the risks caused by nisin depended on variable factors, in particular on different, indeterminable eating habits in the Member States, the ECJ deemed it necessary to grant Member States, in situation of scientific uncertainty, a wide margin of manoeuvre and to consider domestic prohibitions grounded on public health justified under Article 30 EC. The ECJ came to this conclusion after having noted that the controversial doubts about nisin led several international organizations, such as FAO and WHO, undertaking scientific studies on the risk of ingestion, not only from cheese but from all other sources. Similarly, in the *Sandoz* case, the ECJ, facing the uncertainty relating to the daily intake of vitamins by the populations[220], held that:

> "In so far as there are uncertainties in the present State of scientific research with regard to the harmfulness of a certain additive, it is for the Member States, in the absence of full harmonization, to decide what degree of protection of the health and life of humans they intend to assure, in light of the specific eating habits of their own population"[221].

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[218] See, e.g., case C-227/82 Van Bennekom [1983] ECR 3883.
[219] Case C-83/80, Officier van Justitie/Kaasfabriek Eyssen [1981] ECR 409
[220] Although ingestion of vitamins, as contained in foodstuffs, is harmless and even necessary for the human body, it may produce negative effects in case of excessive consumption in addition to the whole uncontrollable diet over a longer period of time.
[221] Case 174/82, Sandoz BV [1983] ECR 2445, para 16.

Therefore, since science could neither determine the exact critical quantities of vitamins nor the specific effects stemming from their consumption, the relevant prohibition of vitamins was justified under Article 30 EC. Although expressed in a mere *obiter dictum*, this 1983 judgment probably represents the first (judicial) recognition, at EC level, of the idea underlying the precautionary principle: a criterion allowing for public action even in the absence of conclusive scientific evidence[222].

Further recognition of this approach may be found in the *Heijn*[223] and *Mirepoix*[224]cases, where although there was no doubt as to the harmfulness of pesticide residues for the human organism, there was uncertainty with respect to the non-calculable intake quantity of such residues. This degree of uncertainty was sufficient for the Court to justify the restrictive national measure on public health grounds. However, it must be notice that, notwithstanding the general trend legitimizing domestic prohibitions of free movement whenever there is an uncertain level of evidence, the ECJ did take into expressed account in all the abovementioned cases some particular conditions of the individual cases, such as eating habits, climatic conditions, the state of health of the population and particularly sensitive consumers. Which specific criteria are referred to by the ECJ and which role is played by each of them in the Court's legal reasoning depends on the pleading of the parties concerned and also on the circumstances of the individual case.

In general, it appears from this case law that Member States have recognized a great dose of discretion in deciding to err on the side of caution when adopting food safety measures. This freedom is only limited by one condition: Member States must deliver some scientific evidence by referring to the "results of international research"[225]. However, where there is uncertainty as to the existence or extent of a risk, the treshold of risk, which must be established by a Member State in order to justify its trade restrictive measure, is not clearly defined.

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[222] Alemanno, *Le principe de precaution* ..., supra note 187, (« Pour la première fois, la Cour semblerait avoir reconnu, bien que dans un obiter dictum ne mentionnat pas le principe de précaution, la possibilité pour les Etats membres d'adopter des mesures dans une situation d'incertitude sciéntifique »), as cited by A.G. Mischo, Opinion in Case C-192/01, Commission v Denmark, para 51, («En ce sens, cet arret me parait constituer une application avant la lettre du principe de précaution »).

[223] Case 94/83 Heijn [1984] ECR 3263.

[224] Case 54/85 Mirepoix [1986] ECR 1067.

[225] See, e.g., Case 304/84 Ministere Public v Muller and others [1986] ECR 1511, para 24 and Case C-42/90 Bellon [1990] ECR 4863, para 17.

*(b) The early judicial shaping of the PP*

Although in this set of judgments the ECJ dealt with issues that might today be described under the "precautionary principle" label[226], it was only in the so called "BSE judgments" on the validity of the Commission decision 96/239/EC of 27 march 1996 on emergency measures to protect against bovine spongiform encephalopathy that the precautionary approach was sketched out as it is today[227]. Notwithstanding the ECJ's efforts to define the scope of a precautionary approach as stemming from Article 130R(1) and (2), it did not refer expressly to the precautionary principle in its reasoning.

It is worth analyzing these cases not only because they do represent the first in which the precautionary principle was upheld by the Court, but also because they laid the ground for the development of this principle within EC law.

Following the UK Spongiform Encephalopathy Advisory Committee (SEAC) opinions concerning the existence of a possible link between BSE and a variant of Creuzfeldts-Jakob disease[228], the Commission adopted a decision (hereinafter, the "BSE decision") imposing, on a temporary basis, a ban on exports of bovine animals, bovine meat and derived products from the territory of the United Kingdom to the other Member States and to third countries[229].

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[226] See, *ex multis*, case C-212/91 Angelopharm v. Hambourg, [1994] ECR I-17, in which the ECJ, called to assess the validity of Directive 90/121(adapting to technical progress Annexes II, III, IV, V and VI to Council Directive 76/768/CEE on the approximation of the laws of the Member States relating to cosmetic products, OJ 1990 L71, p.40), had to defined the extent of the obligation for the Commission to consult the competent scientific committee, notably the Scientific Committee on Cosmetology; and also case C-151/98 P, Pharos v. Commission [1999] ECR I-8157, relating to the conditions under which the Commission was entitled to submit a scientific issue concerning public health for further advice to the competent scientific committee, notably the Committee for Veterinary Medicinal Products. For previous situations in which the ECJ had to deal with scientific uncertainty, see case C-227/82 Van Bennekom [1983] supra note 211, p. 3883. For a comment on this early case law on the "precautionary principle", see A. Aresu, *Derniers developments jurisprudentiels en matière de libre circulation des produits alimentaires*, in Revue du droit de l'Union européenne, 4/1992, p. 251ss.

[227] Case C-157/96, National Farmers' Union, supra note 179, and case C-180/96, United Kingdom v. Commission, [1998] supra note 112.

[228] SEAC is an independent scientific body which advises the United Kingdom Government. See Case180/96 UK v. Commission [1998], supra note 112, para 9.

[229] The Decision was adopted by the Commission and was based on the following legal sources: Council Directive 90/425/EEC (notably on its Article 10(4), concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (OJ 1990 L224, p.29), as amended by Council Directive 92/118/EEC of 17 December 1992 laying down animal health requirements governing trade imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC (OJ 1993 L62, p.49); Council Directive 89/662/EEC (notably on its

According to the Commission, despite the fact that BSE previously existed, the SEAC's opinion had "significantly altered the *perception of risk* which that disease represented for human health"[230]: BSE was no longer regarded merely as affecting cattle, but as a hazard to human health, thus authorizing the adoption of safeguard measures in accordance with Directives 90/425 and 89/662.

The ban was challenged not only by the United Kingdom under Article 173 EC, but also by a lobby of farmers, the National Farmers' Union before national courts, who referred the matter to the ECJ[231].

In its analysis, the ECJ, after recalling the scope of judicial review in matters concerning the common agricultural policy, where the Community has a discretionary power corresponding to its political responsibilities[232], developed the following line of reasoning.

The ECJ's analysis started off by noticing that, at the time of the adoption of the ban, there was great uncertainty as to the risks stemming from BSE-infected bovine animals, bovine meat and derived products[233]. The publication of new scientific information (SEAC's opinion) had established a probable link between a disease affecting cattle in the United Kingdom and a fatal disease affecting humans for which no known cure yet exists[234].

Against this backdrop, the ECJ developed what it had to become the general definition of the precautionary principle within the EC by stating that

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Article 9) concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (OJ 1989 L395, p. 49), as amended by Directive 92/118; and also on EC Treaty rules (but with no mention of specific articles).

[230] Case C-180/96, United Kingdom v. Commission, [1998] supra note 112, para 53.

[231] Case C-157/96, National Farmers' Union, supra note 179.

[232] In case C-157/96 the Court stated at para 61 that "With regard to judicial review of compliance with the abovementioned conditions, in matters concerning the common agricultural policy the Community legislature has a discretionary power which corresponds to the political responsibilities given to it by Articles 40 to 43 of the Treaty. Consequently, the legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institution is seeking to pursue". See also Cases 160/88 Fedesa v. Council [1988] ECR 6399, para 14 and Case 368/89 Crispoltoni I (1991) ECR 3715, para 42.

[233] Case 157/96, para 62.

[234] Case 180/96 UK v. Commission, supra note 112, para 61.

"where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent"[235].

The ECJ found that this approach is borne out by Article 130r(1) of the EC Treaty (current Article 174), according to which Community policy on the environment is to pursue the objective *inter alia* of protecting human health. Although not expressly referring to the precautionary principle as enshrined in the EC Treaty since the Maastricht Treaty, the ECJ stated that environmental protection requirements must be integrated into the definition and implementation of other Community policies[236]. Thus, the precautionary principle was for the first time extended beyond the environmental protection arena becoming a food safety general principle before being codified by the General food law regulation.

The ECJ continued its analysis by stressing that the contested decision was adopted as an 'emergency measure' 'temporarily' banning exports (fifth recital in the preamble). It also upheld the concerns expressed by the Commission, the SCAN committee and one of its Members[237] about the scientific uncertainties concerning the risks of transmissibility of BSE.

In light of this, the ban on export of live bovine animals could not be regarded as a "manifestly inappropriate measure" . Furthermore, as regards the claims that alternative measures were possible, the ECJ concluded that, "in view of the seriousness of the risk and the urgency of the situation", the Commission did not react in a manifestly inappropriate manner by imposing, on a temporary basis and pending the production of more detailed scientific information, a general ban on exports of bovine animals, bovine meats and derived products. Consequently, the Commission was not found in breach of the proportionality principle.

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[235] *Ibid.*, para 99.

[236] Case 180/96, UK v. Commission, supra note 112, p. 100. This principle has been recently confirmed in Case 41/02 Commission v. Netherlands [2004], para 45, where the Court has held that "it follows from case law of the Court that the precautionary principle may also apply in policy on the protection of human health which, according to Article 152 of the EC Treaty likewise aims at a high level of protection".

[237] Case 180/96, UK v. Commission, supra note 112, p. 105.

Although giving shape to the precautionary principle, the BSE judgments did not refer to the principle as such. The first explicit reference to principle in a court ruling has been made by the CFI in the *Bergaderm* case, where the Court affirmed that

"[...] the appellants dispute the references to the precautionary principle in paragraph 66 of the contested judgment"[238].

A previous reference to the principle was originally made by A.G. Tesauro in his opinion in Case *Diego Cali*, where he limited himself to quoting the new Article 130r(2) EC and the Rio Declaration. In further case, Advocates General, without developing a comprehensive analysis of the principle, contributed nevertheless to the evolution of its understanding[239].

Other explicit references to the principle may be found in the *Lirussi and Bizzaro* judgment[240], where the ECJ mentioned it together with the principle of preventive action, in relation with Article 4 of Directive 75/442/EEC of July 15 1975, on waste, in conjugation with Article 130r of the Treaty. The principle was then invoked by *Greenpeace France* to contest the functioning of Council Directive 90/220/EEC of 23 April 1990, on the deliberate release into the environment of genetically modified organisms (GMOs)[241].

Yet, although the number of cases expressly dealing with the principle was growing, one could not say that its invocation by either EC institutions (*BSE* cases), Member States (*Eyssen*, *Sandoz*, *Hijn*, etc.) or private parties against the EC institutions (*Greenpeace*) had been systematized.

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[238] Case C-353/98 P Laboratoires pharmaceutiques Bergaderm a.o. v. Commission [2000] ECR 5291, para 52.
[239] See, for instance, Opinions of A.G. Mischo (Case C-184/97 Commission v. Germany [1999] ECR I-7837), La Pergola (Case C-94/98 Rhône Poulenc Rore a. O. v. Licensing Authority [1999] ECR I-8789), Cosmas (Case C-318/98 Criminal proceedings against Giancarlo Fornasar a. O. [2000] ECR I-4785) and Fenelly (Case C-352/98 P [2000] I-5291).
[240] Joined cases C-175/98 and C-177/98, Paolo Lirussi and Francesco Bizzaro [1999] ECR 5291, para 51-52.
[241] The ECJ came to the conclusion that observance to the precautionary principle was reflected, within the Directive, in the notifier's obligation to notify the competent authority of new information concerning the risks of the product to human health and also in the right of any Member State to provisionally restrict or prohibit the use and/or sale on its territory of a product which has received the consent, every time there is a justifiable reason to consider that it constitutes a risk to human health or the environment. See para 44.

*(c) The 2000 Communication on the PP*

Against this backdrop, the Commission decided to issue a Communication on the use of the precautionary principle[242], mainly aimed at:

- outlining its approach to using the principle;
- establishing Commission guidelines for applying it;
- building a common understanding of how to assess, appraise, manage and communicate risks that science is not yet been able to evaluate fully, and
- avoiding unwarranted recourse to the principle, as a disguised form of protectionist.

Among the reasons that spurred the Commission to adopt such a Communication, there was not only the internal pressure exercised from the other EC institutions[243], but also some external elements such as the comments of the Appellate Body on the precautionary principle in its report in the *Hormones* case[244] and complaints by WTO Members that the principle was not adequately defined.

After having described the precautionary principle itself, by pinpointing the factors that trigger recourse to it and the kind of measures that may result from its application, the Commission provides some guidelines for its use as "to avoid unwarranted recourse to the principle, as a disguised form of protectionist".

In applying the principle, decision-makers are called to balance "the freedom and rights of individuals, industry and organizations with the need to reduce the risk of adverse effects to the environment, human, animal or plant health". In order to achieve the correct balance, they are required to adopt a "structured decision-making process", relying on "detailed scientific" and "other objective" information. More pragmatically, the implementation of the principle should start with a scientific evaluation, "as complete as possible", and "where possible, identifying at each stage the degree of scientific

[242] Commission Communication on the precautionary principle, supra note 215.
[243] For instance, in a Resolution of 28 June 1999 on Community Consumer Policy 1999-2001, the Council called on the Commission "to be in the future even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer-related activities and develop as a priority a clear and effective guidelines for the application of this principle".
[244] *EC – Hormones*, AB Report.

uncertainty". Judging what it is as "acceptable" level of risk for society is an eminently political responsibility".

Where action is deemed necessary, precautionary-based measures should be: *proportional* to the chosen level of protection, *non-discriminatory* in their application, consistent with similar measures already taken, *based on an examination* of the potential benefits and costs of action or lack of action, *subject to review*, in the light of new scientific data, and *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment.

It has been argued that, contrary to its declared goals, this communication did not place meaningful and effective constraints on the application of the precautionary principle. While imposing a 'balancing' activity in deciding whether to have recourse or not to the principle, the communication clearly tipped in favor of adopting preventive measures by thus failing to set a risk threshold triggering its invocation[245]. More in general, it can reasonably be argued that the Communication's approach to the principle completely overlooked the costs entailed by the adoption of a protective measure, by emphasizing solely the expected benefits to health.

*d) The EFTA Kellog's case*

Following the adoption of the 2000 Commission Communication, the EFTA Court has delivered a major judgment which has significantly contributed to the shaping of the precautionary principle, notably when it is invoked by a Member State[246].

At the origin of this judgment there is an infringement proceeding brought by the EFTA Surveillance Authority against the Kingdom of Norway because of its legislation prohibiting the import and marketing of fortified corn flakes which had been lawfully manufactured and marketed in other EEA States. On the one hand, the Norwegian Authorities oppose the import and marketing of these cereals on the grounds that there is no nutritional need in the Norwegian population for the fortification and that, lacking scientific data on this point, its "approach is in accordance with the precautionary

[245] N. McNelis, *EU communications on the precautionary principle*, in J Int Economic Law 2000 3, at 545-551.
[246] EFTA Court of 5 April 2001, Case E-3/00 Efta Surveillance Authority v Norway [2001] EFTA Court Report 2000/2001, 73, para 30. For a comment of this case, see Alemanno, *Le principe de precaution* ..., supra note 187, at 947-50. Among the EFTA Court's cases dealing with the precautionary principle, see also Case E-4/04 Pedicel AS v Directorate for Health and Social Affairs [2006] not yet reported.

principle, as developed and applied internationally and within the Community" . On the other hand, the EFTA Surveillance Authority argue that the ban on imports of fortified products cannot be justified under Article 13 EEC (corresponding to Article 30 EC)[247], because Norway has not substantiated its claim that the fortification in question would constitute a danger to public health.

Facing these opposing claims, the EFTA Court had for the first time to take position on the emerging precautionary principle within the EEA. By building upon the ECJ's *Sandoz* case[248], the Court held that

> "In the absence of harmonization of rules, when there is uncertainty as to the current state of scientific research, it is for the Contracting Parties to decide what degree of protection of human health they intend to assure, having regard to the fundamental requirements of EEA law, notably, the free movement of good within the European Economic Area"[249].

After having laying down the basis for the invocation of the precautionary principle within the EEA, the Court showed to be rather familiar with the traditional structured risk analysis model not yet codified within the EC/EEA context, by stating

> "This means that a *risk management* decision rests upon with each Contracting party. It is within the discretion of the Contracting Party to make a policy decision as to what level of risk it considers appropriate" (para 25).

Against this backdrop, the Court has set the conditions under which EEA Contracting parties may validly invoke the precautionary principle

> "[...] measures taken [...] must be based on scientific evidence; they must be proportionate; non-discriminatory, transparent and consistent with similar measures already taken" (para 26).

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[247] Article 13 EEA states that Article 11 EEA (corresponding to Article 28 EC) does not preclude prohibitions justified on grounds of *inter alia* protection of human health, as long as a given prohibition does not constitute a means of arbitrary discrimination or a disguised restriction of trade.

[248] Case 174/82, Sandoz BV [1983] ECR 2445, para 16-18.

[249] Case E-3/00 Efta Surveillance Authority v Norway [2001] EFTA Court Report 2000/2001, 73, para 25.

In particular, concerning the scientific requirement, it added that while "[a] purely hypotetical or academic consideration will not suffice" (para 29), it is required "a comprehensive evaluation of the risk to health based on the most recent scientific information" (para 30).

By applying these criteria on the case at hand, the Court concluded that the Norwegian did not fulfill the requirement of EEA law to the exent

> "Firstly, it was inconsistent on that, on the one hand, authorization to market fortified cornflakes had been refused because of a lack of need, while on the other hand, Norway maintained as a matter of policy fortification of brown whey cheese [...]" (para 41).
>
> Secondly, it had not been demonstrated that a comprehensive risk assessment had been carried out by the Norwegian authorities in response to Kellogg's submission of its application for authorization" (para 42).

*2. Definitions*

Article 7 of regulation 178/2002 provides the first legally binding definition of this principle in Community law[250] by essentially reaffirming the guidelines, provided in the 2000 Commission Communication on the precautionary principle[251] and building upon the ECJ's case-law developed on the matter. According to this principle, when a risk assessment concludes that "the possibility of harmful effects on health is identified but scientific uncertainty persists", *provisional* risk management measures *necessary* to ensure the high level of health protection chosen in the Community may be adopted, while waiting for other scientific information to complement the assessment[252].

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[250] It is the first time that the precautionary principle finds an explicit reference in a specific policy field.
[251] Commission Communication on the precautionary principle, supra note 215. This was endorsed by the Resolution of the 2000 Nice European Council calling on the Commission to systematically apply its guidelines and to rely on the precautionary principle wherever necessary in the drawing up of its proposals.
[252] Article 7.1 of the Regulation defining the principle reads as follow: "In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment".

This formulation of the principle is relevant to the extent it seems to allow it to be invoked both by the Community and the Member States, although always within the limits of the proportionality principle.

This definition builds also upon the European Court of Justice's original formulation of the principle in the *BSE* where it is said that:

> "Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent".

It appears that the first stage of decision-making, which is based on scientific and factual judgment, is followed by a second stage, which is "political", in which the measures to be taken have to be worked out. This approach was confirmed by the Court in *Artegodan* where it is stated that:

> "where scientific evaluation does not make it possible to determine the existence of a risk with sufficient certainty, whether to have recourse to the precautionary principle depends as a general rule on the level of protection chosen by the competent authority in the exercise of its discretion"[253].

As shown above, in real life the separation between scientific advice and the discretionary assessment of the competent authority is much more complex and Courts struggle in drawing clear line of distinctions between these two stages of decision-making[254].

A disturbing element of the wording employed by Article 7 is that it does not determine when the scientific evidence is insufficiently uncertain as to trigger the application of the principle. At the same time, it does not establish who will establish that scientific uncertainty exists: should it be the national or EC authorities? Hence, disputes and divergences between national and community bodies are likely to arise.

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[253] Joined Cases T-144/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00 and T-141/00 Artegodan a.o. v. Commission [2002] ECR 4945, para 199.

[254] Alemanno, supra note 187, at 940; N. de Sadeleer, *Le statut juridique du principe de précaution en droit communautaire: du slogan à la règle*, Cahiers de droit européen, 2001, n. 1, at 79-120, at 105, Ladeur, supra note 169, at 1457.

To fully understand the philosophy underpinning the precautionary principle it must be borne in mind that neither its meaning not its significance end with scientific analysis. The principle invites a more overtly political decision about the balance of risks involved. As we have seen, deciding on the appropriate balance between burden and risk involves social choices transcending the mere scientific data. Thus, the European Courts referred to the possibility of including "consumer concerns" in the process of balancing.

As scientific uncertainty is the essence of the precautionary principle, it is therefore necessary to identify the situation triggering its invocation. The definition of scientific uncertainty that has always been at the root of applying precaution within the EC reads

> "lack of evidence establishing a direct causal link between an activity, process or substance and an identified adverse effect"[255].

### *3. Encadrement and Conditions of application*

After acknowledging the protectionist's spill-over effects potentially stemming from its improper invocation, the Regulation tries to define the scope of the principle and to lay down the necessary limits on its use by both the EC institutions and the Member States "in order to adopt a uniform basis throughout the Community"[256]. Similarly to what was previously established in the abovementioned Communication, the measures adopted on the basis of the precautionary principle must be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, having regard to "technical and economic feasibility and other factors regarded as legitimate in the matter under consideration"[257]. These measures are to be reviewed within a reasonable period of time, depending on the nature of the risk to life and health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive assessment.

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[255] Christoforou, *The precautionary principle and democratizing expertise: a European legal perspective*, supra note 194, at 207.

[256] Preamble (20).

[257] Article 7.2 reads as follow: "Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment".

This formulation of the principle builds upon the jurisprudence developed by the Community courts during the last years, without adding any additional requirements. However, it remains to be determined how much scientific certainty about uncertain risks must be provided, i.e. the scientific treshold triggering its invocation. The level of proof needed to prompt the application of the precautionary principle has been called "knowledge condition" in order to show the "uncertainty paradox" underlining its functioning: if on the one hand, the principle assumes that science cannot provide decisive evidence on uncertain risks, on the other hand decision-makers appeal for science for some kind of certainty[258].

A crystal clear expression of the precautionary paradox may be found in *Pfizer*:

> " ...a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified ... Rather, it follows from the Community Courts' interpretation of the precautionary principle that a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be *adequately backed up by the scientific data available* at the time when the measure was taken"[259].

In other words, although scientific uncertainty is recognized, science is still expected, under the current approach, to tell the truth about uncertain risks. Science is still the tool both Member States and EC institutions must rely upon when they want to adopt measures in situation of scientific uncertainty. We will see, in reporting the *Pfizer* judgment, how this "knowledge condition" represents the most difficult requirement to assess for the judiciary: to what extent may a judge, who is by definition non scientist, discuss scientific validity and the merits of the scientific arguments advanced by the parties?

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[258] M. Van Asselt and E. Vos, *The Paradox of the Precautionary Principle*, in Risk Analysis, 2004.

[259] *See* Case T-13/99, Pfizer v. Council, supra note 161, paras 143-144. For a brief review of the judgment, A. Alemanno, *Protection des consommateurs: Arrêts Alpharma/Pfizer*, *in* 4 Revue du droit de l'Union Européne 842-845 (2002) and V.R. Walker, *The Myth of Science as a Neutral Arbiter for Triggering Precautions*, supra note 189, at 221-225; for a critical assessment of the judgment, *see* also K.H. Ladeur, *The Introduction of the Precautionary Principle into EU law: A Phyrric Victory for Environmental and Public Health Law?* supra note 169 and the reaction to this article by S. Wolf, *Risk Regulation, Higher Rationality, and The Death of Judicial Self-Restraint: A Comment on Ladeur*, 41 Common Market Law Review 1175-1180 (2004).

Notwithstanding the efforts undertaken by the framers of the new food safety regime, the scope of the precautionary principle remains vague and still responds to the idea contained in the Communication, according to which "like other general notions contained in the legislation, such as subsidiarity or proportionality, it is for the decision-makers and ultimately the courts to flesh out the principle"[260]. In other words, remaining textually vague, it is likely that the EC Courts will define the scope of the principle, by listing the factors prompting its application.

This outcome is certainly unfortunate and likely to exacerbate even further the debate over the scope of the precautionary principle currently going on not only within the European Union, but also between the two sides of the Atlantic. During recent years the EC has heavily relied upon this principle in the area of food policy and has triggered trade disputes with the United States. Although the US have traditionally followed a precautionary approach in adopting risk regulations, it has been opposing the recognition of it as a principle of risk assessment[261].

The main argument against the invocation of this principle is that, by providing a basis for action in the face of scientific uncertainty, it may be easily invoked to adopt protectionist measures. The same EC Commissioner Byrne has recently conceded

> "Precaution can be a thinly disguised trade protection measure, not to mention a badge of political cowardice"[262] if not adequately framed.

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[260] See supra note 215, at 10.

[261] Although the "conventional wisdom" is that the EU endorses the precautionary principle and seeks proactively to regulate risks, while the U.S. opposes its invocation, basing risk assessment on scientific evidence, "neither actor can claim to be more precautionary than the other" and "sometimes one actor is more precautionary than the other and sometimes it is the other way around". *See* Speech by T. van der Haegen, *EU View of Precautionary Principle in Food Safety*, American Branch of the International Law Association, New York, Oct. 23-25, 2003 *available at* http://www.eurunion.org/News/speeches/2003/031023tvdh.htm. See also on this point Christoforou, *The Precautionary Principle, Risk Assessment, and the Comparative Role of Science in the European Community and the US Legal Systems*", supra note 207, at 18, 41. These "impressions" have recently been confirmed by a study which relied for the first time on quantitative methods in order to compare reliance on precautionary action between the two sides of the Atlantic. See J.K. Hammit, J.B. Wiener, B. Swedlow, D. Kall and Z. Zhou, *Precautionary Regulation in Europe and the United States: A Quantitative Comparison*, 25 Risk Analysis 1215 (2005).

[262] *See* Speech D. Byrne, *The Regulation of Food Safety and the Use of Traceability/Tracing in the EU and USA: Convergence or Divergence?*, Food Safety Conference, Washington D.C., 19 March 2004, 4, available at http:// europa.eu.int/comm/dgs/health_consumer/library/speeches/speech168_en.pdf

To analyze to what extent these reserves on the precautionary principle are well-funded, it may be worth it to analyze the most recent cases in which that principle had been invoked.

The *Pfizer/Alpharma* cases have delineated in great detail the circumstances in which regulators may invoke the precautionary principle and how European courts should review the legality of precaution-based regulations.

### *4. Recent case law*

*Pfizer/Alpharma judgments*

On September 2002, the CFI delivered two important judgments dealing with the role of the precautionary principle. Two pharmaceutical companies, Pfizer and Alpharma, brought an action to ask for the annulment of Regulation 2821/98 by which the authorization to use certain antibiotics, which include Virginiamycin and Bacitracin zinc as growth promoters, in animal feeding stuff is withdrawn[263]. At the outset of the adoption of this Regulation there are the requests by Sweden and Danemark.

In reliance on the safeguard clause provided for in article 11 of Directive 70/524, the Kingdom of Denmark, adopted a ban on the use in its territory of virgiamycin in feedingstuffs. In doing so, it relied on a report from the National Veterinary Laboratory. The Commission asked the Scientific Committee for Animal Nutrition (SCAN) for its opinion on the risks to be expected from the use of these antibiotics as growth promoters[264]. Despite of the fact that SCAN concluded that the use of virgiamycin did not constitute an immediate risk to public health in Denmark[265], both the Commission and the

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[263] The use of additives in feedstuffs has been regulated at the Community level since 1970 (Council directive 70/524/ECC concerning additives in feedstuffings, OJ L270/1). In 1996 a Community authorization system was introduced according to which only additives that obtained prior Community authorization could be used in feedstuffs (Council directive 96/51/EEC, amending Council directive 70/524/ECC concerning additives in feedstuffings, OJ L235/9).This regulatory regime allows Member States to temporily suspend or restrict the use of an authorized additive. In this case, the relevant Member State has a duty to immediately inform the other Member States and the Commission and share its grounds on which it considers the additive dangerous. It is up to the Commission or the Council to confirm the national safeguard decision or to decide that the Member State must lift the measure.

[264] More precisely, it asked SCAN to give an opinion on whether the conclusions in the Danish report "are scientifically justified"and on the question "whether or not" the use of virgiamycin as a growth promoter constitutes a public health risk in the future.

[265] Opinion of the SCAN on the immediate and longer-term risk to the value of Streptogramins in Human Medicine posed by the use of Virgiamycin as an animal growth promoter of July 10 1998.

Council, relying on the precautionary principle, referred to the remaining uncertainty[266], which has, albeit to a different degree, been confirmed by the scientists consulted, and, subsequently, decided to revoke the authorization. Therefore, notwithstanding the SCAN's opinion, the Commission proposed to issue a ban. Both the Commission and the Council reached this conclusion after having evaluated and weighted the same uncertainty information different than SCAN.

As it has been stated, although SCAN tried to provide a plausibility proof, as requested by the Commission, "because of the impossibility to provide certainty about uncertain risks, uncertainty information unsystematically crept into its advice"[267].

Pfizer invoked several grounds supporting its challenge to the Council Regulation of which the most important relate to manifest errors of risk assessment and management and a misapplication of the precautionary principle.

As the Court did not detect any manifest errors it eventually upheld the Council's decision.

Although the Court relentlessly repeated to be solely on the position to carry out a limited review, it could not avoid discussing scientific validity and the merits of the scientific arguments raised by the parties.

In order to prevent these abuses, the European Court of First Instance (hereinafter: the "CFI"), after endorsing the philosophy behind this principle, has somehow defined the terms in which the principle can be invoked. Thus, the Court has stated:

> " [...] a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified ... Rather, it follows from the Community Courts' interpretation of the precautionary principle that a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by

[266] Indeed, the SCAN report, though concluding that "the use of virginiamycin as a growth promoter does not constitute an immediate risk to public health in Denmark", also recognised that "the nature of resistance to the streptogramins is not fully understood and mechanisms other that those described above may operate".
[267] van Asselt and Vos, supra note 258, at 11.

conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken"[268].

This principle can therefore be validly applied only in situations in which there is a risk, notably to human health, which, although it is not founded in mere hypotheses that have not been scientifically confirmed, has not yet been fully proved. The precautionary principle's invocation requires a prior objective evaluation of the existing scientific relevant as "it is not a joker or wild card that can be played at any moment as a pretext for unjustified measures"[269]. However, even after the Pfizer judgment, the treshold of risk which must be established by a Member State in order to validly take precautionary action would seem to remain largely undefined. As it has been noted, only a negative condition has been laid down in the Court's case law: it is insufficient to rely on hypothetical considerations to establish scientific uncertainty[270]. That means that the main condition triggering the application of the principle, scientific uncertainty, can be shown only at the end of an assessment of risk.

*Vitamins Line of Cases*

A recent line of judgments involving fortified food has provided a useful judicial opportunity for further defining the conditions triggering the application of the precautionary principle by the Member States. In these cases the Court had been called to examine four infringement proceedings brought against Denmark[271], France[272], Italy[273] and the Netherlands[274]. In particular, the Commission contested, on one side, the Danish and Dutch practices entailing that fortifies foodstuffs lawfully produced and marketed in other Member States may be marketed in their territories only if its shown that such enrichment with nutrients meets a need in the Danish and Dutch populations. On the

[268] *See* Case T-13/99, Pfizer v. Council, supra note 161, paras 143-144. For a brief review of the judgment, A. Alemanno, *Protection des consommateurs: Arrêts Alpharma/Pfizer*, supra note 259 and V.R. Walker, *The Myth of Science as a Neutral Arbiter for Triggering Precautions*, supra note 189, at 221-225; for a critical assessment of the judgment, see also van Asselt and Vos, supra note 258; K.H. Ladeur, *The Introduction of the Precautionary Principle into EU law: A Phyrric Victory for Environmental and Public Health Law? Decision-making Under Conditions of Complexity in Multi-Level Political Systems*, supra note 169 and the reaction to this article by S. Wolf, *Risk Regulation, Higher Rationality, and The Death of Judicial Self-Restraint: A Comment on Ladeur*, supra note 259, at 1175-1180.

[269] *See* Speech D. Byrne, supra note 175, at 4.

[270] Opinion by AG Poiares Maduro, C-41/02 [2004] not yet reported, para 28

[271] Case 192/01 Commission v Denmark [2003] ECR 9693.

[272] Case C-24/00 Commission v France [2004] not yet reported.

[273] Case C-270/02 Commission v Italy [2004] not yet reported.

[274] Case C-41/02 Commission v Netherlands [2004] not yet reported.

other side, the Commission contested the French and Italian systems of prior approval for fortified foods lawfully produced and marketed in other Member States[275]. At the time of the infringement actions, no Community legislation had been adopted laying down the conditions regulating the addition of vitamins and minerals to foodstuffs. While it proved rather easy for the Court to come to the conclusion that the national practices and prior approval procedures qualified as obstacles to intra-Community trade under Article 28 EC, it proved much more difficult to establish whether and to what extent such restrictions to the free movement could be justified under Article 30 EC.

As both the Danish and the Dutch government relied on the precautionary principle to justify their trade-restrictive administrative practices, the ECJ recalled, by drawing on the 2001 EFTA Kellog's case, that

> "a proper application of the precautionary principle presupposes, in the first place, the identification of the potentially negative consequences for health of the proposed addition of nutrients, and, secondly, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research"[276].

After having recalled these procedural requirements for a valid application of the principle, it has made an attempt at defining the treshold triggering its invocation, by helding that

> "when it proves to be impossible to determine with certainty [after having undertaken the prescribed comprehensive risk assessment] to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the *likelihood of real harm to public health persists should the risk materialise*, the precautionary principle justifies the adoption of restrictive measures"[277].

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[275] For a comment on the Italian and French judgments, see F. Erlbacher, *Restrictions to the Free Movement of Goods on Grounds of the Protection of Human Health: Some Remarks on Recent ECJ Judgments*, European Law Reporter, 2004, at 118.

[276] Commission v Denmark, para 51; Commission v The Netherlands, para 53.

[277] Commission v Denmark, para 52; Commission v The Netherlands, para 54.

That means that under EC law Member States may take precautionary action whenever their comprehensive assessment show that the likelihood of real harm still persists were the negative eventuality to occur.

Although it is doubtful whether this rather vague treshold might translate into a useful benchmark for the judge called to verify the legality of a precautionary-based measure, the Court's efforts to better define the "knowledge condition" prompting its invocation must be applauded. Indeed, the Court has for the first time went beyond the mere negative condition ruling out all the alleged hypotetical risks as a basis for precautionary action and it has established a positive treshold for the invocation of the principle: whenever a comprehensive assessment shows that the likelihood of real harm may persist should the negative eventuality occur.

Yet, what is strucking in these two judgments is the lack of any reference to the provisional nature of all precautionary-based measures. As it is clearly stated in the 2000 Communication and in the General food law regulation, precautionary measures are, by their very nature, provisional and may only be maintained for so long as the scientific data remain inadequate, imprecise and unconclusive. The ECJ's lack of reference to the limited duration of precautionary measures results particular controversial if examined within the WTO/SPS context. In fact, all measures adopted under Article 5.7 SPS are subject to a strict time limit, under which a precautionary measure may be authorised only insofar as as scientific research has not proved yet the existence of a risk or the extent of that risk to public health.

### *5. Conclusion*

Although the introduction of a precautionary approach in the health field dates back from the 70s, it is only in 1992 that this principle, though limited to the environmental protection field has been codified by Article 130r(2) of the Treaty. Its scope has been subsequently widened by the interpretative activity of the ECJ so as to apply also to other domains of EC law, such as public health.

In particular, it was in the BSE line of cases that this principle has been upheld by both the ECJ and the CFI. However, it was only in the *Pfizer/Alpharma* judgements that the CFI has sketched out a sistematisation of the principle by clearly defining its conditions of application while it is invoked by Member States.

According to the Court, in case of scientific uncertainty as to the existence of a risk to human health, the EC institutions as well as the Member States may invoke the precautionary principle in order to adopt protective measures, in spite of the fact that a proper risk assessment showing conclusive scientific evidence cannot be conducted. Such measures cannot, however, be based on a purely hypothetical approach founded on mere hypotheses and may be adopted only if the risk, although the reality and the extent thereof have not been fully demonstrated by conclusive scientific evidence, appears to be properly backed up by the scientific studies available at the time when the measure is taken. However, the treshold of risk which must be established by a Member State in order to validly take precautionary action remains largely undefined.

Once the competent authority has enacted a precautionary-based measure, the principle of proportionality is called upon to verify the legality of the measures intended to pursue the declared public policy objectives. The measure will be considered disproportionate if it is manifestly inappropriate or when it may be shown that other, less onerous, measures exist and would allowed the objective pursued by such measure.

It is interesting to observe that the language employed by the CFI, and today codified within the general food law regulation, to frame the invocation of the precautionary principle is largely resonant that of the Appellate Body in the *Hormones* case. As it has been sharply noticed, although WTO law has been denied direct effect within the EC legal order to preserve the autonomy of the political and legislative branches, these judgments prove how this marge of manoeuvre may be easily bypassed by way of judicial interpretation[278].

[278] On this point, see J. Scott, *European Regulation of GMOs: Thinking about 'Judicial Review'* in the WTO, in Jean Monnet Working Paper, 04/04, 5.

### D. General obligation to ensure that food is safe

Article 14 introduces an EC-wide general obligation to ensure that only foodstuffs which are safe, wholesome and fit for consumption be placed on the market for consumers[279]. As was recently stated:

> "The universalistic and abstract language of the provision condenses local difference and provides a single, objective standard for safety enabling economies of scale and trade liberalization across the Union"[280].

The introduction of this general obligation was originally envisaged in the 1997 Green Paper on Food Law to "reinforce the overall level of consumer protection within the Community, by encouraging all businesses to introduce their own internal safety and supervision procedures"[281]. In this document the Commission noted that although Community food legislations set out a series of specific obligations on food manufacturers and traders[282], it does not contain a "general legal obligation that only food which is safe, wholesome and fit for human consumption should be placed on the market". Thus, for instance, if Directive 92/59/EEC on general product safety imposes on manufacturers the obligation to place solely safe products on the market, a foodstuffs adulterated with substances not considered unsafe within the meaning of the directive would not fall within its scope and would not trigger any liability[283].

This obligation of safety is an obligation owed by foodstuffs businesses directly to the competent authorities under the criminal or administrative law of the Member States concerned. Being applicable to the whole food chain, from primary production to the final sale of the foodstuff to the consumer, it introduces a greater joint responsibility throughout the food chain, rather than dispersing individual responsibilities. It is indeed

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[279] In line with the language of the Codex Alimentarius, the food safety requirement imposed by Article 14 comprises two elements: a) food should not be injurious to health; or b) unfit for human consumption. Only one of these two elements has to be in place for the food to be considered unsafe.

[280] Chalmers, supra note 103, at 545.

[281] Green Paper, see supra note 107, at 45.

[282] Thus, for instance, the general hygiene directive (Council Directive 93/43/EC (OJ 1993 L175/1)) imposes, in its Article 3 (1), a precise obligation on manufactures: "in the preparation process in manufacturing, packaging, storage, transportation, handling and offering for sale or supply of foodstuffs, shall be carried out in a hygienic way".

[283] For a detailed analysis of the European regime on the Liability for Defective Products, see M. Cannarsa, *La responsabilité du fait des produits défectueux: étude comparative*, Milano (2005).

likely that at each level of the food chain economic operators will take the measures necessary to ensure food safety within the context of their specific activities.

In sum, introducing a general food safety obligation at the European level contributes to reinforcing the overall effect of consumer protection within the EC, by inducing all food businesses to establish their own internal food safety and supervision measures. Last, but not least, by virtue of Article 21, the insertion of this general obligation does not prejudice the application of the Product Liability directive 85/374/EEC[284] containing the principle that a producer is liable for a defect in its product[285]. It follows that, to the extent the product directive currently applies also to foodstuffs, the marketing of an unsafe product could virtually give rise to two separate violations of EC law: breach of the general obligation to ensure that food is safe, established by article 14 of the regulation, on one side, and violation of the Product Liability Directive on the other[286].

Along these lines, Article 21, though concise, has contributed to the creation of macro system of food safety liability on which final consumers may rely upon in order to recover damages suffered as result of business operators' violations.

However, we know that in practice it is particularly difficult for the person injured by a defective product to prove the damage, the defect and the causal relationship between these two. This is because of the difficulty to pinpoint precisely the source of outbreaks, such as *BSE*. We reasonably believe that in presence of an EFSA's opinion suggesting that a product is not safe, it would be easier for plaintiff to prove its case.

Of particular significance is the last paragraph of Article 14 codifying the principle of mutual recognition within the food safety arena: where there are no specific Community provisions, "food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed". This provision comes close to establishing a presumption in favor of Community-wide free trade in foodstuffs that are lawfully available in a Member State.

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[284] Council directive 85/374/EEC of 25 July 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States concerning Liability for Defective Products, O.J. (L 210) 29, as amended by Directive 1999/34/EC O.J. 1999 (L141) 20.

[285] Article 1 provides for an absolute liability for damage caused by any defective (subject to a number of exceptions that are not relevant here).

[286] See Chalmers, supra note 103, at 542.

## E. Allocation of responsibilities among food actors

Article 17 allocates the responsibilities between food business operators and Member States in the implementation of food regulation.

It first imposes a general duty on business operators to ensure that foods and feeds satisfy the requirements of food law which are relevant to their activities. It then entrusts public authorities with the mission to enforce food law and to monitor its compliance by food and feed business operators at all stages of production, processing and distribution. Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law[287].

It follows that the primary responsibility to monitor and verify that the relevant requirements of food law are fulfilled lies on the businesses, which are entrusted with the following duties: a duty to be informed and to inform (traceability) and a duty to act (withdrawal and recall).

### *1. Traceability*

The introduction of a general obligation to ensure that food is safe requires the introduction of a mechanism providing a continuous flow of information, allowing for the retrieval of the history and of the origin of a product at any point of the food chain.

Traceability is a risk management tool which aims at make the recall of a product easier. That is why Article 18 of the Regulation imposes a duty requiring food operators to be able to identify any person from whom they have been supplied with a food and other businesses to which their products have been supplied.

There is also another important purpose pursued by a traceability system which is related to consumer information. A traceability system, by making products identifiable, does not only facilitate recall but it also allows for the verification of the authenticity of labeling claims, thus guaranteeing to consumers that the information stated on the label is truthful.

[287] See Article 17.

In other words, traceability enables consumers to be provided with targeted and accurate information concerning a certain product. Traceability is also intended to avoid the potential for unnecessary wider disruption in the event of food safety problems.

Traceability is defined by Article 3, point 15, of the Regulation as "the ability to trace and follow a food, feed, food-producing animal or substance intended to be or expected to be incorporated into a food or feed in all stages of production, processing or distribution".

The current system of traceability has been defined as "a one up one down approach" requiring each operator to know the step before him in the food chain and the step after[288]. Everyone involved in the food chain has to be made in the position of identifying any person responsible for the supply of an unsafe food. Thus, Article 18 (1) establishes the principle of traceability:

> "The traceability of food, feed, food-producing animals and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution".

To facilitate the implementation of this principle, it is provided that food or feed which is placed on the market, or is likely to be placed on the market, in the Community be adequately labeled or identified through relevant documentation and information in accordance with the relevant legislation. Such system has also been conceived to facilitate the withdrawal of goods that can be traded potentially through 25 Member States.

Prior to this Regulation, the EC adopted specific traceability regimes in the sector of beef and genetically modified organisms (GMOs). In the first sector, the EC adopted Regulation 1825/2000 with the express aim to avoid the spread of diseases such as BSE and to protect the health and safety of consumers. Under this Regulation, operators must keep a complex identification and registration system for been at each of the various stages of production and sales. Such system must be able to record the quantity of the cattle and provide a link between the cattle and the meat consumed. As to the GMOs,

[288] Speech by D. Byrne, supra note 175.

they are subject to a similar set of rules, in accordance with a Common position adopted by the Council on 17 March 2003[289]. The goal pursued by the GMOs' regime is to facilitate the labeling of products consisting of, or containing, GMOs, in order to monitor their effects on the environment and to implement appropriate risk management measures. Business operators must set up systems and procedures to allow the identification of the parties to each transaction.

Although in the U.S. there is still a tendency to stick with voluntary recall and trace-back approaches, after the "Starlink" GM contamination of foodstuffs and the finding of the first *BSE* case, there has been a growing demand for trace-back and for mandatory animal identification systems.[290]

Some degree of convergence with Europe on the issue of traceability is therefore likely to happen notwithstanding the past disagreements within Codex. In that context, although it has been impossible to reach an agreement on a common definition of traceability, a consensus was reached as to the need to develop a definition[291]. A "Preliminary Set of Principles on Traceability/Product Tracing" (CL 2005/23-FICS) is currently circulating amongst Codex Members for comments.[292]

### 2. *Withdrawal and Recall*

To ensure compliance with food law regulations, business operators have also the duty to act by withdrawing their products every time they consider that a food which they have imported, produced, processed, manufactured or marketed does not fulfill all the relevant requirements of food law. Moreover, should their product have reached the consumer, the

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[289] Common Position (EC) No 21/2003 of 17 March 2003 adopted by the Council, acting in accordance with the procedure referred to in Article 251 of the Treaty establishing the European Community, with a view to adopting a regulation of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, OJ C113 E/21.

[290] *Id.*

[291] Report of the 18th meeting of the Codex Commission on General Principles, April 2003, para 97.

[292] Preliminary Set of Principles on Traceability/Product Tracing (CL 2005/23-FICS). See also the EC Comments to Circular Letter 2005/23-FICS, Request for comments on a Preliminary Set of Principles on Traceability/Product Tracing, where the EC states that: "The EC is fully convinced that the two main objectives of Codex, protecting the health of the consumers and ensuring fair practices in the food trade, cannot be dissociated when dealing with the question of traceability. Traceability/product tracing is indeed a tool that may be applied within a broader food inspection and certification system for different purposes: food safety, protection of consumers against deceptive marketing practices and facilitation of trade on the basis of accurate product description".

operators shall "effectively and accurately" inform the consumers of the reasons for its withdrawal, and if necessary, recall from consumers products already supplied to them "when other measures are not sufficient to achieve a high level of health protection"[293]. Disposing of an adequate traceability system may favour the withdrawal activity.

Food business operators have also a duty to inform the competent authorities if they consider or have reason to believe that a food which has placed on the market may be injurious to human health[294]. This provision is likely to become controversial to the extent it does not establish whether the information which business operators are supposed to provide could be used by the authorities while imposing sanctions stemming from the contested behaviour. The German Act on food and equipment[295], imposing an equivalent duty of disclosure, explicitly holds that the information provided by the food business operator may not be used against him in criminal proceedings. A similar provision, by undoubtedly providing an incentive to food business operators to come forward with problems they may encounter in their activity, should be inserted into the EC legislative framework as well.

Finally, food business operators are required to collaborate with the authorities on action subsequently taken to avoid or reduce risks posed by a food which they have supplied[296].

Similar obligations are imposed also on feed business operators by Article 20 of the Regulation.

One may observe that these provisions by imposing a burden on business operators in a phase subsequent the production and marketing of the product, do give rise to a different and autonomous liability hypothesis than one contemplated by the product safety directive (albisinni 339) which refers solely to the "place to the market".

The food operator cannot disregard the product once it has been marketed, but it is rather liable of monitoring the whole market where it operates.

[293] Article 19 of the Regulation.
[294] Article 19.3 of the Regulation.
[295] Article 40a of the Lebensmittel-und Bedarfsgegenständegesetz.
[296] Article 19.4 of the Regulation.

### F. EU Enlargement and food safety issues

Enlargement negotiations were concluded in Copenhagen in December 2002. The ten new Member States signed the Treaty of Accession and the Act of Accession attached to it in Athens on 16 April 2003[297]. As a result, they acceded the Union on 1 May 2004. With this date the whole EU *acquis* (the existing body of EU law) has become effective in the new Member States. In the meanwhile also Bulgaria and Romania have signed the Treaty of Accession.

Food safety is an element of the enlargement process and the EC made clear from the beginning that it would have not accept a situation that might lead to lower food safety standards or to any risks for consumers. Accordingly, the new Member States recognise that compliance with the Union's *acquis* on food safety was essential.

As seen above, the *acquis* related to food safety covers a large number of legislative acts, many of which are broad in scope and demanding in terms of transposition, implementation, and enforcement. It is vitally important to ensure that the *acquis* is fully transposed into the national legislation of each new Member State and that administrative structures and procedures are strengthened and reformed in good time prior to accession.

The Commission has however considered a limited number of properly justified requests for transitional arrangements. In the veterinary and phytosanitary sector, transitional periods were negotiated on the basis that there should be no increased risk to public, animal or plant health in the EC.

Food safety issues have been spread mainly over two areas of the accession negotiations:

- Chapter 1: " Free Movement of Goods" covers food legislation;
- Chapter 7: "Agriculture" covers veterinary and phytosanitary issues, and animal nutrition.

[297] Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia' The Accession Treaty can be is available at http://europa.eu.int/comm/enlargement/negotiations/treaty_of_accession_2003/index.htm

In particular, the major impact of the Enlargement on the EC food safety policy is likely to be felt in the following key issues:

a) - the capacity of the new Member States to implement EC compliant controls for trade inside the EC and for imports from third countries;

b) - compliance with the high level of EC health protection rules regarding BSE;

c) - bringing food processing establishments up to EC standards.

a) EC controls on third country imports require a system of border inspection posts (BIPs) to be completed to EC standards at external borders with third countries. On this question the EC has made clear that no compromise concerning facilities or procedures would be possible. Only for the specific case of the temporary border between Hungary and Romania a special regime was agreed. Currently there are some 283 EC Border Inspection Posts (BIPs) operated by national authorities. Most of these are ports and airports, others are road or rail links located in particular at the current eastern borders of the Union.

The accession of the 10 and later 12 new Member States has extended the eastern frontier with Russia and move the frontier eastwards to border with Belarus, Ukraine, Moldova and Turkey. New BIPs will equally have to be established along the borders with Croatia, Serbia and Montenegro, and with Macedonia.

In practice veterinary checks on imports include documentary, identity and physical checks of the animals or animal products presented. Following these checks at the first border crossing point into the EC, animals and products can in principle circulate freely in the internal market. It is therefore essential that BIP facilities and procedures are adequate to maintain animal and public health safety.

Setting up BIPs for veterinary and other controls in the new Member States requires buildings, equipment and staff to be in place to carry out the required border checks. EC legislation sets out minimum standards for BIP facilities, depending on the type of products to be checked. The Commission is monitoring developments carefully and only those BIPs fully ready at accession will be approved and listed.

b) All new Member States recognise that the risk of BSE is real and are progressively implementing measures to manage that risk. They have all agreed to comply fully with all EC legislation at the time of accession. This includes active BSE surveillance, removal of specified risk materials (SRMs) from the food chain at slaughter, the effective implementation of feed bans and of systems for the identification of cattle and bovine products. All the countries are implementing a basic ban on feeding meat and bonemeal (MBM) to ruminants, but not all have implemented the total feed ban and others are still feeding MBM to pigs and poultry - a practice that is prohibited in the EC. Large-scale BSE testing has been launched in the new Member States and the EC is co-financing the testing programme through Phare programmes. The Commission continues to closely monitor progress in implementing the BSE measures.

c) Bringing food processing establishments up to EC standards is a big challenge for the new Member States. A lot has been done and many establishments already fulfil the EC requirements. Others still have significant upgrading work to do before accession if they want to reach EC compliance. Six of the new Member States have requested transitional periods to upgrade a limited number of food processing plants after accession[298]. These transitional arrangements are limited in time and scope, lasting until 2006 or 2007. The European Commission required the new Member States to present detailed information on the situation of the food processing establishments and a binding plan for upgrading each of those which request a transitional period.

Additionally, severe conditions have been imposed as regards the marketing and the special marking of the products coming from establishments in transition: Products must stay on the domestic market of the new Member States and cannot be sold within the EC. Therefore these products will have to be clearly marked so as to distinguish them from those that can be traded within the internal market. The Commission is closely monitoring the situation in the establishments and the new Member States will have to report regularly on developments.

EC food safety and veterinary/phytosanitary legislation sets high standards in terms of transposing the legal requirements but particularly as regards the administrative structures which need to be in place. Therefore most new Member States need to make major

[298] Czech Republic, Hungary, Latvia, Lithuania, Poland.

efforts in putting the relevant legislation in place, organising effective lines of responsibility for food safety, in upgrading plants, getting analytical and laboratory capacity up and running and training personnel for inspection services, laboratory staff and cetera.

At the moment, the new Member States have many agri-food establishments that may not fulfil the detailed requirements of EC legislation governing the infrastructure and organisation of the production chain. In food factories, implementation of EC rules may mean bigger investments in rebuilding/ refurbishing part of the factory.

To implement effective pesticide residue monitoring for example, the new Member States need to set up a sampling programme (covering both domestic production and imported food), an analytical programme, have the necessary laboratory infrastructure and equipment and have properly qualified staff. They also must put in place effective procedures for identifying lots, reporting results of analysis and for taking appropriate action should problems arise.

Laboratories need to be accredited according to norms on good laboratory practice, such as ISO. Similar requirements apply to the monitoring of residues such as hormones, antibiotics and contaminants, and also testing for the presence of diseases, such as BSE.

All new Member States are working hard towards meeting the required standards. In any event, the EC has made clear that it will not compromise its standards. The existing safeguard clauses (as laid down in Articles 53 and 54 of the general food law regulation) can be invoked if a food or feed constitute a risk to public health. In addition, the Accession Treaty provides in its Article 38 of the Accession Treaty for a complementary safeguard clause where negotiation commitments are not met and where this is causing an imminent risk for the functioning of the Internal Market. It can be invoked during a period of up to three years after accession, but the measures may be applied beyond that period as long as the relevant commitments have not been fulfilled. The Commission may act either upon the request of a Member State or on its own initiative.

## G. External dimension of EU food legislation

The effects of the Community's food legislation are not confined to the Community alone. In accordance with the EEA agreement, Community food legislation is applied in Norway and Iceland, and it will shortly be applied in Liechtenstein. The new acceding countries Bulgaria and Romania are in the process of adjusting their legislation to apply Community rules in preparation for their accession to the Community. The customs union agreement between the Community and Turkey provides for the harmonization of legislation, legislation and negotiations with Switzerland are also at an advanced stage. A number of other third countries are also using Community legislation, which often closely reflects the relevant international standards established by Codex Alimentarius, as a model for their own legislation.

The principles of the internal market also apply to goods from non-Member countries which have been put into free circulation. Such products must meet all the requirements which are laid down in Community legislation for products produced within the Community. For foodstuffs of animal or plant origin, there are specific veterinary and phytosanitary inspection and certification procedures which are undertaken at the point of entry into the Community, and specific controls relating to quality standards for unprocessed fruits and vegetables for export and import. The Community also carries out inspections in non-Community countries.

In other cases, there are no special procedures for the inspection or certification of imports and exports. Controls on products are undertaken on a random basis, at the point of entry, or at the point of destination, and the activities of importers may also be subject to control. Consideration may need to be given to better coordination of controls on imports. It is also worth recalling that foodstuffs are part of the list of products which are more specifically covered by controls performed under Council Regulation (EEC) 339/93 on checks for conformity with the rules on product safety in the case of products imported from third countries.

In addition, to being a major food importer, the Community is also a major food exporter. In these circumstances, it is important to ensure that the Community's own internal

legislation provides adequate reassurances for our major trading partners, and that our exports do not encounter unjustified restrictions in gaining access to markets outside of the Community.

Recent years have seen important changes in the multilateral trading system applicable to foodstuffs, and in the bilateral relationships between the Community and its major trading partners. This will constitute the object of Part II focusing on the Regulation of Food within the WTO.

# CHAPTER III: THE EUROPEAN FOOD SAFETY AUTHORITY: THE CORNERSTONE OF THE NEW FOOD SAFETY POLICY

Undoubtedly, the establishment of the much-awaited European Food Safety Authority is the most prominent innovation introduced by the new Community food regime[299]. However, it must be borne in mind that the Authority merely represents one of the components of an entirely new strategy adopted by the European Union to food safety. Although pivotal to the functioning of the new food safety regime, the EFSA has not been vested with any regulatory power in the matter, which remains with the Commission and the Member States. However, as food law is heavily based on science the delegation for scientific assessment of risk to the Authority almost provides EFSA with a quasi-regulatory power.

The primary responsibility of the Authority is to provide scientific opinions in the food arena, activity which was previously exercised by six sectoral committees. Thus, its body is to replace and to absorb the Community's scientific committees.

In the following pages, we will provide a detailed description of the EFSA origins, of its institutional structure and powers by stressing, when necessary, its main differences with the U.S. Food and Drug Administration.

## 1. THE ORIGINS

There have been recurrent pleas calling for the creation of a Community food regulatory agency long before the outbreak of the food scares which have outraged Europe[300]. At least until the mid-1990s, such suggestions were seriously taken into consideration by the

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[299] On the European Food Safety Authority, see I.S. Roda, *La Autoridad Alimentaria Europea: la problematica eficacia de una nueva agencia comunitaria para la protección de los consumidores*, in Comunidad Europea Aranzadi, 11, 2001, at 29; S.Romero Melchor, *La futura Agencia europea para los alimentos: ¿ un organismo sin autoridad?*, in Gaceta iuridica de la UE, 212, Marzo/Abril 2001, p. 113.

[300] See M. D. Matthee, *Regulating Scientic Expertise with regard to Risks Deriving from Genetically Modified Organisms : Procedural Rules on Risk Assessment Committees under European Community and International Law*, in V. Kronenberg, The European Union and the International Legal Order : Discord or Harmony ?, T.M.C. Asser Press, Amsterdam; J.L. Valverde, A.J. Piqueras Garcia, M.D. Cabezas Lopez, *La nouvelle approche en matière de santé des consommateurs et de sécurité alimentaire : la nécessité d'une agence européenne de sécurité des aliments*, Revue du Marché Unique Européenne, 1997, n. 4, p. 31 ss.

EC Commission[301]. They were subsequently abandoned[302] before being revamped by the President of the EC Commission Jacques Santer when, appearing before the European Parliament Temporary Committee of Enquiry into *BSE*, he declared:

> "Our job is and will no doubt remain, in a spirit of subsidiary, to monitor the monitoring mechanisms set up by our Member States and their operation, even if, personally I think that in the long term the *creation of an agency modeled on the American Food and Drug Administration should not be ruled out*"[303].

Only a month later, facing a motion of censure from the European Parliament for alleged mismanagement of the *BSE* crisis[304], the same Santer seemed to be more determined about the need to establish an independent European Food Agency modeled on the US Food & Drug Administration :

> "I also think that *an independent agency*, to meet the specific needs of the Community but *based on the positive aspects of the United States Food and Drug Administration*, should be considered. Compliance with the principle of subsidiary, to which we are all attached, must not be used as a pretext for obstructing the emergence of a credible European health protection system, as a necessary follow-on from the single market"[305].

From this moment on, most of the advocates of a European food agency have crafted their proposals taking as a model the U.S. FDA, a very large and centralized agency in

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[301] See, *e.g.*, Lister, supra note 100, at 295-6. See the discussions in Snyder, supra note 106. For instance, following the BSE crises, the creation of a European Agency for Veterinary and Phytosanitary Inspection was launched (Commission's proposal for a Council Regulations, [1996] OJ C239/9), but subsequently withdrawn in the Commission communication to the European Parliament and the Council on Food, Veterinary and Plant Health Control and Inspection, COM (98) 32 final.

[302] Finally, the Council adopted a system of scientific assistance and cooperation in the scientific examination of food issues. See Council directive 93/5/EEC on assistance to the Commission and co-operation by the Member States in the Scientific examination of questions relating to food [1993] OJ L52/18. See also Written Question 904/91, O.J. (C 311), 18; Financial Times, 15 March 1991. Several reasons justifying the deferral of a new agency were put forward by the EC Commission ranging from burocratic concerns linked to the establishment of a new entity to the belief that the agency might distract the Commission's specialists from the primary objective of completing the 1985 programme for the internal market. See also the interview with Caroline Jackson, MEP, in 1 World Food Regulation Review 22-23 (1991).

[303] EP Temporary Committee on BSE – President Santer Statement of 15 January 1997.

[304] In the European Parliament's debate on the report by the Temporary Committee of Inquiry into BSE on the 18 February 1997, the Parliament called on the Commission to bring together all the activities spread out among the various directorates general within a single DG, to set up a framework directive on food law, to ensure the safety of the foodstuffs which circulate freely within the Community, to change the way in which scientific committees work, etc. See Debate in plenary session of the EP, 18 Feb. 1997, EU Bulletin, 1-2, 1997, 163-6.

[305] Speech by Jacques Santer, President of the European Commission, to Parliament on 18 February 1997 available at http://europa.eu.int/abc/doc/off/bull/en/9701/p203001.htm

charge of risk assessment, risk management controls and inspections throughout the US, as well as risk communication[306]. By relying on the great confidence that both US consumers and the food industry have in its activities, they played, not without some ambiguity, on the FDA analogy to gain consensus around their proposals for the creation of a not well-defined European-style FDA. While Health Commissioner Emma Bonino, after visiting the States in 1997, declared that the FDA was not a good model for Europe mainly because of its lack of political independence[307], the EC Commission President Romano Prodi in its first 1999 speech to the EC Parliament advocated the establishment of a "European FDA"[308].

The ambiguity embedded within these proposals lay in the question whether to invest the agency not only with risk assessment and communication powers, but also with management tasks.

The *conundrum* facing the Community in shaping the administrative powers of the agency has been effectively summed up by the following question: "to what degree should, could, or does 'expertise' replace legal, political and ethical criteria?"[309] In other words, should the agency be invested with regulatory and enforcement powers similar to those of the U.S. FDA?

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[306] For a detailed exam of the FDA's power and administrative organization, see Barton Hutt & Merril, *supra* note 1, at 4-6; for an historical overview, see P. Barton Hutt, *A Historical Introduction*, 45 FDC L.J. 17, (1990). For the purpose of our analysis, it is sufficient to know that the FDA is an institution under the responsibility of the Secretary of Health within the US Department of Health; it has 9,000 employees and monitors the manufacture, import, transport, storage and sale of a broad range of products throughout the U.S. It relies on about 2,100 scientists working in 40 laboratories throughout the country. It goes without saying that it is one of the most powerful administrative agencies in the world.

[307] Among the other reasons she provided: FDA did not cover the primary products of meat, poultry and fish and it would be unrealistic at EU level to have an organization with a staff of 9,000. It is worth noticing that the European Commission currently employs approximately 20,000 individuals.

[308] Address delivered to Parliament by Romano Prodi, President-designate of the Commission, on 21 July 1999, in Bulletin EU 7/8-1999, available *at* http://europa.eu.int/abc/doc/off/bull/en/9907/p202001.htm. *See* also International Herald Tribune, *Prodi Urges EU to Set Up a U.S.-Style Food Overseer* ("The European public has lost confidence in both national and European food and drug regulators. They no longer trust their governments or the scientists. In my view, we have to take the initiative and look toward the idea of an independent European food and drug agency to help win back consumer confidence") *available at* http://www.iht.com/IHT/BJ/99/bj072299.html. *See* also Speech of Romano Prodi to European Parliament, Plenary Session, 5 October 1999 (SPEECH/99/121).

[309] C. Joerges, *Law, Science and the Management of Risks to Health at the National, European and International Level – Stories on Baby Dummies, Mad Cows and Hormones in Beef*, in 7 Columb. J. Eur. L. 1 (2001) .

This question was central to the mandate given by the Commission to three leading European Scientists – James, Kemper and Pascal[310] – who had "to consider the most effective system for providing scientific advice which was independent, transparent, excellent and readily understood by non-expert" and to assess "whether an independent agency type structure could lead to further improvements in scientific advice at the EC level"[311]. The "Future of Scientific Advice" report, presented by these three scientists, represented the first serious attempt to analyze the opportunity and desiderability of establishing an independent agency by setting out the benefits and the drawbacks relating to the development of a system analogous to the U.S. FDA[312].

Starting from the premise that it would be "unwise to continue to deal with issues of such immense public concern simply by devising an improved system within DG SANCO", James, Kemper and Pascal expressed the need for "structural changes" in the way these issues are handled within the Community in order to recapture public confidence[313].

They proposed the institution of a Brussels-based organization, to be called the European Food and Public Health Authority (EFPHA), with the combined scope of the U.S. Centers for Disease and Control (CDC)[314] and the Food and Drug Administration. Although the proposed agency would have shared some features with the U.S. FDA, it was conceived as more "independent of political and industrial interests"[315]. Stressing the importance to do not artificially compartmentalize the analysis of risk between risk assessment and risk management, they decided not to confine the new organization to providing scientific advice. They rather promoted interactions between risk assessors (EFSA's scientists) and risk managers (Commission's services in charge of drafting legislation) from the beginning of the process when the questions are defined, to the final stage when the advice is translated into management proposals. According to the report:

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[310] This informal working group, composed of the three Professors and the four Secretaries, was referred to as "Future of Scientific Advice" (FSA) and the final report as "A European Food and Public Health Authority: The Future of Scientific Advice" (Brussels: Commission, 1999).

[311] The full text of the mandate given to them has been made public at http://europa.eu.int/comm/food/fs/sc/future _mandate _en.html

[312] Philippe James, Francois Kemper, Gérard Pascal, *A European Food and Public Health Authority: The Future of Scientific Advice in the EU*, Report commissioned by the Director General of DG XXIV (now DG SANCO), Dec. 1999, 6.

[313] *Ibid.*, at 15.

[314] According to the report, the CDC "has a crucial influence in ensuring that activities of industrially sensitive issues such as those handled by the FDA are geared to public concerns", 6. To know more about this institution see http://www.cdc.gov/

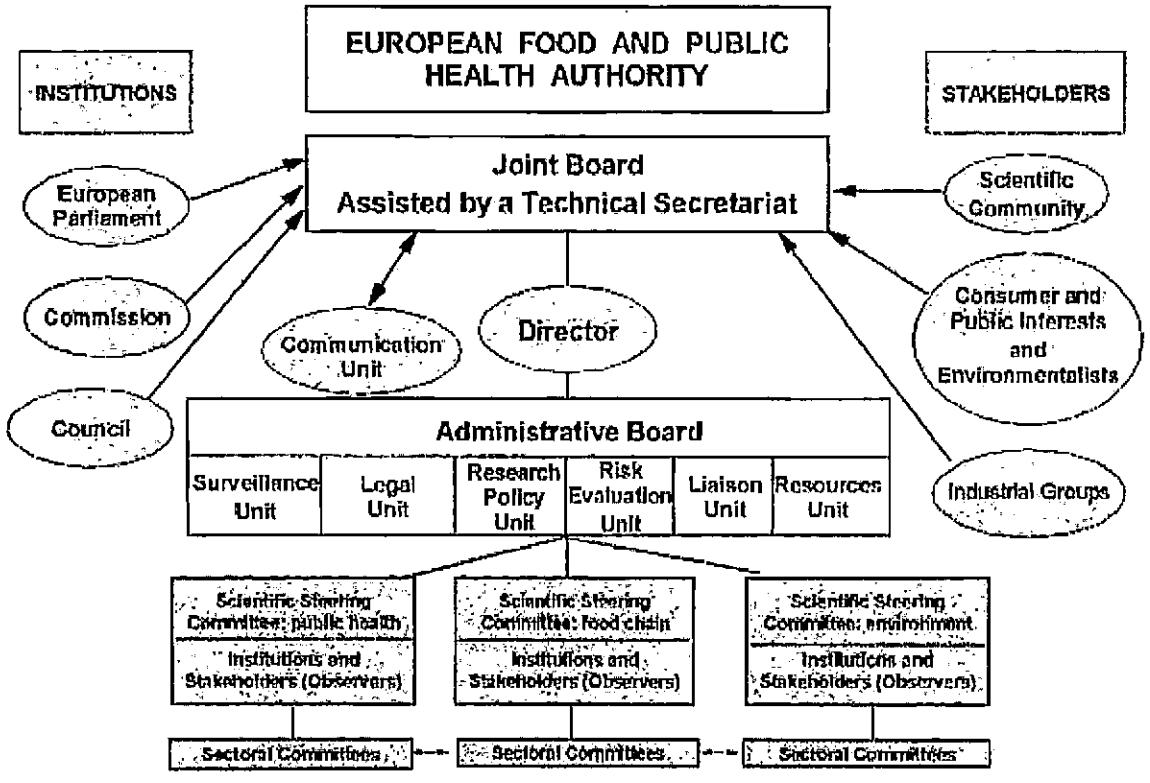
[315] Report, supra note 131 , at 7.

"Confining a new organization to providing advice which is divorced from the realities of what consumers have to confront will lead to further disenchantment with the European system for assuring public health and is therefore unwise"[316].

In other words, under their proposal "in one bold brush" the Commission, the Council, and Parliament would have lost legislative and executive power to a regulatory authority[317]. Finally, since "the current scientific advice relates to many areas in addition to those of food safety", the Report underlined the importance of including also environmental and public health concerns within their proposed authority as "public health issues are in health terms a greater burden on society than the effects of poor food safety which has dominated thinking so far"[318] (*see* diagram 3).

[316] Report, supra note 131, at 8.
[317] See L. Buonanno, in Ansell C. and Vogel D. (eds.), *Why the Beef? The Contested Governance of European Food Safety, in European Food Safety Regulation: The challenge of Multi-level Governance*, (MIT Press, forthcoming 2006).
[318] Report, supra note 131, at 6.

**Diagram 3**. The proposed structure of the new EC institution (EFPHA) by James, Kemper and Pascal[319]:




However, three month after the release of this report, the Commission published its White Paper on Food Safety[320], calling for the establishment of an independent agency, the European Food Authority (EFA), entrusted with a number of key tasks embracing:

- independent scientific advice on all aspects relating to food safety (risk assessment)

- communication and dialogue with consumers on food safety and health issues (risk communication)

Thus, the Commission, under the pressure of the Member States, who were reluctant to give up their involvement in the risk management stage by devolving food control powers to an independent food agency, clearly rejected the transfer of risk management

[319] Report, supra note 131, at 46.
[320] White Paper, supra note 133.

powers from the Commission (*rectius*, from the Food & Veterinary Office (FVO)) to the EFA as suggested by the James, Kemper and Pascal report. To justify this decision the White Paper raised "three very serious issues"[321]:

- The transfer of regulatory powers to an independent Authority could lead to an "unwarranted dilution of democratic accountability";

- The Commission must retain both regulation and control if it is to discharge the responsibilities placed upon it under the Treaties;

- An Authority with regulatory power could not be created under the current institutional arrangements of the EC, and would require modification of the existing provisions of the EC Treaty[322].

Although debatable[323], these arguments led to the definitive abandonment of the FDA analogy in the European food policy's discourse: the FDA was not considered a valid model anymore. Presenting the White Paper to the European Parliament majority's party group, the EC Commissioner David Byrne said:

"Looking across the Atlantic, I saw the American public placed great confidence in the work of the US food and Drug Administration. An institution that was science-based. But also an institution that was involved in management and legislation. I concluded that *such a model, while attractive in itself and clearly working for the US,*

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[321] *Id.*, at 15.

[322] *Id.*, at 17, para 33.

[323] The last assumption is especially controversial among scholars since it heavily relies on the so-called 'Meroni doctrine', establishing the principle of the institutional balance of powers. According to this doctrine, the delegation of power to Agencies would be subject to the following conditions: the Commission cannot delegate broader powers than it enjoys itself; it can delegate only "clearly defined executive powers"; no discretionary power may be delegated; the exercise of delegated powers remains subject to the conditions to which they would have been subject if they had been directly exercised by the Commission; the institutional balance between the EC institutions may not be distorted. The EU Parliament Committee on Legal Affairs and the Internal Market, in its opinion on the White Paper, clearly adopted a narrow interpretation of the doctrine by stating: "If the authority is to act autonomously, then official authority must be transferred to it. However, limits have been placed on the transfer of official authority by the Court of Justice case law. The transfer must relate to precisely defined implementing powers, the exercise of which is fully supervised by the transferring bodies, without the authority to which the powers are transferred being given any margin of discretion. A transfer of power does, however, entail a shift of competencies, which are thus removed from the sphere of influence of the bodies legitimised by the Treaties [...] Legal provisions on food safety exist at both national and European level. It is, however, extremely doubtful whether a Food Authority could carry out local checks or impose sanctions, even in order to enforce the rules, or whether this would be desirable". For a reconstruction of the debate about the scope of the Meroni doctrine, *see* K. Lenaerts, *Regulating the Regulatory Process: "Delegation of Power" in the European Community* 18 European Law Review 23-49 (1993) and J.H.H. Weiler, *Epilogue: 'Comitology' as Revolution—Infranationalism, Constitutionalism and Democracy* in C. Joerges and E. Vos (eds.), *EU Committees: Social Regulation, Law and Politics*, supra note 62, at 339-350.

*would not be appropriate for the European scene.* I wanted to ensure that risk assessment and risk management would be separated. Such an approach would be in line with the provisions of the Treaty, which entrusted management, and legislation, to the Commission, Parliament and Council"[324].

Although the White Paper did not settle all aspects of the EFA's activities[325], it sketched out the main features of the new agency by paving the way to the publication of the first regulation's proposal[326]. The amended proposal[327], after completion of first reading by the EC Parliament and Council, was finally adopted on January 28, 2002[328].

Finally, from a political science perspective, the establishment of EFSA may be explained in light of "credibility theory" according to which governments delegate powers to independent agencies in order to increase the credibility of their policies[329].

## 2. Mission and Tasks of the Authority: the "scientific point of reference" for the whole Union

The primary responsibility of the Authority is to provide scientific opinions in the areas falling within its broad jurisdiction by relying on its eight Scientific Panels.

### 1.1. Mission

Article 22 of the Regulation establishing the EFSA defines its mission as providing "scientific advice and scientific technical support for the Community's legislation and

[324] Speech by David Byrne, European Commissioner for Health and Consumer Protection to the Group of the European People Party and European Democrats in the European Parliament (EPP/ED), Brussels, Sept. 27 *available at* http://europa.eu.int/comm/dgs/health_consumer/library/speeches/speech57_en.html

[325] A significant number of questions remained open, such as the exact relationship between the EFA and the Commission, the functioning of the network with national agencies, the composition of the internal bodies and the management of the early warning system. For a report of the reactions triggered by the presentation of the White Paper EFA's idea, *see* Libération, 13 January 2000; Financial Times, 12 January 2000 and Donald G. McNeil, "At birth, EU's Food Watchdog is on Defence", International Herald Tribune, 13 January 2000. For a reaction of the Scientific Steering Committee, see Integrated Comments and Remarks of the SSC on the White Paper on Food Safety, 14 April 2000.

[326] Proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety. COM (2000)716, Brussels, Nov. 8, 2000.

[327] Amended Proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in the matter of food safety. COM (2001) 475 final, Brussels. Jul. 8, 2001.

[328] The regulation came into force on 21 February 2002. See Article 65 of the Regulation.

[329] F. Gilardi, *Policy Credibility and delegation to independent regulatory agencies: a comparative empirical analysis*, 9:9 Journal of European Public Policy, 2002, 873.

policies in all fields which have a direct or indirect impact on food safety and feed safety. It shall provide independent information on all matters within these fields and communicate on risks". Thus, in accordance with the White Paper, the EFSA is supposed to "become the scientific point of reference for the whole Union"[330], by providing scientific opinions which will serve as the scientific basis for the drafting and adoption of Community measures in the fields falling within its mission[331]. As it is said in recital 32 of the regulation the scientific and technical basis of Community legislation relating to the safety of food and feed should contribute to the achievement of a high level of health protection within the Community. In other words, this regulation reflects the strong belief of the EC legislator according to which there is a tight connection between science base food safety legislation and the assurance of consumer confidence in the decision-making process underpinning food law.

Its mission also includes the provision of scientific advice on matters related to human nutrition, animal health and welfare and plant health.

In the exercise of these activities, the Authority shall act "in close cooperation with the competent bodies in the Member States carrying out similar tasks to these of the Authority"[332]. This provision is crucial in understanding the *raison d'être* underpinning the creation of Authority: EFSA has not been conceived as a pan-European scientific body aimed at imposing its scientific voice over national opinions in food matters, rather it aims at providing an independent European view which ideally complements Member States' studies. Along these lines, the Authority, the Commission and the Member States must cooperate to promote the effective coherence between risk assessment, risk management an risk communication functions. Lacking clear indications within the regulation, it still remain be seen how this cooperation will be realized in practice.

### 1.2. Tasks

More precisely, the EFSA is given responsibility of the following tasks:

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[330] White paper, supra note 133, at 2.

[331] In particular, Article 22 (7) States that "The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it".

[332] Article 22 (7) of the Regulation.

a) to provide the Community institutions and the Member States with the best possible scientific opinions in all cases provided for by Community legislation and on any question within its mission (Articles 23 (a) and 29);

b) to promote and coordinate the development of uniform risk assessment methodologies in the fields falling within its mission (Article 22 (b));

c) to provide scientific and technical support to the Commission in the areas within its mission and, when so requested, in the interpretation and consideration of risk assessment opinions (Articles 22 (c) and 31)[333];

d) to commission scientific studies necessary for the accomplishment of its mission (Articles 22(d) and 32);

e) to search for, collect, collate, analyze and summaries scientific and technical data in the fields within its mission, notably in order to identify emerging risks (Articles 22, 4 and 34);

f) to undertake action to identify and characterize emerging risks, in the fields within its mission (Articles 22 (f) and 34)[334];

g) to establish a system of networks of organizations operating in the fields within its mission and be responsible for their operation (Articles 22 (g) and 36);

h) to provide scientific and technical assistance, when requested to do so by the Commission, *in the crisis management procedures* implemented by the Commission with regard to the safety of food and feed (Articles 22 (h) and 55);

i) to provide scientific and technical assistance, when requested to do so by the Commission, with a view to improving cooperation between the Community, applicant countries, international organizations and third countries, in the fields within its mission (Article 22(i));

[333] This work does not involve 'scientific evaluation' but rather the application of "well-established scientific or technical principles". These tasks may include the establishment or evaluation of technical criteria or assisting the Commission in the development of technical guidelines. See Article 31 of the Regulation.
[334] The EFSA is to establish monitoring procedures with a view to 'systematically searching' for and collecting information about emerging risks.

j) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission (Articles 22(j) and 40);

k) to express independently its own conclusions and orientations on matters within its mission (Articles 22(k) and 37);

l) to undertake any other task assigned to it by the Commission within its mission (Article 22(l)).

These tasks should be undertaken in conditions that respect the virtues of 'independence', 'scientific and technical quality', 'transparency' and 'diligence'[335].

It must be noticed that under Regulation 178/2002, the EFSA has received less functions than those originally provided by the original regulation's proposal[336]. In particular, the Authority is not responsible for the operation of the Rapid Alert System for food and feed established by this Regulation (which is under the Commission's responsibility) and it has also lost its role in the communication on health-policy-related nutritional issues[337].

From a reading of the list of tasks given to EFSA it stems clearly that EFSA's scientific activity cannot be reduced to the delivery of scientific opinions in response to questions posed by its (institutional) customers. Rather EFSA's scientific involvement may be broken down in four main activities:

- Providing scientific opinions, guidance and advice in response to questions submitted by the European Commission, the European Parliament or the Member States;

- Assessing the risk of regulated substances, such as GMOs, pesticides and food/feed additives, following notification procedures and time schedules established by EC legislation;

- Monitoring of specific risk factors and diseases as well as identify and characterise emerging risks;

[335] Article 22.7 Regulation 179/2002.
[336] See supra note 141.
[337] See Article 22 (h) and (k) of the amended proposal, supra note 140.

- Developing, promoting and applying new and harmonised scientific approaches for hazard and risk assessment of food and feed.

In accomplishing the first two tasks, the EFSA fulfils its main mission: to prepare and present scientific opinions. While in the former case the Authority acts in response to food safety questions addressed on a voluntary basis by the competent institutions, in the latter EFSA's intervention is requested by European legislation. Thus, for instance, the legislative framework for the marketing of food additives[338] and feed additives[339], being based on positive list system, relies on the EFSA's assessment. Similarly, the new GMOs legislative regime provides for the risk assessment of GMOs and derived food and feed to be carried out by EFSA[340]. Given their character of *lex specialis*, these legislations dealing with regulated substances determine the modalities of EFSA's scientific intervention.

### 3. INSTITUTIONAL FRAMEWORK

The Authority consists of:

3.1 a Management Board;

3.2 an Executive Director and his/her staff;

3.3 an Advisory Forum;

3.4 a Scientific Committee and Scientific Panels

[338] Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption, as amended.
[339] Since 18 October 2004, applications for authorising the placing and use of feed additives in the market, are regulated in the European Union under Regulation (EC) No 1831/2003. EFSA is responsible for the scientific assessment of the feed additives.
[340] Regulation 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L268, p. 1-23.

### 3.1 Management Board

The Management Board is responsible for guiding the EFSA's activities and ensuring that the Authority carries out its mission and perform its tasks. Unlike other EC agencies[341], it is not composed of representatives of all Member States since Management Board's Member are chosen for their independence, not for their linkage to Member States: they are experts in their own right and collectively have a blend of expertise in the management of key organizations involved in food safety and in the most current issues within the area.

It counts fourteen Members appointed by the Council in consultation with the European Parliament from a list (a 'roaster') provided by the Commission[342], plus a representative of the Commission. Although the Council would have preferred to have the board formed solely by national representatives[343], four of its Members "shall have a background in organizations representing consumers and other interests in the food chain"[344]. These Members inevitably represent a particular interest in the food sector since they retain their previous posts while sitting at the Board. Given the 'free movement bias' affecting the EFSA's foundations, it would be advisable to increase the number of consumer representatives, who do not dispose of the same resources as the food industry to lobby the Commission or to carry out their own risk assessment to be opposed to the EFSA's opinions.

The Board composition represents a significant and innovative institutional aspect aimed at ensuring "its independence, high scientific quality, transparency and efficiency"[345].

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[341] Within the other EC agencies, Members of the Board are appointed either by the Member States independently or by the Council on the basis of one Member per Member State. See E. Chiti, *The Emergency of a Community Administration: the Case of European Agencies*, in Common Market Law Review 37, at 309-342 (2000); see also K. Kanska, *Wolves in the clothing of sheep? The case of the European Food Safety Authority*, 24 E.L.Rev. 2004, 715.

[342] The Commission, by preparing 30 candidates for 14 places, did not give the Council much margin of manœuver in the exercise of its appointment power.

[343] E. Vos, *Mondialisation et régulation-cadre des marches – Le principe de précaution et le droit alimentaire de l'Union européenne*, in 2-3 Revue international de Droit Economique (2002), 219 at 244.

[344] Article 25 (1).

[345] See *whereas* (40) and (41) of the Regulation.

After the Enlargement, the size of the Board turned out to be much smaller than the number of the Member States. However, in order to partly mitigate the situation of under representation, the Regulation provides that "the broadest possible geographic distribution within the Union" should be guaranteed within the Board[346]. Furthermore, Recital 41 of the Preamble dictates a "rotation of the different countries of origin of the Members of the Management Board without any post being reserved for nationals of any specific Member State". To fully understand the meaning of such a provision, reference must be made to the BSE crisis when "the influence of "British thinking" on the Commission was increased by the presence of many persons of British nationality on the two committees operating in this field: the Scientific Veterinary Committee and the Standing Veterinary Committee"[347].

This crises clearly showed the need for a geographical rotation of Members as different Member States have not only different interests as regard the food sector but also different perceptions as regard risk assessment.

As the term of office of the Board Members is four and six years (only for half of its Members), nationals of the new Members may not be appointed before 2007[348].

The Commission, after a widely publicized call for interested candidates, has published a short list of suitable candidates on April 8, 2002. Those candidates who had a background in organizations representing consumers and other interests in the food supply chain have been specifically identified on the short list from which 5, not 4 as textually provided, have been selected by the Council and they met for the first time on September 18-19, 2002[349].

### 3.2. Executive Director

Together with the Management Board, the regulation provides for the appointment of an Executive Director, who is the legal representative of the Authority and is responsible for:

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[346] Article 25 (1).

[347] Vos, supra note 62, at 144. See also the Temporary Committee of Inquiry into BSE available at http://www.bseinquiry. gov.uk/evidence/ibd/idb.htm

[348] As of today, only one Member of a scientific committee comes from a new Member State.

[349] *See* Council decision appointing the Members of the Management Board of the European Food Safety Authority [2002] OJ C179/2. See also EFSA, Annual Report for the year 2002, 5-6, available at http://www.efsa.eu.int

a) the day-to-day administration of the Authority;

b) drawing up a proposal for the Authority's work programs in consultation with the Commission;

c) implementing the work programs and the decisions adopted by the Management Board;

d) ensuring the provision of appropriate scientific, technical and administrative support for the Scientific Committee and the Scientific Panels;

e) ensuring that the Authority carries out its tasks in accordance with the requirements of its users, in particular with regard to the adequacy of the services provided and the time taken;

f) the preparation of the Statement of revenue and expenditure and the execution of the budget of the Authority;

g) all staff matters;

h) developing and maintaining contact with the European Parliament, and for ensuring a regular dialogue with its relevant committees.

Among these tasks, the most relevant one is to design the work program of EFSA because, due to its limited capacity, the agency cannot deal with all possible issues within its mission. He is therefore responsible for priority setting, as confirmed by Article 27 (3) stating that the "Director may also ask the Advisory Forum for advice on the prioritization of requests for scientific opinions". Contrary to what originally required by the original proposal, in designing the work program of EFSA, the Director is not required to obtain the agreement of the Commission, but simply to consult it. This undoubtedly reinforces his independency vis-à-vis the Commission.

As regards the term of office, the Director is appointed for five years by the Management Board on the basis of a list of candidates proposed by the Commission after an open competition. Being the Authority a legal separate entity, independent from the other EC institutions, the Executive Director is not answerable to the Commission or other Community or national institutions but to the Management Board. The entire

responsibility for risk management decisions remains with the competent EC institutions (Commission, Council and Parliament) as established in the Treaty. However, he might be dismissed by the Board by simple majority of votes.

Since February 1, 2003, Geoffrey Podger, former Chief Executive of the UK Food Standards Agency[350], is the EFSA's Executive Director. His appointment was certainly motivated by his role played in UK food policy in the aftermath of the BSE crisis.

### 3.3 Advisory Forum

The Advisory Forum is the link between EFSA and the Member States[351]. It is composed by representatives from competent bodies (*e.g.*, national food agencies[352]) in the Member States which undertake tasks similar to those of the Authority, these representatives being designated by each Member State. Members of the Advisory Forum may not be Members of the Management Board. The Executive Director convenes and chairs the Forum, but also a third of its Members may initiate a meeting. The Forum has to meet at least four times per year and its meetings are open to the participation of Commission's officials. Also representatives from the European Parliament and other relevant bodies may be invited to participate.

The Advisory Forum gives the Executive Director advise on all aspects of his tasks, and notably on setting up a proposal for the EFSA's work programme. The Director may also ask the Forum for advice on the prioritizing of requests for scientific opinions.

Being an organ totally unknown in Community agency structure, it is the most original organ within the EFSA. In the words of the regulation, it constitutes a "mechanism for an exchange of information on potential risks and the pooling of knowledge"[353].

The creation of this mechanism may be seen as responding to two different goals: one was reinforcing Member States participation into the EFSA's activities and the other to facilitate co-operation between the agency and the Member States.

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[350] Midday-express, Oct. 2, 2002, Executive Director of the European Food Safety Authority nominated.
[351] Article 27 of the Regulation.
[352] Unlike in the area of drugs, not all Member States have a national food agency. Thus, for instance, Luxembourg and Italy do not have one as yet.
[353] Article 27.4 of the Regulation.

In fact, being a forum, it aims at fostering co-operation between the represented national food bodies and the EFSA, thus avoiding conflicts rising among these entities on specific scientific opinions or on their role within the system. In particular, the Advisory Body also ensures close cooperation between the Authority and the competent bodies in the Member States to avoid duplication of the EFSA's scientific studies with Member States, to promote the European networking of organizations operating within the fields of the Authority's mission and where the EFSA or a Member State identifies emerging risk[354].

### 3.4 Scientific Committee and Scientific Panels: the very heart of EFSA

The Scientific Committee and the eight permanent Scientific Panels, being responsible for providing the scientific opinions, constitute the hardcore of the Authority. These Committees were attached to the EC Commission, now they are part of the EFSA.

The Scientific Committee, replacing the former Scientific Steering Committee[355], is responsible for the general coordination necessary to ensure the consistency of the scientific opinion procedure[356]. It is composed of the Chairs of the Scientific Panels and six independent scientific experts who do not belong to any of the scientific panels. The six independent experts are appointed by the Management Board. It may provide scientific opinions that are either not within the competence of any of the Scientific Panels or within the competence of more than one panel.

As for the Scientific Panels, they are composed of independent experts who are not employees of the Authority. The following are the Scientific Panels, replacing five of the former DG SANCO Scientific Committees, which dealt with issues falling within the competence of EFSA, following the 1997 reform:

a) Panel on Food Additives, flavorings, processing aids and materials in contact with food (ACF);

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[354] Article 27.4 a), b), c) and d).
[355] This Committee (Commission Decision 97/404/CE of June 1997 setting up a Scientific Steering Committee, OJ L 169, p. 85) coordinated the work of eight other scientific committees (Commission Decision 97/579/EC of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety, OJ L237, p. 18).
[356] Article 28 of the Regulation.

b) Panel on additives and products or substances used in animal feed (FEEDAP);

c) Panel on plant health, plant protection products and their residues (PPR);

d) Panel in genetically modified organisms (GMO);

e) Panel on Dietetic products, nutrition and allergies (NDA);

f) Panel on biological hazards (BIOHAZ);

g) Panel on contaminants in the food chain (CONTAM);

h) Panel on animal health and welfare (AHAW).

The eight panels are responsible for providing the scientific opinions of EFSA. Their tasks are stated in similar terms to those of the former Scientific Committees. Thus, the ACF panel delivers "scientific opinions" on questions relating to "safety in use of food additives, flavourings processing aids and materials in contact with food; associated subjects concerning the safety of other deliberately added substances to food and questions related to the safety of the processes". The Scientific Committee and the Panels can form working groups of additional experts on specialized subjects so as to draw on the best scientific advice available in the EC and, when necessary, beyond.

All scientists sitting in the Committee and in the Panels are appointed by the Management Board upon proposition of the Executive Director on the basis of an open competition. Neither the Commission nor the Member States play a formal role in the selection process. Their term of office is of three years and is renewable.

EFSA's own scientific staff supports the Scientific Committee and Expert Panels. In addition, the Authority expects to reinforce its Science department by creating a series of expert service "teams" each dedicated to a specific area of risk assessment (*e.g.*, data collection, epidemiology and exposure...). EFSA has created scientific experts groups composed of some of its own scientists and experts from Member States. This applies to: the peer review of existing pesticides; geographical BSE risk assessment; the evaluation of TSEs (Transmissible Spongiform Encephalopaties), and the coordination and scientific assessment of the monitoring of zoonoses and zoonotic agents. In total, EFSA's team of

highly qualified scientists, experts in their respective fields, and support staff is expected to number 70 in 2004, representing approximately 50% of total headcount.

The procedures for operation and cooperation of the Scientific Committee and the Scientific Panels have been laid down, conforming to the Regulation[357], by the Decision concerning the establishment and operations of the Scientific Committees and Panels[358]. Furthermore, rules on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it have been set up by Commission Regulation 1304/2003 of July 2003[359].

Decisions are made with a simple majority vote, minority opinions are recorded with the name of the author and the main arguments supporting it.

Members of the Scientific Committee, the Scientific Panels, and the Working Groups have to sign a commitment of independence, and have to report each year on their direct or indirect interests that are relevant for EFSA[360]. Scientific Committee and permanent Scientific Panels may, when necessary, organize public hearings.

During 2002 this component of the Authority was not operational. Instead the Commission continued to provide management and support to its own Scientific Committees. The call for the recruitment of scientists to the Committee and Panels was launched in 2003.

### 3.5 Resources: Personnel and Budget

The Authority's activities are funded from the Community budget based on a proposal from the Commission and approved by the budgetary authority of the Council and the Parliament. Although in principle it is up to the EFSA to determine how to use the available resources, there exist some limits to this freedom. Thus, for instance, a recent amendment to the Regulation has introduced a provision according to which the EFSA is

[357] Article 28, paragraphe 9, of the Regulation.
[358] Adopted by the Management Board on 17.10.2002.
[359] Commission Regulation 1304/2003 of July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it, JO L185/6.
[360] Decision adopted by Management Board on 10.03.2004 (MB Doc.10.03.2004-5), "EFSA Code of Conduct on Declaration of Interests", amended by Guidance on Declarations of Interests, endorsed by the Management Board on 16 December 2004.

to seek an opinion of the budgetary authority if it intends to implement a project which "may have significant financial implications for the funding of the budget"[361].

The Authority will employ up to 250 people by the end of 2005, with a budget of approximately € 40 millions[362].

Once it will be fully operational, the EFSA, similarly to the US FDA, will try to rely exclusively on his substantial in-house scientific expertise[363].

Unlike the FDA, EFSA does not currently collect user fees from industry to fund its activities. However, the Regulation requires the Commission to publish a Report within three years after the effective date of the legislation "on the feasibility and advisability of presenting a legislative proposal under the co-decision procedure and in accordance with the Treaty and for other services provided by the Authority"[364]. Collecting these fees may contribute to the EFSA's financial independence since Article 16 of the Framework Financial Regulation provides that if the balance of accounts of the agency is positive, the EFSA has to repay to the Commission only the amount up to the subsidy granted, but all the amounts exceeding the subsidy may be kept as revenue in its budget for the next financial year[365].

### 3.6 Location

The regulation establishing the Authority does not specify a location for its seat. Although both the James, Kemper and Pascal report and White Paper underlined the need to locate the EFSA in an "easily accessible place close to the risk managers" (Brussels),

[361] Regulation 1642/2003 amending Regulation 178/2002 [2003] OJ L245/4.
[362] These figures have to be reviewed within three initial years of operation. It may be interesting to observe that, by comparison, the Food Standards Agency in the UK has a staff of 570 for food safety functions only, and its annual budget is approximately euro 140m (about $125m). See also EFSA, Information Note Budget 2003-2004, available at http://www.efsa.eu.int/mboard/statutory_texts/business_documents/408/mboard_meeting_012_doc5_en11.pdf
[363] The U.S. FDA obtains more than 90% of its scientific opinions and studies from its own services. Information collected from an FDA official.
[364] Article 45, Fees received by the Authority.
[365] Council Regulation 2343/2002 on the Financial Regulation applicable to the general budget of the European Communities [2002] OJ 357/72.

Member States finally agree to establish the Authority's permanent head quarters in Parma, Italy[366].

## 4. Operation

### 4.1. Risk Assessment: Scientific Opinions

As we have previously seen, EFSA's primary responsibility is to provide scientific advice in the areas falling under its broad competence. To fully understand EFSA's operation it is therefore important to analyze who is entitled to ask the Authority for a scientific opinion, when the Authority may or should refuse such a request, which is the procedure applied by the Authority to requests for scientific opinions referred to it and, finally, what is the legal status of EFSA's scientific opinions. Some attention has also to be devoted to EFSA's role within the Rapid Alert System.

Most of the rules governing the operation of the Authority are contained in Regulation 178/2002, but some have been introduced by Commission Regulation 1304/2003 of July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it[367].

We start this analysis by turning to the question of referral to the Authority.

#### A. Referral to the EFSA

Unlike the previous system where only the Commission could request advice from the Scientific Committees, the EFSA may respond to requests for scientific advice from a variety of entities, such as the Member States, national food authorities and the EC Parliament[368]. This is vital to the EFSA in establishing itself at the centre of the networks

[366] *See* http://www.efsa.eu.int/press_room/press_release/32/15-12-2003_en1.pdf
[367] Commission Regulation 1304/2003 of July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it, JO L185/6.
[368] Article 29 of the Regulation.

as originally envisaged by the White Paper. However, where consultation is mandatory under Community law, the Commission continues to have exclusive authority to obtain scientific advice from EFSA[369]. Furthermore, the Authority may refuse the request for an opinion if the background information explaining the scientific issue is not given, the Community interest is lacking[370] or there are no new scientific elements justifying the re-examination[371].

Furthermore, the EFSA, acting *ex officio*, may carry out scientific assessment on any matter that may have a direct or indirect effect on the safety of the food supply, including matters relating to animal health, animal welfare and plant health[372]. This increases both its independence and scientific respectability. The Authority is also entitled to give scientific advice on non-food and feed GMOs, and on nutrition, particularly in relation to Community legislation.

The Authority is also authorized to modify a request for an opinion, or refuse it, when it is unclear, different requests are made on the same issues or when it has already delivered a scientific opinion on the specific topic[373]. In these circumstances, the finalised request, as agreed to by the applicant, must be forwarded to the scientific committee or a permanent scientific panel of the Authority for preparation of an opinion.

Opinions issued by the Scientific Committee and Scientific Panels are subject to mandatory public disclosure as soon as possible after adoption[374], provided that their publication does not violate the prohibitions against disclosure of proprietary information and of personal data[375]. However, EFSA's scientific opinions relating to foreseeable health effects can never be kept confidential[376].

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[369] See, e.g., Directive 2001/18 on the deliberate release of genetically modified organisms, O.J. 2001, (L 106) 1 and food supplements.
[370] Article 29, paragraph 4 of the Regulation.
[371] Article 29, paragraph 5 of the Regulation.
[372] Article 29 1 (b) of the Regulation.
[373] Article 29, (4) and (5) of the Regulation.
[374] Article 38 1 (b). Also the agendas and minutes, the annual declarations of interest, the results of its scientific studies and research and the annual report of its activities have to be made public. See Article 38 1.
[375] Article 39 of the Regulation.
[376] Article 39 (3) of the Regulation.

If we look at the Register of requested opinions listing all scientific opinions asked to the EFSA during the first years of its existence (from 2003 to 2005)[377], we discover that in a total of almost 600 requests more than 400 have been introduced by the Commission, around 40 by Member States and some have also been commenced by the agency *sua sponte*[378]. However, it is well known that the Commission does not see with favor the EFSA self-tasking.

There is also one request introduced by the EP (on "the salmon marketed in the EC") and another by France (on "the risk of BSE and the embargo on Portuguese products")[379].]

The question has arisen whether a national court may refer questions to the EFSA. In case *HLH Warenvertriebs* [380], a German court has notably asked the ECJ to establish whether a national judge may refer questions on the classification of a product to EFSA.

The Court has denied such a possibility by mainly relying on textual arguments. Neither Regulation 178/2002, where listing EFSA's tasks, nor Regulation 1304/2003, on EFSA's procedure to requests for scientific opinions, include national courts among the applicants authorised to ask the Authority for a scientific opinion[381]. In particular, the latter by referring to "government authorities or authorities authorised to request scientific opinions" would not seem to consider the national courts among those to which it refers[382].

Therefore, as the Community rules stand, national courts may not refer questions to EFSA.

Finally, the Authority may be requested by the Commission not solely to issue scientific opinions but also to provide scientific and technical assistance, consisting in scientific or technical work involving the application of well-established principles which does not require scientific evaluation by the Scientific Committee or a Scientific Panel.

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[377] The register for requested opinions and own-initiative opinions has been established by Commission Regulation 1304/2003 of July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it, "to ensure sound management" (see preamble (3)). It must be accessible to the public and allow the progress of requests for opinions to be followed with effect from the date on which they are received. See its article 2.

[378] Around 35 by the end of July 2005.

[379] See the Register of requested opinions available at www.efsa.eu.int/register/qr_applicants_1_en.html

[380] Case HLH Warenvertriebs GmbH [2005], supra note 149, paras 89 – 94.

[381] *Ibid.*, para 90-91.

[382] *Ibid*, para 91.

*1. Refusal of requests for opinions*

The Authority may refuse to issue a scientific opinion in the following events:

- when different requests are made on the same issues[383];

- when the request is not accompanied by background information explaining the scientific issue to be addressed and the Community interest[384] (as provided by);

- when the request is unclear[385].

In all these circumstances, justification of the refusal shall be given to the institution or the Member State that made the request. However, whenever the requesting institution falling in one of these cases is the Commission, EFSA may ask it for additional information or propose an amendment to the request, thus rendering less likely the refusal of its request for scientific opinion.

Regulation 1304/2003 on the procedure applied by EFSA to requests for scientific opinions referred to it has recognised some new hypothesis of refusal[386]. Thus, the Authority shall not issue a scientific opinion in the event of requests from applicants not authorised to ask EFSA for a scientific opinion under Community legislation or requests for opinions on matters which are part of the Authority's mission[387]. Unlike the cases referred to in Regulation 178/2002, those introduced by this regulation does not allow the Authority to decide whether or not to provide a scientific opinion, but prevent it from doing it. To fully implement the duty of refusal imposed on EFSA in the first case, Member States are supposed to inform the Authority of the "government authority or authorities authorised to request scientific opinions from the Authority"[388].

[383] Article 29, paragraph 4, of the Regulation.
[384] Article 29, paragraph 2 and 4, of the Regulation.
[385] Article 29, paragraph 4, of the Regulation.
[386] See Regulation 1304/2003, supra note 337.
[387] *Ibid.*, Article 3, paragraph 1.
[388] *Ibid.*, Article 9.

*2. Time limits and emergencies*

While the general food law regulation does not provide any rule concerning the time limits for the delivery of a scientific opinion, Regulation 1304/2003 establishes that, in as far as Community legislation does specify a time limit for such a delivery, the applicant may stipulate a deadline by when the opinion is required, giving the reasons. Where the Authority cannot meet this deadline, it should inform the applicant, explain the reasons and propose a new deadline. Should the applicant not stipulate a deadline, the Authority should inform the applicant of the anticipated time needed to deliver the opinion.

There are special rules governing the time limits in case of emergencies. In particular, the EFSA is supposed to take the necessary measures to ensure that a request or a own-initiative opinion is delivered as soon as possible where the information accompanying the request testifies an urgent need for a scientific opinion. There is urgent need either when it exists an emerging risk likely to constitute a serious risk to human or animal health or the environment and likely to have a Community dimension or when the Commission looks for a more detailed scientific basis for managing a serious risk to human or animal health or the environment.

*3. Transparency requirements for scientific advice*

The regulation provides for several provisions establishing transparency requirements for the scientific opinions. Transparency is a must for EFSA. All its activities, according to Article 38, have to be carried out with a high level of transparency meaning that not only the agendas and minutes of the meetings of its scientific bodies shall be made public but also the opinions including minority opinions. Nevertheless, confidential information for which a confidential treatment has been requested shall not be divulged by EFSA with the exception that conclusions of the scientific opinions delivered by the Authority relating to foreseeable health effects shall on no account be kept confidential[389].
Any other non confidential information concerning the mission of the Authority shall be made public rapidly. Wide access to documents in its possession shall be equally ensured.

[389] Article 39, paragraph 3.

### B. The legal status of the EFSA's Scientific Opinions

Although the EC institutions are expressly required to take EFSA's opinions into account when drafting a Community measure[390], the Agency lacks formal authority to reach binding resolutions on potentially contentious scientific issues[391]. In other words, similar to all the other Scientific Committees[392], it does not have the final word in case of diverging scientific opinions between its own decisions and those issued by other bodies. This may be inferred from Article 30 of the Regulation that, while establishing a procedure aimed at solving problems arising out from "diverging scientific opinions", it does attribute neither an authoritative nor a mediating role to EFSA, but simply "vigilance" and "cooperation" duties. This outcome is at least *prima facie* surprising if analyzed in the light of the EFSA's ambition to become "the point of reference in risk assessment" for the whole Community[393].

More precisely, under the Regulation, the Authority has to exercise vigilance in order identify at an early stage any potential source of divergence between its scientific opinions and the opinions issued by national food agencies or other bodies carrying out similar tasks[394]. Where there is a conflict between its opinion and those of bodies carrying out similar tasks, the EFSA must contact the body in question to ensure that all relevant scientific information is shared and to identify potentially contentious scientific issues[395]. Where accommodation is not possible despite EFSA's effort and the body is either a Community agency, a Commission Scientific body or a Member State body, the Authority is "obliged to cooperate"[396] either to resolve the differences or to present a joint document, which will be made public identifying the uncertainties and the "contentious

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[390] Article 22 (6) of the Regulation.

[391] This is obviously not the case when EFSA risk assessments are required by EC legislation. In this situation EFSA's opinions enjoy the express status recognised by the legislation. Thus, under the GMO pre-market approval system, EFSA is in charge with issuing an opinion on any application for the authorization of GM Food or Feed. Where the Commission's decision is not in accordancde with this opinion, it must provide an explanation for the differences. See also S., Krapohl,, *Credible Commitment in Non-Independent Regulatory Agencies: A Comparative Analysis of the European Agencies for Pharmaceuticals and Foodstuffs*, in European Law Journal 10 (5), at 532.

[392] Case 247/84 Motte [1985] ECR 3887, para 20, where the Court said that the Member States must "take into account" the results of international scientific research", but it also stated that "it must be emphasized that the Opinions of the Committee do not have binding force ".

[393] Preamble (34) and (47), Article 22 (7).

[394] Article 30 (1) of the Regulation.

[395] Article 30 (2) of the Regulation.

[396] Although it is not expressly provided within the regulation, this duty of cooperation must be read in light of Article 10 of the Treaty.

scientific issues"[397]. This system recalls the compulsory notification system of draft technical regulations, by functioning as a preventive mechanism (sort of 'early-warning) aimed at solving ex ante any conflict arising between the national and European views of risk[398].

A *prima facie* reading of these provisions clearly shows that EFSA has not been entrusted with the power to act as the ultimate body of scientific advice in the European Union. To understand the practical consequences stemming from this decision, it is sufficient to remember the crisis involving France and the United Kingdom and regarding the Commission's decision to lift the embargo on beef exports in July 1999, two years after the *BSE*'s outbreak[399]. The French food Safety Authority (AFFSA) and the EC Commission Scientific Steering Committee strongly differed on the scientific interpretations of the risks associated with beef. France, relying on its scientific opinion, refused to lift the embargo on British beef in contravention of the EU scientific data and the EC Commission brought France before the European Court of Justice claiming a violation of EC law[400]. This case clearly exemplifies the likelihood that, in spite of the high degree of integration within the EU food safety arena, conflicts may arise in the future between national authorities and the EFSA on contentious scientific issues.

The introduction of a mere duty of co-operation does seem to fall short in providing an effective answer to the fundamental question of the relationships between the EFSA and the national authorities responsible for food safety issues. The institution of an Advisory Body, as a mechanism of exchange of information between the national authorities and the EFSA, is unlikely to prove decisive in overcoming the difficulties arising from diverging scientific opinions. In light of the above, the current regulatory framework and

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[397] Article 30 (3-4) of the Regulation.

[398] J. Scott and E. Vos, *The Juridification of Uncertainity: Observations of the Ambivalence of the Precautionary Principle within the EU and the WTO*, supra note 43, at 283.

[399] For background information and a detailed description of the situation leading to the case, see Shears, Zollers and Hurd, supra note 102; Harmoniaux, *Principe de précaution et refus de la France de lever l'embargo sur la viande de bovin britannique*, L'actualité jurisprudentielle, droit administratif 164-169 (Février 2002).

[400] For a review of this judgement, *see* A. Alemanno, *Contentieux, Arrêt "Commission /France"*, Revue du droit de l'Union Européenne, 1/2002, at 159-162 2002; C. Szawloska, *Risk Assessment in the European Food Safety Regulation: Who is to decide Whose Science is Better? Commission v. France and Beyond ...*, in 5 German Law Journal No. 10 (1 October 2004) - European & International Law and Harmoniaux, supra note 399.

the institution of the EFSA does not seem to be apt to putting an end the competition in scientific matters pertaining food among national authorities in the Member States. And this notwithstanding the committed declaration by EFSA Deputy Executive Director that EFSA should not "compete with the excellence science in the Member States"[401]. Finally, the abovementioned provisions certainly cast some doubts about the possibility that EFSA becomes "the scientific point of reference for the whole Union" as announced by the Regulation.

However, the Regulation promotes also an alternative method to tackle the issue of diverging scientific opinions between the EFSA and the national scientific bodies. In order to prevent the emergence of such a scientific controversies, the EFSA is required to develop the "European networking of organizations" operating in food safety risk assessment. More specifically, the official aim of such networking is "to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices"[402]. This sort of network activity is not without precedent[403], but it plays a crucial a role within the EFSA. In fact, the establishment of this network will be necessary to support EFSA's scientific activities, notably in the examination of authorizations dossiers[404].

### *1. Indirect legal effect*

Outside the case of diverging scientific opinions between the EFSA and other bodies carrying out similar tasks, the Authority's opinions are likely to produce some significant indirect normative effects. In particular, the EFSA's opinions have the potential to become a source of constraint not only for the EC institutions, but also for the Member States and the private parties.

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[401] EFSA news, 2, 2004, at 1.
[402] Article 38 of the Regulation.
[403] T.A. Borzel, *Organizing Babylon – On the different Conceptions of Policy Networks* (1998) 76 Public Administration 253.
[404] Article 46(4) of the Regulation.

Being at the centre of the collection and communication of scientific information, the EFSA has the potential to create a new information network through which it might qualify as the leading competent source for all EC actors.

As for the EC institutions, the recent *Pfizer Animal Health* judgment has clearly established a general duty to consult the available scientific reports prepared by experts on behalf of the EC[405]. The EC institutions would be allowed departing from this duty only in those exceptional circumstances where equivalent scientific evidence can be found and a justification for relying on it is provided. There are therefore good reasons to believe that these constraints on the possibility of departing from scientific evidence will be maintained by the EC courts with regard to the EFSA's opinions by transforming them in *de facto* authoritative measures. In other words, it is likely that within the new food safety regime it will be more and more difficult for the EC institutions exercising their discretion beyond the boundaries drawn by a scientific administrative network led by an independent and authoritative authority such as EFSA.

The EFSA's opinions are likely to acquire some authoritative value vis-à-vis National decision-makers as well. Although the Regulation introduces the presumption that, in the absence of specific Community provisions, all food is deemed to be safe where it complies with the specific national provisions of the country where it is marketed[406], the same regulation imposes on Member States the duty to take account of the results of risk assessment, in particular the opinions of the Authority when regulating the food sector. In sum, while domestic authorities are not procedurally required to consult the EFSA, they are still required to abide by its scientific opinions in passing new legislation[407]. It would seem therefore impossible for the national authorities to derogate from the EFSA's opinions without giving some reasons justifying their rejection.

The Authority's position has also the potential to acquire some legal significance for private parties. As seen above, the Regulation also imposes a general obligation on private business operators engaged in production, processing and distribution to ensure

[405] Case T-13/99 Pfizer Animal Health v. Council, supra note 161. See also the parallel case T-70/99 Alpharma v. Council, 2002 E.C.R. II-3495. For a review of these judgments see, e.g., Alemanno, supra note 259.
[406] Article 14 (9) of the Regulation.
[407] Article 6 (3) of the Regulation.

that food placed on the market be safe[408]. Any breach of this duty gives virtually raise to two separate violations of EC law: breach of the general obligation to ensure that food is safe, established by article 14 of the regulation, on one side, and violation of the Product Liability Directive on the other[409]. Although national courts are not required to consult the Authority while investigating on these violations, they are likely to rely on its scientific opinions. In other words, if the EFSA has issued an opinion suggesting that a product is unsafe, it would be extremely difficult for a private individual to prove the opposite.

Finally, EFSA's opinions can produce also some legal effects vis-à-vis national courts. In *HLH Warenvertiebs*, where the ECJ has expressly been asked to determine whether the scientific opinions of that Authority may be binding force on the national courts, it has been held that

> "An opinion delivered by that Authority, possibly in a matter forming the subject-matter of a dispute pending before a national court, may constitute evidence that that court should take into consideration in the context of that dispute"[410].

Notably, the Court has stated that national courts should ascribe to such an opinion the same value as that recognized to an "expert report"[411]. Thus, EFSA's scientific opinion may susceptible of acquiring a legal status similar to that of scientific expertise requested by the same national courts to third parties. Although not binding *per se*, the scientific report "should be taken into consideration in the context of the dispute"[412].

In conclusion, whilst the EFSA's opinions have not been expressly granted a direct regulatory authority, they are likely to acquire a *de facto* legally binding value for both the EC and the Member States authorities when passing legislation and a strong probative authority against private business operators placing on the market unsafe food. More in general, it can be reasonably expected that the EFSA's opinions will structure the terms of debate on several issues by influencing enforcement within the Member States and

[408] Article 14 (1) of the Regulation.
[409] Chalmers, supra note 103.
[410] HLH, supra note 149, para 94.
[411] HLH, supra note 149, para 93.
[412] HLH, supra note 149, para 94.

public opinion. Lastly, it remains unclear and difficult to predict whether the EFSA will play a role in trade relations with third countries.

## C. Judicial review of EFSA's scientific opinions

### *1. ECJ and scientific opinions*

Although the issue whether Community courts may review the legality of an EFSA's scientific opinion is an open question to the extent it has not yet been resolved, it is possible to elaborate some reflections.

Judicial persons can bring a nullity claim against decisions by the European institutions in front of the EC courts, notably the CFI, if that decisions are *addreessed to that person.* They may also bring an action against a decision which, although in the form of a regulation or a decision addressed to another person, is of *direct and individual concern* to the former.

Being merely preparatory act, EFSA's scientific opinions would not seem to fall within either of these categories.

However, notwithstading their lack of binding legal nature, it has recently been established, with reference to the scientific opinions given by the EMEA's Committee for Proprietary Medicinal Products (CPMB), that they are

> "none the less extremely important so that any unlawfulness of that opinion must be regarded as a breach of essential procedural requirement rendering the Commission's decision unlawful"[413].

In other words, although these scientific opinions do not bind the Commission, they provide it with the evidence of scientific assessment which is necessary to determine, "in

[413] Joined Cases T-144/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00 and T-141/00 Artegodan a.o. v. Commission [2002] ECR 4945, supra note 253, para 197.

full knowledge of fact", the appropriate measure to ensure a high level of health protection.

In the light of the above, in the *Artegodan* judgments, the CFI, then confirmed by the ECJ has held that the EC Courts may be called upon reviewing the formal legality of an agency scientific committee's opinion as well as the Commission's exercise of its discretion.

Although the CFI has stated that it cannot "substitute its own assessment for that of the scientific committee", it has held that it may review the proper functioning of the committee, the internal consistency of the opinion and the statement of reasons contained therein.

It remains to be seen whether the EC Courts will extend this reasonment to the review of EFSA's scientific opinion. There are no reasons for which EFSA's opinions may not be subject to an analogous standard of review should the Courts be called to review the legality of a Commission decision based on a EFSA's scientific opinion delivered by one of its panels, such as the Panel on genetically modified organisms.

### *2. National courts and scientific opinions*

Although in case *HLH* the question has arisen whether national courts may review the legality of EFSA's scientific opinions[414], neither the opinion of the A.G. nor the judgment have tackled this issue. The Court has solely held that such opinions, although not binding, "may constitute evidence that the court would have to take into consideration as such"[415], notably by ascribing to them "the same value as that recognized to an expert report"[416]. However, the possibility for a national court to review the legality of a scientific opinion delivered by EFSA may be rendered controversial not because of their mere preparatory nature, but rather because of the ECJ's monopoly on the legality review of EC acts under the *Foto-Frost* jurisprudence[417]. According to this case law, national

[414] See Opinion of A.G. Geelhoed, Case C-211/03, HLH Warenvertriebs, not yet published, point 98. supra note 149.
[415] HLH, supra note 149, para 94.
[416] HLH, supra note 149, para 93.
[417] Case 314/85, Foto-Frost [1986] ECR 2333.

jurisdiction do not have the power to declare acts of the Community institutions invalid and, accordingly, when they consider the arguments put forward by the parties well funded, they are supposed to refer the validity matter to the ECJ through a preliminary ruling.

### 4.2. The Rapid Alert System for Foodstuffs (RASFF)

The Rapid Alert System for food emergencies, originally established by decision 84/133/CEE[418] then integrated into the general product safety directive 92/59/EC[419], was revamped by the Regulation and it is activated when the health of EC consumers may be under threat from a food safety problem in more than one Member State.

Origin of the system in De Grove-Valdeyron, La protection de la santé et de la sécurité du consommateur à l'épreuve de l'affaire de la dioxine, Revue du Marché Commun, 1999, p. 700 ss.

Although both the White Paper and the original regulation's proposal entrusted EFSA with the management of the RAS[420], the current regulation designates the Commission as the "responsible for managing" the system[421].

The system relies on a network involving Member States, the Commission and the Authority. When a Member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information has to be notified to the Commission, who will transmit that to the other Member of the network. In particular, Member States are supposed to notify the Commission of any measures they adopt to restrict the placing of a product on the market or to demand its withdrawal.

However, neither the Commission not the EFSA are entitled to determine whether a product presents a risk to human health. The system simply aims at disseminating risk information in response to notifications from Member States and does not provide for a procedure assessing whether the risks warrant a European reaction.

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[418] OJEC 1984, L70.
[419] OJEC 1992 L228/24.
[420] See Article 22 (h) of the amended proposal, *supra* note 145.
[421] Article 35 of the Regulation.

We believe the RAS could have become more effective if the Regulation had expressly entrusted the EFSA with the authority to use its scientific expertise to assess the urgency of the notifications and analyze the information notified by the Member States to formulate scientific advice, rather than simply using the Authority as a mere conduit for information supplied to the system by Member States.

### 4.3 Risk Communication

The Regulation entrusts the Authority with the duty to communicate on its own initiative the "results of its work" by acting in close collaboration with the Commission and the Member States "to promote the necessary coherence in the risk communication process"[422]. While EFSA's mission includes communication of scientific information on risks, the Commission remains responsible for communicating risk management measures. The Commission, being extremely concerned to about losing this power, remains entrusted with the communication of risk management decisions event though they are based on scientific opinions of the Authority.

In developing public communication, EFSA will seek to translate scientific evidence into accessible and meaningful communications, addressing the needs of key audiences. The challenge is therefore to disseminate complex scientific information in a consumer-friendly way in order to become the indispensable port-of-call for the most up-to-the-minute data on risk. Under the umbrella of the Advisory Forum, EFSA has recently set up a Communication Working Group to facilitate message development and co-ordination with Member States as well as the sharing of best practices in the area of risk communications[423].

However, the modest communication budget (2.5% of the overall budget of the Authority) seems to cast some doubts about the performing of this task[424].

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[422] Article 40 of the Regulation.
[423] See http://www.efsa.eu.int/advisory_forum/working_groups/165_en.html
[424] EFSA Report, see supra note 205.

## 5. ORGANIZATIONAL INDEPENDENCE AND ACCOUNTABILITY

It should not be surprising that the mission pursued by EFSA is not purely consumer protection-oriented. This is because the Authority's *raison d'être* can be found, similarly to the *ratio legis* underpinning regulation 178/2002, in the free movement imperative. Indeed, although the Regulation mentions that EFSA should contribute to "a high level of protection of human life and health", that mission must be done "in the context of the operation of the internal market".

The result is that the Authority finds itself caught in the same legislative tension underlying the functioning of Regulation 178/2002: on the one side, it aims at offering at high level of health protection and on the other at ensuring the effective functioning of the internal market. It is therefore no accident that the Regulation talks about "consumer confidence" in the internal market rather that consumer protection. Thus, from a *prima facie* reading of the EFSA's mission it stems clearly that the internal market objective may, somehow, overshadow consumer protection.

Against this backdrop, one may legitimately wonder to what extent such a constant tension between the free trade imperative and the consumer protections goal may have been reflected into the institutional framework within which the Authority is called to operate. In other words, to what extent the EFSA's activities are going to be biased by this tension? Is the EFSA an "independent scientific source of advice"[425]?

In order to find out to what extent the EFSA may be regarded as an autonomous and independent body, notwithstanding the tension underlying its functioning, various factors may be taken into account, such as the composition of its organs, the relationship of the Authority with the Commission, its financial status, organizational autonomy, etc.

In the following pages, to assess EFSA's autonomy I will mainly focus on the composition of the Managing Board and the mode of appointment of the scientists sitting in the scientific committees. I will then turn to assess the organizational independence of EFSA vis-à-vis the Commission.

[425] See Preamble(35) of the Regulation.

### 5.1. The questionable independency of the Management Board

Given its relevance in the functioning of the EFSA, it is important to start by analyzing the Management Board's composition and its mode of appointment. Unlike other Community agencies, the Board is not composed of representatives of all the Member States. It rather consists of 15 Members, out of which one is a representative of the Commission and four should have their background in organizations representing different interests related to the food chain. To partially compensate this situation of Member States' under representation, the Regulation expressly provides that "the broadest possible geographic distribution " should be secured within the Board[426]. Along the same lines, Recital 41 of the Preamble provides that there should be "a rotation of the different countries of origin of the Members of the Management Board without any post being reserved for nationals of any specific Member State".

This institutional frame seems to be mainly guided by the idea that the Board should not represent national interest but rather operate as an independent organ. However, as Member States may have different interests as regards the food-chain and, especially, different perceptions of risk, it might be important to ensure the geographical rotation of its Members.

While this institutional design, notably its composition, may seem to be effective in assuring the independency of the organ, the mode of appointment of its Members seem to raise some doubts[427]. The regulation provides that the Management Board Members be appointed by the Council in consultation with the European Parliament from a list drawn up by the Commission. However, as the Regulation does not provide for an open competition for candidates to the Management Board, it is not clear on what basis the Commission is to draw the list of candidates to the post. The only guideline concerning their selection is that they should be appointed "in such a way such as to secure the highest standards of competence, a broad range of relevant expertise"[428]. However, mere professionalism and competence are not sufficient guarantee of independence. This is

[426] Article 25(1) of the Regulation.

[427] Contra, S. Krapohl, *Credible Commitment in Non-Independent Regulatory Agencies: A Comparative Analysis of the European Agencies for Pharmaceuticals and Foodstuffs*, supra note 391, at 531, who argues that, contrary to what happen with the EMEA, since the Council, the European Parliament and Commission "have control over the recruitment of the of the management board of the agency", the EFSA's personnel would be recruited independently from the Member States.

[428] Article 25(1) of the Regulation.

because they do not guarantee that the person concerned acts in the public interest, but simply indicate the level of knowledge and expertise possessed by the individual.
Furthermore, it must be noticed that four Members of the Board, having their background in organizations representing consumers and other interests in the food chain, *de facto* represents a particular interest in the food sector. One may wonder whether it is at all appropriate to have Members of the Board that while retaining their previous posts may have a say on the functioning of the Authority in charge of conducting scientific assessment within the sector of their main activity. If it is true that their presence may be useful to the extent they possess an in-depth understanding of the different parts of the food supply chain, the danger exists that their particular interest in the sector may offset this potential benefit. This may reveal particularly true for those Members of the board 'having a background' in the industry . How can the main addressee of the EFSA's activities, the food industry, be represented in the Board?
If it is true that the "background Members" of the Board have been called to be part of it because of their expertise in food safety matters, it is argued that it would have been possible to draw people with an equivalent level of knowledge from other environments, such research institutes, national authorities and controlling bodies. In case of doubts as to the functioning of the food chain, the Board could have always asked help to the industry.

### 5.2 The scientists' autonomy

As EFSA is in charge of scientific advice, the mode of appointment of its scientists is crucial for determining its independency[429]. Contrary to what happen for the appointment of the Board Members, neither the Commission nor the Member States formally have a say in their selection process. All scientists sitting in the Committee and in the Panels are appointed by the Management Board upon proposition of the Executive Director on the basis of an open competition.

[429] On the recruitment of the expert or scientific committee of the agency, see S. Krapohl, *Credible Commitment in Non-Independent Regulatory Agencies: A Comparative Analysis of the European Agencies for Pharmaceuticals and Foodstuffs*, supra note 391, at 531-532.

However, one may wonder whether this mode of selection is capable of eliminating any risk of political (by the Commission) or economical (by the industry) influence over the scientists.

Some Authors suggest that the short term of office (3 years) and the possibility to be renewed may allow their selection and reselection to be guided by political factors[430]. It is undisputable that by having the chance to assist to two selections of scientists during its 5-year term of office, the Commission may be tempted to influence the selection process. However, the most serious way in which the Commission could actually exercise some political influence on the scientists' selection may be represented by the Commission officials' attendance to the deliberations of the panels. This is expressly authorized by the Regulation, which States that "the representatives of the Commission's departments shall be entitled to be present at the meetings of the Scientific Panels and their working groups"[431]. In the 2003 EFSA's annual report, we read that Commission's officials have actually attended all scientific panels' meetings to "ensure a seamless interface between the scientific advisor and the decision makers"[432]. Although the officials' participation is subject upon the condition according to which they "shall not seek to influence discussions", it is likely that their mere presence at the meetings may somehow influence the delivery of scientific opinions. Thus, the scientists, depending on the circumstances, may be induced to deliver opinions which are expected of them or they may fail to take in due account some scientific information available to them. According to Greenpeace, the latter is exactly what it already happened in the assessment made by the EFSA of the first two genetically engineered crops submitted to its examination[433]. This NGO severely criticized European scientists for having ignored two critical scientific factors[434].

Apart from this risk of political pressure over the scientists, the other source of influence may come from the industry. Given the growing trend among multinationals to devote

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[430] K. Kanska, *Wolves in the clothing of sheep? The case of the European Food Safety Authority*, supra note 341, at 720.

[431] Article 28(8) of the Regulation.

[432] 2003 EFSA annual report, supra note 206, at 17.

[433] See the critique made by Greenpeace to the EFSA's scientific assessment of NK603 maize available at http://eu.greenpeace.org/issues/gmo.html

[434] Thus, for example, in its analysis of the risk assessment conducted by EFSA on Monsanto's Roundup Ready Maize, NK603, Greenpeace concluded that: "Unintended fragments in NK603 appear to be functional. By itself, this should render this GE product unsafe. The EFSA have not evaluated the full significance of these fragments, including the ineffectiveness of the "stop" codon. Significant differences have been noted between NK603 and its conventional counterpArticle The significant differences have not been further investigated, but regarded simply as "not of biological significance".

private resources to the financing of scientific education and academic research, scientists employed in the panels might still have close ties with the industry.

In light of the above, the system for ensuring the independency of EFSA's Members set up by the Management, being solely based on "declarations of interests"[435], does not seem to be adequate to overcome the flaws inherent in the composition of EFSA's organs.

### 5.3 EFSA and the European Commission

According to the functional separation between risk assessment and risk management laid down in Regulation 178/2002, the EFSA is functionally and organizationally separated from the Commission.

While the former is in charge of scientific advice, the latter is responsible for taking risk-management decisions. However, notwithstanding this clear-cut separation of roles, there exist some 'grey areas' where the EFSA's and the Commission's activities may dangerously enter into contact, by thus blurring the distinction between risk assessment and risk management. Thus, for instance, the power given to the Commission to assign the Authority "any other task [...] within its mission"[436] may lead the Commission to shape the EFSA's scientific agenda, by imposing its own priorities. The Commission's influence over EFSA's activities may even be further strengthened by the lack of formal rules governing the requests addressed to the Authority. Notably, lacking a clear indication on how the terms of reference of a scientific request may be formulated, the Commission may be tempted to frame its request according to the particular result it may expect to obtain. This seems to have already happened on the request for a scientific opinion introduced by the Commission and related to the Austrian notification of national legislation governing GMOs under Article 95 (5) EC. In the related opinion EFSA stated that it

[435] This system has originally been set up by the EFSA Management Board as the Code of Conduct on Declaration of Interests (Decision adopted by on 10.03.2004 (MB Doc.10.03.2004-5), then amended by Guidance on Declarations of Interests on 16 December 2004.

[436] Article 23 (l) of the Regulation.

"[...] was not asked by the Commission to comment on the management of coexistence of GM and non-GM crops, but the Panel recognized that this is an important agricultural issue"[437].

However, this danger is partly mitigated by Article 23 (k) of the Regulation allowing EFSA "to express independently its own conclusions and orientations on matters within its mission".

A further 'grey area' in the relationship existing between the Authority and the Commission may be found in the GMO food and feed Regulation[438] where it is has been inserted the so called "administrative review" clause[439]. According to this clause, any EFSA's decision, or failure to act, may be reviewed by the Commission on its own initiative or in response to a request from a Member State or individuals concerned[440]. Such an open-textured provision inevitably vests broad powers of review in the Commission, who may hence be tempted to interfere with EFSA's scientific activities. It follows that such an administrative review clause has not only the potential to endanger the EFSA's reputation, but also to put into question the functional separation between risk assessment and risk management underpinning the new food regime.

Besides the administrative review clause, another possible situation when the functional separation between the Commission and the EFSA may be put at stake is represented by the possibility recognized to the former to ask for scientific and technical support to the latter "in the interpretation and consideration of risk assessment opinions"[441]. In fact, in providing a sort of "authentic interpretation" of its scientific opinions or by merely interpreting some others' evidence, the EFSA may considerably influence the Commission in its scientific understanding. By doing so, the Authority would leave the scientific assessment field to enter into the political arena of risk management, without however bearing any related responsibility.

[437] See EFSA journal 1, 2003, p. 3.
[438] Regulation 1829/2003 on genetically modified food and feed [2003] OJ L268/1.
[439] A similar clause has also been inserted in Regulation 1831/2003 on additives for use in animal nutrition.
[440] Article 36 of Regulation 1829/2003.
[441] Article 23 (c).

## 6. THE EFSA V. FDA: WHY THE EFSA IS NOT A EUROPEAN-STYLE FOOD AND DRUG ADMINISTRATION? SOME ELEMENTS FOR A COMPARISON

### 6.1. Different missions

If compared with both the imposing institutional and substantive framework of the U.S. FDA, the newly-established EFSA comes across as a weak authority[442]. Both its resources and its powers are far from being like those which make the FDA one of the most authoritative administrative agencies in the world. However, it must be noticed from the outset that these agencies pursue different missions: while the FDA protects the public health of Americans citizens, by monitoring the safety and effectiveness of products entering the market (or already in use) and by enforcing the Food and Drug Act against those who are in breach of its provisions[443], the EFSA is a scientific advisory body charged with providing independent and objective advice on food safety issues associated with the food chain. In particular, the duality of EFSA's mandate (protecting consumers and ensuring free movement) contrasts sharply with the FDA's overarching mandate to protect public health.

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[442] That's how the Authority has been welcomed by many newspapers. See, e.g., Financial Times, *Comment and Analysis: EU Food Safety*, 12 Jan. 2000.

[443] FDA's public health protection role and mission were incorporated into the Federal Food, Drug, and Cosmetic Act by the FDA Modernization Act of 1997 (PL 105-115). The Act outlined bold and innovative approaches to meet the increasingly complex public health challenges of the 21st century. More precisely, the FDA's statutory mission is:

- To promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.
- With respect to such products, to protect the public health by ensuring that:
    - foods are safe, wholesome, sanitary, and properly labeled;
    - human and veterinary drugs are safe and effective;
    - there is reasonable assurance of the safety and effectiveness of devices intended for human use;
    - Cosmetics are safe and properly labeled, and; public health and safety are protected from electronic product radiation.
- To participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and,
- As determined to be appropriate by the Secretary of the Department of Health and Human Services, to carry out these activities in consultation with experts in science, medicine, and public health and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

See http://www.fda.gov/oc/oms/ofm/budget/2001/fdamission.htm

### 6.2. Different regulatory universes

As shown above, by assuming a linear relationship between science and political decision-making, the EC legislator has shaped the new EC food institutional framework in accordance with a functional distinction between risk assessment and risk management. Accordingly, while the EFSA has been conceived as the risk assessor, the body in charge of doing risk assessment on behalf of the EC institutions, the EC Commission has remained the risk manager, the entity in charge of adopting the decisions. Both entities exercise their functions in conformity with the risk analysis framework (the *Grundnorm*) sketched out by the Regulation, which, as we have seen, allows the Commission to take into account, apart from the scientific opinions, also "other factors legitimate to the matter under consideration" and the precautionary principle[444].

The FDA's universe differs greatly from the EFSA's in the following respects:

1) its substantive powers overcome the rigid distinction between risk assessment and risk management functions, since the FDA is in charge of both;

2) its decisions are more science-based than those adopted within the Community, as the FDA risk managers are supposed to rely exclusively on scientific factors and not on "social factor"[445];

3) as shown above, its institutional organization comprises approximately 9,000 employees in charge of monitoring the manufacture, import, transport, storage and sale of a broad range of products throughout the U.S and relies on about 2,100 scientists working in 40 laboratories throughout the country; and finally

4) The FDA obtains more than 90% of its scientific opinions and studies from its own services, while EFSA heavily relies on a plethora of Member States' organisations and external scientific bodies[446];

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[444] Article 6 (3) of the Regulation.

[445] *Briefing paper: US Experience*, see supra note 158.

[446] See Article 36 of the Regulation. Thus, for instance, the EFSA Guidance Document for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed (April 2004) states that "if EFSA is not in a position to realise of the (GMO scientific assessment) workload, EFSA may ask the appropriate food assessment body of

5) unlike the EFSA, the FDA does not derive its powers from a Regulation merely laying down general principles and requirements of food law, but rather from a powerful text such as the Food, Drug and Cosmetic Act (private enforcement)[447].

Moreover, the EFSA has been not only denied both regulatory and enforcement powers, but, it seems to play a limited role even within its own area of competence, risk assessment. Although providing a common standard for conducting risk analysis throughout the Community to be followed by both the EC and the Member States[448], the current regime does not empower the EFSA to impose its own scientific vision on the Member States' competent authorities in case of diverging opinions.

As shown above, notwithstanding their relevant indirect effect not only on the EC institutions, but also on the Member States and the individuals, the Authority's scientific opinions do not prevail in case of conflict with those elaborated by the national competent agencies. It follows that the lack of authoritative power is likely to produce conflicts analogous to those already seen in the past between the EC scientific authorities and the national competent bodies.

Does this outcome weaken or strengthen the EFSA's functioning and the overall EC food policy?

Unlike the U.S. where arguably all local food differences have been obliterated[449], Europe still shows long-rooted culinary traditions symbolizing strong identity values. Thus, a claim by a domestic food authority that a certain good is safe or unsafe is likely to involve not only an assertion about science, but also the willingness of this country to bear or not to bear the level of risk considered acceptable in order to continue or reject a certain local tradition. In contrast, the assertion made at the EC level about the safety of a product to be marketed throughout the Community is both a claim about its risk component and a political claim aimed at favoring economic integration and free trade within Europe. Along these lines, conflicts about food safety within the European context

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a Member State to carry out its an initial part of the safety assessment of the food or feed in accordance with Article 36 of the Regulation 178/2002".

[447] For a comment on the evolution of the Federal Food and Drug Legislation, see P. Barton Hutt & R A. Merrill, supra note 1, at 6-15. The text of the Act is reproduced in P. Barton Hutt & R.A. Merrill, 1996 Statutory Supplement, at 1-269 and it is *also available at* http://www.fda.gov/opacom/ laws/fdcact/fdctoc.htm

[448] Article 6 of the Regulation.

[449] E. Schlosser, *Fast Food Nation, The dark side of the All-American Meal* 5 (Perennial ed., 2002).

inevitably involve a tension between a European (universal) and a national (local) vision of both safety and of the socio-cultural perception of a particular food[450].

Against this backdrop, giving the Authority the last word in all scientific contentious matters would have amounted to forcing the establishment of a Pan-European food safety standard, inevitably leading to the obliteration of local traditions[451]. Thus, although the lack of authoritaive power in scientific matters may *prima facie* be seen as weakening the EFSA, it expresses the Community dislike for the mounting trend toward a standardization of the food supply by revealing at the same time the strong Member States' willingness to defend their national perception of risk[452].

Therefore, under the current regulatory framework, it is us up to the European Courts, and not to the EFSA, to solve the conflicts arising between the national and the Community's scientific opinions. More precisely, the EC Courts are called to conduct a delicate balancing exercise between the local and the universal visions of risk.

The case presented above involving the French refusal to lift the embargo against British beef two years after the *BSE* outbreak symbolizes the logic followed by the current approach. Although the ECJ condemned France for not having lifted the embargo, as requested by EC law[453], it also recognized that traceability of UK Beef, essential up to the point of sale in order to enable a consignment not fulfilling the conditions of the EC law to be recalled, was not guaranteed at the time of the Commission decision of 23 July 1999 lifting the ban, in particular as regards meat and products which had been cut, processed or rewrapped.

It follows that, in case of divergent scientific opinions between the Community and the local risk assessors, the EC Courts are called upon to carry out the difficult task of

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[450] D. Chalmers, supra note 103.

[451] This was recently confirmed by the EFSA Executive Director, Geoffrey Podger, who stated that since "Member States have important, valid and strongly held views of their own [in scientific matters] that are necessary to in assessing and understanding risk", "We do not want to centralize food science; we want to distribute the work, the research and the expertise which is already present in Europe". *See* The European Policy Centre, Communication to Member (59/03), *The role of the European Food Safety Authority*, EPC-KBF Policy Briefing, 9 Oct. 2003. Available at http://www. kbsfrb.be/files/db/EN/EPC_DocumentsPBP_ Role_of_the_ European_Food_Safety_Authority_09.10.2003.pdf

[452] P. Testori Coggi, Conference on Risk Perception: Science, Public Debate and Policy Making, Speaking Notes, Brussels, Dec. 2003 available at http://europa.eu.int/comm/food/risk_perception/sp/testori_coggi.pdf

[453] Commission decision 98/256/EC O.J. (L 113) 32-43.

reconciling the conflicting visions by looking at the value of domestic measures to the local population in relation to the damage to the Community (free trade) interest.

As it has been said, this approach "condenses" local difference without providing a single, objective standard for 'safety enabling economies of scale and trade liberalization across the Union'[454].

This seems to be confirmed by Article 1.1 of the Regulation which States that, in assuring a high level protection of human health and consumers' interest in relation to food, it must be taken into account

> "[...] the diversity of the supply of food including traditional products, while ensuring the effective functioning of the internal market".

In sum, the new Community food regime constitutes an attempt to extend the mutual recognition model, originally developed to avoid a totalizing operation of standardization of food identity throughout Europe, in the field of analysis of risk between the Community and the Member States. Although the Regulation provides for the first time ever a common model of analysis of risk applicable to both the Community and the Member States, it does not give the last word in scientific matters to the EFSA, but rather introduces a presumption of safety for all those products found in compliance with EC law, or lacking Community provisions, for those foods conforming to the national food laws of the Member States. Should the Community or a Member doubt about the presumed safety of a particular food, the question is decided by the EC Courts and the burden of proof lies on the party claiming the product unsafe. Similarly as to what happens in the situations when the mutual recognition principle does not work because of the lack of trust among Member States, it is up to the Courts, not to the EFSA, to weigh the conflicting interests thus striking a balance between the local and the universal interests involved.

[454] Chalmers, supra note 103.

### 6.3. Different Cultures

This study ventures to suggest that the main institutional and substantive differences between the EFSA and the FDA may be ultimately understood not only as a result of different systems of governance and regulatory environments, but also as a reflection of entirely different societal contexts. In recent years, Europeans and Americans have developed conflicting perceptions of risks and, inevitably, different cultural norms regarding food safety. This seems to be due to the complex inter-play of inherent cultural models that we, as humans, use to interpret the environment and the world around us. In other words, the public perceives the risk within its own cultural model.

EC risk regulation is said to have become more risk averse in recent years[455].

Conflicting perception of risks may significantly influence how these authorities respond to given risks by elaborating divergent risk analysis methods. It is becoming increasingly clear that risk perception plays a crucial role in the mechanics of risk management. Thus, scientists and citizens look at risks from different perspectives. While the scientific approach is rational, dealing with probabilities and science-based studies, people, being more value driven, behave according to perceptions rather that relying on facts[456].

By taking into account within its risk analysis also the 'social factor', the EC seems to be more willing than the FDA to address the dichotomy existing between the perceptions of scientists and citizens. This may be seen by many as an irrational position, potentially hiding protectionist intent. But for many others, experience has shown that one day's scientific "truth[457]" may turn out to be based on a partial understanding[458].

A comparison of the perceptions of the riskiness of some foods and their production processes shows the impact on food regulation of tradition in Europe and of science in the U.S. Whilst Europeans tend to favor traditional foods and express skepticism for new technologies, Americans have always been more in favor of new technologies than

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[455] D. Vogel, *The Politics of Risk Regulation in Europe and the United States, 3 Yearbook of European Enviornmental Law* 1. See, also, Christoforou, supra note 207, at 238.

[456] R. J. Coleman, Address concerning "Communicating Risk to Consumers", at the Interim Scientific Advisory Forum, Brussels 30th October 2001, available at http://europa.eu.int/comm/dgs/health_consumer /library/speeches/ speech133_en.pdf

[457] D. Vogel, *The Hare and the Tortoise Revisited: The New Politics of Consumer and Environmental Regulation in Europe*, British Journal of Political Science, 33, 4, 557-580.

[458] Thus, for instance, the unquestionable benign nature of nuclear was put into question by successive studies.

traditional food processing. This is best reflected in the European reluctance to consume GMOs and the US's resistance to the consumption of un-pasteurized raw milk cheeses[459].

In sum, the comparison between the EFSA and the FDA clearly shows that culture and tradition play a silent, though crucial, role in the regulatory process and the resulting rules[460].

It remains to be seen whether the EC Commission/EFSA approach will prove more satisfactory in protecting citizens' public health than the longstanding and more scientific-based attitude symbolized by the FDA. The ambition nurtured by the Europeans is that EFSA, though following a different path, could one day be described, similarly to the FDA, as "one of the most venerable institution, whose employees have long memories and a tradition of dedicated, sometimes single-minded public service – in sum a strong commitment to the job of regulation"[461].

## Conclusions: Reconciling Science, Traditions, Consumer Concerns and Free Movement

In order to assess the success of EFSA within the context of the new European Food Safety regime, one has to verify whether this Authority has provided a credible answer to the most pressing questions among policy-makers and lawyers: whose science to use?

The creation of the EFSA and the enactment of the new food policy regime stem directly from the contested governance's wave that slapped Europe at the end of the 1990s. It would have certainly taken longer for the Community to conceive this reform if several food scandals had not rendered its system of governance "contested", by showing the absence of a centralized European scientific assessment and a unifying text setting out the fundamental principles of EC food law. By producing a collapse of public trust in the European institutions, the contested governance of European food safety has not only accelerated this reform, but it has considerably helped the EC food law to get rid of its

[459] Echols, see supra note 55, at 531-533.
[460] *Ibid.* at 543.
[461] Barton Hutt, see supra note 1, at 5.

original sin, its pro-market-bias, by illustrating the importance of assuring the safety of the products in free circulation throughout the Community. Under the new policy, only foodstuffs that are safe, wholesome and fit for consumption can be placed on the market for consumers.

By ceasing to be a fragmented area of Community law, European food law lies for the first time on a comprehensive legislation covering the entire 'farm to fork' distribution chain and directly enforceable in all the EC Member States.

The role of EFSA in the implementation of the new food regime is remotely far from that of the FDA within the U.S. context. This is due not only to the authorities' different missions and diverging regulatory universes, but also to the conflicting perceptions of risk developed by their respective citizen-consumers. Being risk analysis the *Grundnorm* of the new regime, one could have expected the EFSA becoming the scientific authoritative body for the whole Union and having the final word in all scientific contentious matters. But Member States did not want to make the Authority an oracle of Delphi spelling out the "truth" in all scientific matters. They rather wanted to preserve the right of their national food agencies to carry out scientific studies thus expressing their specific perception of a certain risk. In the words of EFSA:

> "EFSA does not want to compete with the excellence science conducted in the Member States. On the contrary, is eager to work with scientists from all Member States to share data and results from scientific studies and to harmonize national approaches to risk assessment, as appropriate. EFSA's scientific opinions do not supersede any national opinion; they provide an independent European view which ideally complements national opinions. EFSA's scientific opinions provide an authoritative reference for European risk assessment, and where EFSA risk assessments are required by EC legislation, it is EFSA's opinion which prevail".[462].

While this approach is likely to bring about conflicts among Member States, it expresses the European attempt to defend its cultural patrimony and culinary richness against the mounting trend toward the obliteration of local traditions led by the multinationals of

[462] Front cover article by H. Koëter, EFSA Deputy Executive Director and Director of Science, in EFSAnews, 2/2004.

processed food[463]. Accordingly, in case of diverging opinions between the EFSA and national food authorities, it is up to the EC courts, and not to the EFSA, to solve these conflicts by striking a balance between the universal and the local values. However, this judicial involvement could be reduced if EFSA will be able to establish an effective network with the national food agencies aimed at solving scientific conflicts before they reach the EC Courts[464]. Therefore, the EFSA's success will mainly depend on the creation of a network between the Authority and the national agencies so as to give to all European consumers good grounds for a high level of confidence in the food that they eat[465]. For instance, EFSA's current involvement with GMOs rests on a network[466], in which EFSA carries the duty to address diverging scientific opinions under the General food law regulation[467].

The EFSA is still in its infancy. It remains to be seen to what extent it will become entrusted by the 450 millions of European consumers, by acquiring a reputation, as achieved by the FDA, although in a completely different constitutional, regulatory and societal environment.

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[463] Contra, Chalmers, *"Food for thought": reconciling European risks and traditional ways of life*", supra note 103, at 533 (2003) who argues that the new legal regime will "probably reterritorialise conflicts so that these endemic and irresolvable disputes become reconfigured along European versus particularistic fault lines, with local groups either arguing a right to consume a food that it is considered dangerous under EU law or to be protected from exposure to a product that is considered safe under EU law".

[464] K. Vincent, *Mad Cows and Eurocrats – Community Responses to the BSE Crisis*, supra note 102.

[465] Article 36 of the Regulation and Commission Regulation 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission, OJ L379, p. 64.

[466] Regulation 1829/2003.

[467] Article 30 of the Regulation.

## Part II

## THE REGULATION OF FOOD WITHIN THE WTO

### Introduction: The Multilateral Governance Framework for Food Safety Regulation

Among the several international organizations dealing with food-safety related activities, the WTO is the only one providing for a set of legally binding obligations for WTO Members when they adopt food regulations. As it has been stated, the GATT/WTO agreements provide today for a "Multilateral governance framework for food safety"[468]. Although public health and food safety issues are dealt with in several WTO Agreements[469], the WTO Regulation of food is mainly contained within the Sanitary and Phytosanitary Agreement (SPS) adopted during the 1994 Uruguay Round[470].

Before providing an overview of the main features of this regime, it is important to stress that the core competency of the WTO is trade and that its Members have never shown any interest in turning it into some kind of food safety organization[471].

The Preamble of the SPS Agreement notes the desire of the Members to establish "a multilateral framework of rule and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary (SPS) measures in order to minimize their negative effects on trade".

Therefore, unlike the European regulation of food, the focus of the WTO discipline is on solely on the trade impact that sanitary and phytosanitary may have on international trade, rather than on the safety concerns that may support these regulations. In fact, WTO regime governing food seeks to reduce the negative effects that Members' food safety

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[468] T. Jostling, D. Roberts and D. Orden, *Food Regulation and Trade, Toward a Safe and Open Global System*, supra note 5, at 35.

[469] See GATT, the Agreement on Technical Barriers to Trade (TBT), the Agreement on Sanitary and Phytosanitary Measures (SPS), the General Agreement on Trade in Services (GATS), the Agreement on Agriculture (in the Preamble as well in Article 20 of this Agreement non-trade concerns in the Agricultural sector are mentioned), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). In particular, this Agreement facilitates the international recognition of denominations of origin and certificates of specificity which have been granted in accordance with the relevant Community regulations.

[470] Key terms such as sanitary (to protect human life and health) and phytosanitary measures (to protect animal and plant life and health) are defined in the SPS Agreement, Annex A.

[471] V.R. Walker, *Keeping the WTO from Becoming the "World Trans-Science organization": Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute*, in 31 Cornell international Law Journal 1998, 251, at 261-263.

and quality regulations may have on international food trade by setting forth criteria useful to distinguish between legitimate food safety measures and illegitimate (protectionist) food regulations.

In other words, it aims at minimizing negative trade effects stemming from the adoption of food regulations, rather than establishing minimum benchmark for protection of public health. Thus, the WTO discipline is intended to circumscribe the exercise of Members regulatory autonomy in "negative" by imposing them to minimize trade effects, but not in positive, by requiring them to assure a minimum level of safety for consumers.

In short, while the WTO regime follows exclusively a market-opening agenda, the EC discipline answers to a more complex public demand for health protection within an increasingly integrated Union, by imposing not only on Member States' measures but also on EC-wide regulations to attain a high level of protection. As it will be shown, similarly to what happened in the EC, the GATT/WTO's involvement in food safety polices came as a result of the growing expansion of the organization to cover "beyond the border" policies that may affect trade. In particular, it lies in the belief that while technical food regulations, rules and procedures can facilitate and enhance trade, by reducing the risk for consumers that they might purchase unsafe food, they can also become barriers to trade, in particular if they place an heavier regulatory burden on importers than the one applied to domestic producers. Therefore, its main challenge is to design measures in a way so that they meet science-based food safety objectives while minimizing adverse impacts on trade and the risk that regulations may be employed for protectionist goals.

To address this policy challenge, the Uruguay Round developed a multilateral governance framework for food safety regulation establishing a set of rules that Member States must respect in the exercise of their food legislative powers. According to Article 2(4), SPS measures which conform to this framework are presumed to be in accordance with the Members GATT obligations and, in particular, Article XX(b).

Being the EC a full Member of the WTO, and therefore bound by its agreements, it may be useful to analyze the WTO food safety regime (part II) in order to determine to what extent the current EC food safety regime, as established by Regulation 187/2001, may be held compatible with the WTO discipline (part IV). In particular, this study will emphasize some points of tensions currently existing between the two legal orders.

# CHAPTER I: HISTORICAL BACKGROUND OF THE GATT/WTO REGULATION OF FOOD

GATT 1947's primary purpose was to promote trade in goods by reducing tariffs and eliminating quantitative restrictions. Its main focus has thus been for longtime on the so-called border measures (as opposed to domestic measures). However, already this Agreement recognized the need to subject domestic regulations to international scrutiny so that the discriminatory and protectionist uses of technical regulations would not offset the trade benefits stemming from the gradual lowering of tariffs. GATT 1947 set forth therefore various rules aimed at preventing such abuses, amongst which Article XI, prohibiting quantitative restrictions and Article III requiring Member States to respect "national treatment" for "like products" while adopting their internal taxes and regulations to imports.

As tariffs and quotas fall worldwide due to the success of the first six GATT successive Rounds[472], countries appeared to be increasingly relying on the adoption of national regulations as a way of protecting their own industries[473]. Notably, Member States have gradually increased their used of food safety controls and standards. While the adoption of these national measures may be legitimate to protect human health and the environment in an increasingly integrated food market, it may also be motivated to shield domestic industries from imports coming from foreign countries.

After the 1964-67 Kennedy Round, which resulted from the seventh round of negotiations, Member States' concerns about the increasing adoption of divergent national standards led to launch of a debate on how to tackle the problem of the so-called non-tariffs barriers. On that occasion, most of the countries agreed on negotiating a code which without interfering "with the responsibility of governments for safety, health and

[472] The main result from each of the first six rounds of negotiations to strengthen the GATT framework was to revise and update the list of tariffs bindings thus reducing the tariff impact on trade. Non-tariff measures (or 'beyond the borders' barriers) did not fall within the object of the negotiations.

[473] For the negotiating history of the SPS Agreement, see G. Marceau and J. Trachtman, *The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tariff and Trade, A Map of the World Trade Organization Law of Domestic Regulation of Goods*, 35 Journal of World Trade 5 (2002) 811-881 and S. Zarrilli, *WTO Sanitary and Phytosanitary Agreement: Issues for Developing Countries*, TRADE Working Paper, South Centre, 1999, at 3.

welfare of their people", it may seek "to minimize the effects of such actions on international trade"[474]. Against this backdrop, during the following negotiating, the 1979 Tokio Round, the Standards Code, which covered mandatory and voluntary technical specifications, mandatory technical regulations and voluntary standards for industrial and agricultural products, was signed by 43 countries. It prohibited discrimination and the protection of domestic production through specifications, technical regulations and standards, but also it also urged its Members to base their national measures on international standards and to cooperate in order to harmonized their norms.

However, Member States failed to adequately comply with the Code. In 1980, a GATT Working group was established to measure the impact of Non-Tariff Barriers (NTBs) to trade and found product requirements to be among the most significant. This shift of attention from tariff to NTBs to trade brought health, food safety and environmental polices under the scrutiny of the GATT and subsequently the WTO, thus paving the way for a greater GATT/WTO's involvement into these areas of regulation.

As the Standards Code seemed not to be adequate in addressing the issue of the regulatory barriers to trade, notably in the area of sanitary and phytosanitary measures, the Uruguay Round negotiations tried to remedy this weakness. Also the GATT framework, being based on Articles I, III, XI and XX, was perceived as incapable of addressing disputes over sanitary and phytosanitary measures.

By 1986, when the Uruguay Round was launched, nearly 90% of U.S. food imports were affected by non tariff barriers to trade, up from only 57% in 1996[475]. To tackle this increasingly abusive use of technical regulations, multilateral disciplines governing the use of technical measures had to be revised, expanded and strengthened. Thus, in the Punta del Este Ministerial Declaration launching the Uruguay Round's negotiations, it was stated that the goal was to set up disciplines that would minimize the "adverse effects that sanitary and phytosanitary regulations and barriers can have on trade in agriculture". It is in the light of the above that during the Uruguay Round not only the Standards Code had been amended as to reappear as the Agreement on Technical Barriers to Trade (TBT), but it also had been negotiated a new Agreement on Sanitary and Phytosanitary Measures (SPS).

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[474] COM.IND/W/13, 20, 23 and Spec (71) 143, Idem.

[475] M.A. Tutwiler, *Food Safety, the Environment and Agricultural Trade: The Links*, 2 International Policy Council on Agriculture, Food & Trade cited in D. Vogel, *Trading Up: Consumer and Environmental Regulation in a Global Economy* 150 (1995).

These two Agreements are designed to prevent technical legislation which is intended for the protection of the human health or safety, the protection of the health or life of humans animals or plants, consumer protection against deceptive practices and environmental protection being used to create or resulting in unjustified barriers to international trade. Since SPS measures introduce specific concerns for trade, a separate Agreement, notably the SPS, was 'carved out' of the TBT. Therefore the two agreements differ in scope. While the TBT covers all technical regulations and voluntary standards, and the procedures to ensure that these are met[476], the SPS agreement applies to all measures to protect human, animal and plant life and health[477].

As it will be shown below, the purpose of this new agreement is to minimize the negative effects on trade stemming from SPS measures, among which food safety regulations, by encouraging harmonization of SPS measures through the adoption of international standards, guidelines and recommendations where the exist. As it has been nicely said, the SPS is a "refined system of applied subsidiarity, subtly allowing national autonomy subject to certain constraints". The complex constraints imposed by the SPS Agreement, combined with the international standards to which it refers, established a system for reviewing certain type of State actions at international level, notably food safety regulations.

The Community[478] is a full party to both agreements, which therefore apply both to Community legislation and to legislation adopted by the Member States.

Finally, the negotiations also led to the conclusion of an Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreements) imposing obligations to provide minimum protection to a set of intellectual property rights, including geographical indications (GIs) of commercial identity for both agricultural products and food.

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[476] Most of the regulations falling under the TBT Agreement aim at protecting consumers through information, mainly in the form of labeling requirements, and at promoting fair trade practices. Other regulations include classification and definition, essential composition and quality factors, packaging requirements and measurements (size, weight, etc.) so as to avoid deceptive practices.

[477] It follows that while it is the type of the measure which determines whether it is subject to the TBT, it is the purpose of the measure which is relevant in determining whether a measure is covered by the SPS agreement.

[478] As competence for trade policy rests wihtin the "first pillar" of the EU (the second and the third pillars deal with foreign and security policy and with judicial cooperation in criminal matters, respectively), it is more appropriate to talk about the EC when dealing with the EU's involvement within the WTO.

Thus, the Uruguay Round, by strengthening the previous regime, improved the legal architecture for food safety technical regulations and standards.

## 1. SPS MEASURES UNDER THE GATT

The original GATT agreement of 1947 - likewise to GATT 1994 - left countries free to establish whatever food safety regulations they wished. The only constraint on the exercise of their legislative autonomy was set by Article III:4[479], imposing that these regulations had to be applied in a non-discriminatory way on imported and domestic goods, and Article XI[480], prohibiting all restrictions "instituted or maintained on the importation or exportation of any product". Thus, the GATT implied that a country's regulation may be whatever it likes but must apply equally to domestic and imported products and did not amount to a restriction to trade. Similarly to Article 28-29 EC, these GATT provisions mandate the prohibition of quantitative restrictions on importation and exportation of goods as well as those measures having an equivalent effect. However, the non-discrimination obligation is rather weak if compared with the Dassonville interpretative formula of Article 28 EC. While the GATT states that Members's food measures may be whatever they like provided they apply equally to domestic and imported good, the EC – according to the catch-all Dassonville formula – prohibits all national measures capable of acting as obstacle to trade, regardless of whether they are discriminatory, unless they are justified on a legitimate ground.

However, notwithstanding this clear prohibition against quantitative restrictions, for many years GATT Members failed to abide by this rules (notably Article XI) by tolerating quantitative restrictions in the fields of agricultural products, textile and clothing.

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[479] According to this provisions: "The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. The provisions of this paragraph shall not prevent the application of differential internal transportation charges which are based exclusively on the economic operation of the means of transport and not on the nationality of the product".

[480] Paragraph of this provision establishes that: "No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party".

Like the EC (Article 30 EC), the WTO maintains general exceptions which enable a Member to justify a violation of the general prohibition of quantitative restrictions. Similarly to Article 30 EC, Article XX GATT[481] provides that Article III:4 and XX GATT, subject to certain conditions, allows the adoption by any Contracting Party of restrictions on imports and exports justified *inter alia* for the protection of health and life of humans, animals and plants (let. b)[482].

Notwithstanding the existence of this general exception, it may not be really common to find a discriminatory measure that is justified on this public policy ground. As it has been nicely said, Article XX recognizes "the importance of a sovereign national being able to promote health interests, even if contrary to its general obligations under the WTO Agreements"[483].

According to the WTO case law[484], a party invoking this exception must prove:

- that the policy in respect of the measures for which Article XX(b) is invoked falls within the range of policies aimed at protecting public health and
- that the measures for which the exception is invoked are necessary to fulfill the policy objective.

In particular, to satisfy the necessity test it must be proved that there no alternative measures consistent with the GATT, which the Member State could reasonably be expected to adopt in order to achieve its health policy objective[485]. Accordingly, to properly apply this test, it must be established the scope of the health policy objective pursued by the invoking Member State and consider the existence of measures consistent with GATT which are reasonably available to the same Member State.

Finally, according to the so-called *Chapeau* of Article XX, it must be assessed whether the adopted public health measure is not applied in a discriminatory manner (this applies

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[481] Article XX states: "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: [...] (*b*) necessary to protect human, animal or plant life or health.

[482] As it has been stated, Article 30 EC has clearly been formulated with Article XX in mind. See J. Scott, "Mandatory or Imperative Requirements in the EU and the WTO", in C. Barnard and J. Scott, The Law of the Single European Market: Unpacking the Premises (Oxford, Hart Publishing, 2002) at 286.

[483] J. Jackson, *The World Trading System: Law and Policy of International Economic Relations*, The MIT Press, Cambridge, 1999, at 233.

[484] *EC- Measures Affecting Asbestos and Asbestos-Containing Products* WT/DS135/R adopted on the 12 March 2001 paras 8.170 and 8.177 (hereinafter: *EC - Asbestos*), para 8.169.

[485] *Thai-Cigarettes*, Panel Report WT/DS10/R, adopted on 7 November 1990, para 75.

solely to Article XI, not III:4) and whether it did not constitute a disguised restriction on international trade.

While the core regulatory discipline of the GATT is contained in Articles III:4, XI and XX(b), the rules governing food safety measures and standards are specifically expressed in the SPS and TBT agreements, which were adopted during the Uruguay Round. In particular, the SPS Agreement may be seen as an extension of Article XX GATT. In fact, it expands the scientific and procedural requirements for a Member to adopt an SPS measure and it urges Members to develop and to adopt international standards. However, though building upon the Article XX GATT, its (scientific and procedural) obligations are independent of GATT, so that Members are obliged to comply with the SPS Agreement regardless of whether their SPS measure is otherwise consistent with a provision of GATT[486]. Should then a SPS measure be conform with the SPS Agreement, it is presumed to be consistent with GATT[487].

This autonomy from GATT it has been confirmed by the WTO judicial bodies' case law which has stated that while under the GATT it is the defending Member who bears the entire burden of proof of showing that its measure falls within Article XX(b), under the SPS it is the complaining party who bears the initial burden of proof of showing a prima facie case of inconsistency with the SPS[488].

This Agreement provides new rules for WTO Members such that, in the event of a trade dispute relating to food safety, the WTO judicial bodies would apply the rules contained within the SPS Agreement to determine whether the complaining party was justified in its complaint and hence whether the contested measure is allowed under WTO law. Therefore the SPS Agreement forms the basis upon which Members operate as to ensure compliance with their WTO obligations.

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[486] See *EC- Measures Concerning Meat and Meat Products (Hormones)* Panel Report WT/DS26/R 1997, para 8.36.
[487] Article 2.4 SPS.
[488] *EC-Hormones* Panel Report, para 8.42; *Australia – Salmon Measures Affecting the Importation of Salmon* WT/DS18/R modified Panel Report (hereinafter: *Australia-Salmon*) para 8.39.

## CHAPTER II: THE SPS AGREEMENTS AND ITS MAIN OBLIGATIONS

The SPS Agreement, which forms part of the 1994 World Trade Agreement[489], applies to all measures adopted by WTO Members to protect human, animal or plant life or health "which, directly or indirectly, may affect international trade"[490]. Notably, SPS measures – as defined in Annex A of the Agreement – are those aimed at protecting animal or plant life or health arising from food-borne risks, pests, diseases, disease-carrying organisms, additives, contaminants, toxins or disease-causing organisms in foods[491]. More precisely, SPS measures can take the form of inspection of products, permission to use only certain additives in food, designation of disease-free areas, determination of maximum levels of pesticide residues, quarantine requirements, import bans, etc.

The basic aim of the SPS Agreement is to maintain the sovereign right of any Member to provide the level of health protection it deems appropriate[492], but to ensure that these sovereign rights are not misused for protectionist purposes and do not result in unnecessary barriers to international trade. To achieve its goals, the scope of the Agreement must receive a broad interpretation. Thus, the Panel in *Japan – Agricultural Products* has stated, in a language resonant with the Dassonville formula, that: "this context indicates that a non-mandatory government measure is also subject to WTO provisions in the event compliance with this measure is necessary to obtain an advantage from the government or, in other words, if sufficient incentives or disincentives exist for the measure to be abided by"[493].

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[489] Being a mandatory portion of the WTO Agreement (according to the 'single package' philosophy), all WTO Members are bound by the SPS Agreement.

[490] The Agreement covers all relevant laws, decrees, regulations, testing, inspection, certification and approval procedures and packaging and labeling requirements directly related to food safety. See Article 1(1), which being similar to Article III GATT, is likely to be interpreted in conformity with its jurisprudence. Jurisprudence on this provision suggests that what is being sought is equality of competitive conditions between domestic and imported goods. See Reports of the Panels in Italian discrimination against imported agricultural machinery (1959) BISD 7S/60, para 12 and in *US – Standards for reformulated and conventional gasoline*, WT/DS2/R, para 6.25.

[491] Following an 'a contrario' reasoning, measures for environmental protection, to protect consumers or for the welfare of animals are not covered by the SPS Agreement. Being the SPS Agreement lex specialis vis-à-vis the GATT and the TBT, these measures are subject to other WTO Agreements, such as the TBT and Article XX GATT.

[492] See the Preamble of the SPS Agreement which stipulates that "no Member should be prevented from adopting or reinforcing measures necessary to protect human, animal or plant life or health".

[493] *Japan - Measure Affecting Agricultural Products* WT/DS76/R, para 8.111 (hereinafter: *Japan - Agricultural Products*) upheld by the AB in WT/DS76/AB/R AB Report adopted 19 March 1999, paras 102-107.

Article 2 of this Agreement gives Member States the right "to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health", as long as such measures are not inconsistent with the provisions of the SPS Agreement. Thus, this Agreement, by supplementing the original Article XX GATT, provides Member States with a (multilateral) framework to develop their domestic public health policies, such as food safety. We will see that, being this regime particularly intrusive into the Member States' regulatory autonomy, all of the major SPS cases to date – the *Hormones*, *Salmon*, *Agricultural products* and *Apples* cases – have been lost by the defending Member.

The following key provisions give shape to the WTO Regulation of food:

- Non Discrimination (Articles 2.3 and 5.5 SPS)
- Necessity and Proportionality Test (Articles 2.2 and 5.6 SPS)
- Scientific Basis (Articles 2.2, 3.3, 5.1-5.4 SPS)
- Harmonization (Article 3.1, 3.5 SPS)
- Mutual Recognition and Equivalence (Article 4.1 SPS)
- Internal Consistency (5.5 SPS)
- Permission for Precautionary Action (5.7 SPS)
- Notification and Transparency Requirements (Article 7 and Annex B)

As it appears from this list, while some of these provisions reiterate the original GATT commitments, others do represent additional principles directed at reducing the number of technical regulations giving rise to obstacles to trade. The following sections will illustrate the scope of these provisions by referring to the case law developed by the WTO judicial bodies.

WTO Members are free to adopt all measures they deem necessary to protect food safety[494], provided that:

- there is a demonstrable scientific basis for their measures;

[494] Article 2 SPS provides that: "Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement".

- their measures are applied only to the extent necessary to protect human, animal or plant life or health.

Under the Agreement, Members also agree to base their standards on international standards, guidelines or recommendations where they exist. Members may introduce or maintain standards which result in a higher level of protection than would be achieved by measures based on such international standards, if there is scientific justification for such increased protection or where the Member has engaged in a process of risk assessment as laid down in Article 5 of the Agreement.

It will be shown below, the effect of the Agreement is to mandate a particular approach to decision-making about issues concerning food security, consumer safety, regulation of GMOs, animal welfare which amount to a risk analysis model, where the production of authorized knowledge and management of risk is mainly based on 'science'.

### 1. NON DISCRIMINATION

SPS measures should not be applied in a way which arbitrarily or unjustifiably discriminates between countries where identical or similar conditions prevail, including between conditions within a country and other countries.

This obligation of non-discrimination contained in Articles 2.3 SPS and Article 5.5 SPS builds upon the operative language of the non-discrimination clause of the *Chapeau* of Article XX GATT discussed above:

However, as interpreted in the *Salmon* case, this obligation prohibits discrimination not only between similar products but also between different products[495]. Its scope is therefore broader that the one contained in the *Chapeau* of Article XX by focusing on the justification for discrimination between situations under SPS prohibition itself.

While Article 2.3 relates to differences between the situations of the regulating Member and other Members and between the situations of the various other Members, Article 5.5 focuses on differences in the level of protection chosen by a Member State in different

[495] *Australia – Salmon*, Panel Report Recourse to Article 21.5 of the DSU by Canada WT/DS18/RW adopted on 20 March 2000, para 7.112: "we are of the view that discrimination in the sense of Article 2.3, first sentence, may also include discrimination between different products, e.g. not only discrimination between Canadian salmon and New Zealand salmon, or Canadian salmon and Australia salmon; but also discrimination Canadian salmon and Australia fish including non-salmonids".

situations. The scope of the latter provision is the focus of paragraph 5, on the consistency test.

## 2. Necessity and Proportionality Test

The necessity test, also called the least trade-restrictive (LTR) discipline, is one of the most important general discipline governing domestic regulation in WTO law. It has been traditionally interpreted as requiring domestic regulations to be the least restrictive means to achieve their goals.

It has been originally developed from Article XX(b) which requires that measures derogating from Article III and XI be "necessary" to protect health.

However, while Article XX referred to the necessity test as a "negative requirement" to be satisfied in order to benefit from an exception, the SPS Agreement, as well as the TBT, has made this discipline a "positive" requirement for all SPS measures.

After reminding Member States to take into account the objective of minimizing negative trade effects when determining the appropriate level of SPS protection (paragraph 4), Article 5 provides that, in establishing or maintaining SPS measures to achieve the appropriate level of protection, Members must ensure that such measures are not more trade-restrictive that required, taking into account technical and economic feasibility (paragraph 6). A related footnote (number 3) qualifies further the SPS LTR discipline by setting forth the test for breach of Article 5.6 SPS. The less trade restrictive alternative a) must be reasonably available; b) must achieve the appropriate level of protection, and c) must be *significantly* less restrictive to trade. It is this last requirement that seems to differentiate the understanding of the necessity test within the SPS Agreement from GATT.

This three-pronged test has been confirmed by the AB in the *Australia-Salmon* case, where it stated that: "These three elements are cumulative in the sense that, to establish inconsistency with Article 5.6, all of them have to be met. If any of the elements is not fulfilled, the measure in dispute would be inconsistent with Article 5.6. Thus, if there is no alternative measure available, taking into account technical and economic feasibility, or if the alternative measure does not achieve the Member's appropriate level of sanitary

or phytosanitary protection, or if it is not significantly less-trade restrictive, the measure in dispute would be consistent with Article 5.6"[496].

In this case, the AB found that, although there existed available alternative measures, there was not sufficient evidence to determine whether they would have achieved Australia's appropriate level of protection. Similarly, in the *Agricultural Products* case, the AB refused to consider the contested measure in breach of Article 5.6 because, though existed alternatives, there was lack of evidence.

In particular, the AB held that it is for the complaining party to suggest alternatives and to make a prima facie case of violation of Article 5.6 SPS. That means that WTO judicial bodies in assessing whether the contested measure complies with the necessity test cannot rely on information provided to them by their experts, but solely on that advanced by the parties.

This rather deferential interpretation of the necessity test must be applauded to the extent WTO judicial bodies cannot realistically assess the degree of necessity of an SPS measure taken out from its particular regulatory, societal and economical contexts. A different more intrusive reading of this norms would inevitably lead the WTO to engage in complex questions of allocation of domestic resources and political choices thus intruding into sensitive areas of Member States' sovereignty.

### 3. Scientific Basis

For a WTO's SPS measure to survive review under the SPS Agreement, it must not only be non discriminatory and necessary, but also based on scientific evidence.

Article 2.2 of the SPS Agreement provides that SPS measures must be "based on scientific principles" and may not be "maintained without sufficient scientific evidence". This provision is the central pillar of the Agreement as it shows its willingness to go beyond discrimination by establishing a new organizing principle enabling the WTO to distinguish between legitimate and illegitimate regulations.

[496] *Australia – Measures Affecting the Importation of Salmon* WT/DS18//AB/R AB Report adopted 6 November 1998, para 199.

However, scientific justification does not aim exclusively at eliminating sham health measure, but also at identifying scientifically unsupported regulations that, though not protectionist *per se*, may unnecessarily restrict trade.

In other words, the scientific requirement, by allowing surviving solely those health measures which are based on a scientific-basis, it brought the GATT trade-liberalization agenda a step further toward the goal of integration.

In particular, the primary SPS scientific justification requirement may be found in Article 2.2 SPS. That Article requires that any Member States' sanitary and phytosanitary measure be "based on scientific principles and it is not maintained without sufficient scientific evidence".

Furthermore, Article 5 SPS translates this duty in operational terms by providing that countries should ensure that their measures be "based on an *assessment*, as appropriate to the circumstances, of the risks to human, animal or plant life or health". This requirement constitutes an attempt by the SPS framers to set up some common structure on the way in which WTO Members enact SPS measures[497].

The panels and AB have elaborated on these requirements, by interpreting them cumulatively[498] as requiring that there must be an "objective or rational relationship" between the SPS measure and the scientific evidence[499]. Therefore, these two SPS obligations focus on the capability of the measure to tackle the health concern. The WTO judicial bodies are called to determine to what extent the measure at issue is reasonably related to the public policy goal it pursues.

Furthermore, the AB offered some further clarification on how to apply this test: "whether there is a rational relationship between an SPS measure and the scientific evidence is to be determined on a case-by-case basis and will depend upon the particular

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[497] Whether SPS scientific requirements establish a real risk analysis scheme remains an open question and is discussed further within Part IV when comparing the EC and the WTO Food Safety Risk Analysis schemes, notably in chapter II.

[498] *EC-Hormones* Appellate Body Report, para 180 reads "Articles 2.2 and 5.1 should constantly be read together. Article 2.2 informs Article 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1"; confirmed by *Japan - Agricultural Products*, AB Report, para 76 where the Appellate Body stated that "the context of the word 'sufficient' or, more generally, the phrase 'maintained without sufficient scientific evidence' in Article 2.2, includes Article 5.1, as well as Articles 3.3 and 5.7 of the SPS Agreement. See, notably, para 82.

[499] *EC – Hormones* AB Report, para 189; then confirmed in *Japan - Agricultural Products* Panel Report WT/DS76 para 8.29, 8.42 and *Japan - Agricultural Products* AB Report, para 82.

circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence"[500].

The country adopting an SPS measure, therefore, is entitled to determine the appropriate level of protection[501], subject to this rational relationship constraint.

However, the meaning of "based on" risk assessment in Article 5.1 soon revealed difficult to interpret[502]. Is this a substantive and/or a procedural requirement? In other words, to what extent does it impose on Members a duty to conduct a risk assessment before acting?

Although the panel in the *Hormones* case has interpreted this requirement as a "minimum procedural requirement"[503], the AB in the same dispute has rejected this interpretation, by emphasizing the 'substantive requirements' that regulate the adoption of SPS measures, notably that a SPS measure must be justified by science. Thus, the Appellate Body held that, absent national procedural requirements, a Member may rely on a risk assessment conducted "by another Member State or by an international organization", and should therefore not carry out its "own risk assessment"[504]. Contrary to a procedural interpretation, this approach promotes greater convergence of Member States' regulatory measures by requiring them to be rationally linked to the results of a risk assessment. At the same time, with a substantive standard, unless a Member adopts the same regulatory measures as those recommended by international bodies, States will need have sufficient

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[500] *Japan - Agricultural Products*, para 84.

[501] This freedom has been recognized not only textually by Article 2 SPS but also by the AB in *Australia – Salmon*. In its report, the AB has expressly stated that the panel or AB should not substitute its own reasoning about the implied level of protection for that expressed consistently by Australia. See para 199.

[502] This question arose in the first SPS case that reached the DSB: the *Hormones* case. For an overview of the *Hormones* case, see M.M. Slotboom, *The Hormones Case: An Increased Risk of Illegality of Sanitary and Phytosanitary Measures*, in Common Market Law Review (1999) 486; Wüger, *The Implementation Phase in the Dispute Between the EC and the United States on Hormone-Treated Beef*, supra note 177, at 777 ss. (2002) and for a follow-up of the case, see A. Alemanno, *Judicial Enforcement of the WTO Hormones ruling within the European Community: Toward an EC Liability for the non-implementation of WTO Dispute Settlement Decisions"*, in 45 Harvard International Law Journal (2004) 547.

[503] The panel, after having found that "[...] there is a minimum procedural requirement contained in Article 5.1", went on by stating that "[i]n our view, the Member imposing a sanitary measure needs to submit evidence that at least it actually took into account a risk assessment when it enacted or maintained its sanitary measure in order for that measure to be considered as based on risk assessment". Concluding that the EC had not met its burden of proving that it had satisfied such a "minimum procedural requirement" stemming from Article 5.1, the Panel held the the EC measures were inconsistent with the requirements of Article 5.1. See *EC- Hormones* Panel Report, para 8.113.

[504] *Hormones*, AB Report, paras 189-190.

technical capability to verify that there is an objective and rational relationship between the scientific data available and the measures they wish to adopt[505].

In the same case, the Appellate Body also rejected the panel's narrow view that the measures must *conform* to the scientific conclusions reached in the risk assessment[506], by stating that this requirement mean that "the results of the risk assessment must sufficiently warrant – that is to say, reasonably support – the SPS measure at stake"[507]. As to the degree of rational relationship between the measure and the risk assessment, the AB made the following Statement:

> "We do not believe that a risk assessment has to come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure. The risk assessment could set out both the prevailing view representing the "mainstream" of scientific opinion, as well as the opinions of scientists taking a divergent view. Article 5.1 does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community. In some cases, the very existence of divergent views presented by qualified scientists who have investigated the particular issue at hand may indicate a State of scientific uncertainty. Sometimes the divergence may indicate a roughly equal balance of scientific opinion, which may itself be a form of scientific uncertainty. In most cases, responsible and representative governments tend to base their legislative and administrative measures on "mainstream" scientific opinion. In other cases, equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources. By itself, this does not necessarily signal the absence of a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety. Determination of the presence or absence of that relationship *can only be done on a case-to-case basis*, after account is taken of *all considerations rationally bearing upon the issue of potential adverse health effects*[508].

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[505] However, as shown below, the increasing demand for specific risk assessment puts a limit on the extent to which WTO Members may rely on risk assessment conducted by other countries or international bodies. See Button, supra note 196, at 67.
[506] *Hormones*, Panel Report, para 8.117.
[507] *Hormones*, AB Report, para 193-94 confirmed in *Japan-Agricultural Products* AB Report, para 76.
[508] *EC - Hormones*, AB Report, para 194.

To sum up, to verify whether a SPS measure satisfies the need for sufficient scientific evidence and the substantive standard required for risk assessment, respectively imposed by Article 2.2 and 5.1 SPS, panels and the Appellate Body must examine whether there is "a rational relationship" between the SPS measure and the scientific evidence. The relationship is to be assessed case-by-case and "will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence"[509]. In particular,

> "a measure as a whole should be considered to be maintained "without sufficient scientific evidence if one or more of its elements are not justified by the relevant scientific evidence addressing the risk at issue"[510].

Annex A of the SPS Agreement defines risk assessment as: "The *evaluation of the likelihood* of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the *evaluation of the potential* for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

The same article lists some of the factors that should be taken into account: "available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest — or disease — free areas; relevant ecological and environmental conditions; and quarantine or other treatment" (5.2-5.4). In the *EC-Hormones* case, the AB interpreted this list a non-exhaustive[511] and as including non-scientific factors as well[512]. The

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[509] *Japan - Agricultural Products*, AB Report, para 84.
[510] *Japan - Measures Affecting the Importation of Apples* Panel Report WT/DS245/R adopted on 10 December 2003, para 8.180 (hereinafter, *Japan - Apples*).
[511] AB Report on *EC-Hormones*, para 187 ("[...] there is nothing to indicate that the listing factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a close list").

scientific justification discipline is also contained in Article 3.3, which allows Members to introduce or maintain SPS measures which result in a higher level of protection than that provided for by measures based on international standards but only if they are grounded on a 'scientific justification'.

Finally, the Agreements also deal with situation of scientific uncertainty by stating that

> "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time"[513].

## 4. HARMONIZATION

While each WTO Member is allowed to adopt its food safety measure, provided it is based on science, the SPS Agreement negotiators clearly hoped that harmonized international standards would evolve. In fact, at the beginning of the Uruguay Round, there was general consensus that harmonization could have significantly contributed to the fight against those trade obstacles stemming from diverging regulatory regimes. For this reason, the SPS Agreement, besides the recognition of Members' right to set their own level of food safety protection, encourages the adoption of international standards, guidelines and recommendations. Harmonization is defined by Annex A of the SPS

[512] AB Report on *EC-Hormones*, para 187 ("[...] the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die"). The interpretation of this statement seems controversial. For a criticism see, *ex multis*, R. Quick and A. Bluthner, *Has the Appellate Body Erred? An Appraisal and Criticism of the Ruling in the WTO Hormones Case*, in 3 Journal of International Economic Law (1999) 603, at 618-9. For a positive comment see R. Howse, *Adjudicating Legitimacy and Treaty Interpretation in International Trade Law: The Early Years of WTO Jurisprudence*, in J.H.H. Weiler, (ed.), *The EU, the WTO and the NAFTA: Towards a Common Law of International Trade?*, Oxford, 2000, at 64 ss.

[513] Article 5.7 SPS Agreement.

Agreement as "the establishment, recognition and application of common sanitary and phytosanitary measures by different Members".

More precisely, harmonization is governed by Article 3 SPS, whose three paragraphs provide for an invitation, an encouragement and a derogation, respectively.

Article 3.1 provides that Member States must base their sanitary and phytosanitary measures on international standards, guidelines or recommendations, where they exist. Article 3.2 introduces a presumption: if the measure conforms to international standards, guidelines and recommendations, it is presumed to be consistent with both the SPS and the GATT 1994. Therefore, in an SPS's dispute adjudicated before the WTO, if a Member adopt a measure which is "based" on an international standard, the Member's measures will be presumably found consistent with its obligations under the SPS Agreement. This provision provides great incentives for Member States to comply with international standards.

However, in derogation of article 3.1, Members may introduce or maintain SPS measures which result in a higher level of sanitary and phytosanitary protection that would be achieved by measures based on the relevant international standards, if there is a scientific justification[514]. In other words, Member States remain free to "introduce or maintain" measures more protective than the standards. The right of a Member State to establish its own level of protection has been seen as "an autonomous right and not an 'exception from a 'general obligation' under Article 3.1"[515]. A footnote to this last paragraph (footnote 2) specifies that, for the purposes of this provision, there is scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary and phytosanitary protection.

Article 3.4 then States that WTO Members must participate "within the limits of their resources" in the relevant international bodies, and "in particular" the Codex, IPPC and OIE. In other words, Member States are expected to contribute to the development of standards within these international organizations. As SPS negotiators considered it

[514] This is one of the main points of divergence with the TBT Agreement. If under the SPS Agreement the only justification for not using such standards for food safety and animal/plant health protection is scientific argument resulting from an assessment of the potential health risks, in contrast, under the TBT Agreement Members may decide that international standards are not appropriate for other reasons, including fundamental technological problems or geographical factors.

[515] *EC – Hormones*, AB Report, para 172.

inappropriate for the WTO to be more prescriptive about risk management, they considered these standard-setting organizations as the better forum for the elaboration of guidelines for regulatory action.

These provisions, being rather obscure, have given rise to the following interpretative issues:

- As to paragraph 1, which is the scope of Member States' duty to base a measure on international standards? Should a Member State 'base' its measure on the standards or rather 'comply' with it? (a)
- As to paragraph 3:
    - in which circumstances may a Member State depart from an international standard? (b)
    - On whom does it lay the burden of proof? (c)

(a) While the Panel in the Hormones case held that a measure to be based on international standards should conform to it[516], the AB rejected this strict interpretation by stating that to satisfy this obligation not all elements of the standards have to be incorporated into the measure, but only some[517]. Therefore, "based on" means simply derived from, thus providing greater flexibility to Members than a "conform to" requirement. It remains to be seen which is the minimum degree of conformity that must be attained by an SPS measure to satisfy this requirement and, accordingly, to benefit benefiting from the presumption of consistency set out by Article 3.2.

(b) As to the circumstances triggering the invocation of Article 3.3 the AB has found that, contrary to what it might appear from a textual reading of the provision, there is only one situation in which a Member State can pursue a higher level of protection: when it has complied with all the SPS discipline, notably the risk assessment requirements[518]. In the EC-*Hormones* case, the AB held that the Panel erred in presuming that measures that did not conform to international standards were inconsistent with the SPS Agreement. As it has correctly been stated, this is "refined system of applied subsidiarity, subtly allowing national autonomy subject to certain constraints". The complex constraints imposed by

[516] *EC-Hormones*, Panel Report, para 8.72.
[517] *EC-Hormones*, AB Report, paras 163-66.
[518] *EC-Hormones*, AB Report, paras 175-76.

the SPS Agreement, combined with the international standards to which it refers, established a system for reviewing certain type of State actions at international level.

(c) As to the burden of proof within Article 3.3, the AB, overturning the Panel"s finding in the *Hormones* case, held that, being this norm not an exception but laying down "an autonomous right" to set higher level of protection, it is the complainant party to bear the burden[519].

It remains to be seen to which standards Member States may choose to conform to.

### 4.1. The SPS Agreement and the Relevant International Standards Organizations

As to the international standards Member States should rely upon, Annex A of the SPS Agreement refers to three different standard-setting organizations, depending on their respective area of competence[520]. Thus, Member States should look at the following:

(a) for food safety: the standards, guidelines and recommendations established by the Codex Alimentarius Commission (CAC);

(b) for animal health and zoonoses: the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics (OIE)[521];

(c) for plant health: the international standards, guidelines and recommendations under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention (IPPC).

As seen above, the standards elaborated by these organizations are referred to by the SPS Agreement as a basis for presumed compliance with the agreement. Prior to the Uruguay Round, these organizations' standards had no value unless voluntarily accepted for application by national legislations[522].

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[519] *EC-Hormones*, AB Report, para 104.

[520] For an overview of these three organizations, see T. Stewart and D.S. Johanson, *The SPS Agreement of the World Trade Organization and International Organizations: the Roles of the Codex Alimentarius Commission, the International Plant Protection Convention, and the International Office of Epizootics*, in 26:27 Syracuse J. Int'l L. & C., (1998), at 27 ss.

[521] As this international organization is based in France, notably in Paris, it is most often referred to by the French-based acronym OIE, which stands for "Office International des Epizooties".

[522] M. Herdegen, *Biotechnology and Regulatory Risk Assessment*, in G.A. Bermann, M. Herdegen and P.L. Lindseth (Eds.), *Transatlantic Regulatory Cooperation: Legal Problems and Political Prospects* (Oxford: Oxford University Press, 2001).

The obligation on WTO Members to base their SPS measures on the international standards elaborated by these organizations justifies not only a description of their composition but also an analysis of the modalities according to which they adopt these standards[523]. In fact, the proper functioning of the SPS Agreement depends in part upon the standard-setting activities of the CAC, the OIE and the IPPC.

In general, the standards they set are voted upon by the delegates of each Member State to these organizations. These delegations are traditionally composed of scientists employed by their respective countries. Despite these common traits, the Codex, OIE, and IPPC diverge considerably both in their roles and organization. Since among the standards established by these three international organizations those of the Codex show the greatest potential to lead to disputes over food safety issues, our analysis will mainly focus on the Codex Commission's operation. Furthermore, as they relate to human health, Codex's standards tend to cause more concerns in the population than those adopted by the IPPC and OIE, which deal respectively with plant and animal health.
Although the operation of these organizations has never been immune from politics, the work undertaken by its scientific bodies has never attracted great political attention. This lack of visibility is mainly due to the fact that the standards they elaborate are not legally binding, but merely advisory, so that they rarely draw the attention from non-scientists.
However, as one might have expected, expressed reliance on these three organizations within the SPS has inevitably impacted not only on their functioning but also on their nature. It is sufficient to look at the first SPS cases brought before the WTO judicial bodies to date to become aware of the relevance of the standards elaborated by these organizations within the international trade arena. In fact, now that international standards may play, directly or indirectly, a role on the outcome of many international trade disputes, WTO Members have incentives to make sure that the new standards of Codex, IPPC and OIE conform with current or future national SPS measures.
Although these three bodies are the only international organizations mentioned by name in the SPS Agreement, others international entities, concerned with SPS issues are

[523] For a summary of procedures for adoption of certain type standards, see D. Victor, *The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment After Five Years*, 32 N.Y.U. J. Int'l L. & P. 4 (2000), at 865, 884-895.

affiliated with the WTO. Thus, the WHO, the FAO, UNCTAD and the ISO have regular observer status at the WTO.

Besides their standard-setting involvement, these international organizations do play a role also within the risk assessment framework provided by Article 5 of the SPS Agreement. In fact, Article 5.1 States that in conducting risk assessment for SPS measures, Members must take into consideration the risk assessment processes developed by the "relevant international organizations", which presumably include the Codex, IPPC and OIE. Furthermore, under Article 5.8 SPS, when a Member State believes that a measure of another Member does not conform with the "relevant international standards, guidelines, or recommendations" and the measure either interferes with or has the potential to interfere with that country's export, that Member can request that the other Member provides it with explanations for the measure and the other Member will be obliged to respond.

### A. Codex Alimentarius Commission (CAC)[524]

The Codex Alimentarius Commission was originally founded in 1962 by FAO and the WHO as an intergovernmental body in charge of implementing their Joint Food Standards Program[525] and setting up the Codex Alimentarius[526]. This Codex, drawing on the previous experience of the Codex Alimentarius Europeus, may be defined as a set of general and commodity-specific standards, guidelines, and recommended codes of practice aimed at protecting health of consumers and to ensure fair trade practices.

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[524] For an overview of the Codex Alimentarius' activities, see T. Stewart and D.S. Johanson, *The SPS Agreement of the World Trade Organization and International Organizations: the Roles of the Codex Alimentarius Commission, the International Plant Protection Convention, and the International Office of Epizootics*, in 26:27 Syracuse J. Int'l L. & C., (1998), at 27 ss.; J. Bizet, *Sécurité Alimentaire: Le Codex Alimentarius*, Les Rapports du Sénat, n. 450, 1999-2000; C. Riemenschneider, *A Meeting of the Codex Alimentarius Commission*, 5 FDLI Update, 3, (1999); D. Jukes, *Codex Alimentarius – Current Status*, in Food Science and Technology Today, December 1998, at 10; I. Meyers, *The New International Trade Architecture and Food Regulation*, Third year paper, Harvard Law School, 2000 (on file with the Author).

[525] The purpose of this program was to protect the health of the consumers and ensuring fair practices in the food trade; to promote co-ordination of all food standards work undertaken by international governmental and non governmental organizations,

[526] More precisely, the Codex was established since the adoption of two resolutions to set the organization in the Eleventh session of the FAO Conference in 1961 and the Sixteen World Health Assembly in 1963.

The CAC elaborates international standards, codes of practice, guidelines an related texts addressing the safety and quality of foods moving in the international food trade[527]. To date, it has developed more than 240 standards ranging from processed foods to raw foods and from maximum levels for pesticides to guidelines for contaminants. Although advisory in nature, as we have seen above, these standards become reference standards through the SPS Agreement.

The Codex's Membership is open to FAO and WHO Members interested in developing food standards. More than 165 countries are represented today in it.

Codex, which is led by a 10-Member executive committee, also comprises 6 Regional Coordinating Committees, 8 General Subject Committees, 12 Commodity Committees and 3 Ad-Hoc Inter-governmental Task Forces. Among these subsidiaries bodies there are at least eight whose main focus is related to food safety, namely: the Codex Committee on Food and Hygiene, Food Additives and Contaminants, Pesticide Residues, Residues of Veterinary Drugs in Food, and Meat Hygiene and Intergovernmental Task Forces on Food Derived from Biotechnology and Animal Feed. Moreover, all the activities related to the elaboration of general principles for food safety, such as the risk analysis working principles, have been considered by the Codex Committee on General Principles.

Most of these committees meet annually or biannually. The Codex allows the establishment of new subsidiary bodies to address new or emerging issues.

Needless to say that the Codex Commission acquired greater visibility only in 1995 when both SPS and TBT Agreements were adopted. Indeed, the SPS Agreement identifies standards, guidelines and recommendations adopted by the Codex Alimentarius Commission as the international benchmark for food safety. For the purposes of the SPS Agreement, WTO does not differentiate between standards, guidelines and recommendations elaborated by Codex. They all benefit from the same status under WTO law. For food safety, the SPS Agreement refers to standards developed by Codex in the following sectors: codes and guidelines of hygienic practices, contaminants, food additives, methods of analysis and sampling, veterinary drug and pesticide residues.

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[527] Its stated goal is "to guide and and promote the elaboration and establishment of definitions and requirements for foods, to assist in the harmonization and, in doing so, to facilitate international trade". See Codex Alimentarius Commission, *This is Codex Alimentarius*, 1995.

With the new role given by the SPS Agreement to Codex, the main center of gravity of Codex activities has shifted from a focus on the (vertical) work of the commodity committees to the (horizontal) work of the general subject committees.

It is worth underlining that not all Codex Members are Members of the WTO. Although Codex standards are referred to by the WTO/SPS framework, Codex does not establish food standards for the WTO. It mainly establishes food standards for the use of its Members. As it has been stated during the Forty-Fifth Session of the Codex Executive Committee,

> "the work of Codex should move forward without concern arising from misunderstandings or misinterpretations as to how Codex standards and related texts might be used"[528].

*1. Operation*

To understand the functioning and operation of Codex it is necessary to look at the Codex Alimentarius Commission Procedural Manual.

When a Codex Committee proposes to elaborate a new or revised standard, it should verify whether it fits within the priorities set up by the Commission in the Medium-Term Plan of Work, before contacting the Codex or its Executive Committee for approval. Subsequently, the elaboration of standards, as provided for by the Codex Elaboration procedure contained in the Manual, may follow two types of procedures:

- Uniform Normal Procedure
- Uniform Accelerated Procedure.

The normal procedure consists of eight steps. It starts with the decision to elaborate a standard and the appointment of the subsidiary body in charge of it (step 1). It follows with the preparation of a proposed draft standard, after having heard either the JMPR or the JECFA, depending on the matter at issue (step 2). The proposed draft is then distributed among CAC Members for their comments (step 3). After reception, the comments are considered by the subsidiary body (step 4) and a draft standard is to be submitted to the CAC for adoption which has to take in due account the comments received (step 5). Once the standard is adopted, it is sent around Members for their comments (step 6), which have to be considered by the Member and the CAC (step 7).

[528] Executive Committee of the Codex Alimentarius Commission, 45th Session, FAO Headquarters, Rome 3-5 June 1998.

The procedure terminates with the adoption of the final standard by CAC after having considered both the amended draft standard and Members' proposals (step 8)[529].

Following the adoption of standards, Members have the chance to accept them. The CAC provides for specified forms of acceptance:

- Full acceptance: the country will apply the standard to all products and will not restrict distribution of products complying with the standard;
- Acceptance with specified deviations: the country will apply the standard to all products except those specific aspects which are not accepted;
- Free Distribution: the country will not restrict distribution of products complying with the standards. This allows the accepting country to retain a separate national standard without blocking imports complying with the food standard.

All discussions at Commission level are made through discussions by Member States delegations. In principle, decisions are adopted by consensus. Codex's history shows that this has been the case until quite recently[530]. This was possible since a national delegate, on returning to its country, could easily ignore the consensus decision taken at the Codex meeting[531]. However, given the heighten status recognized to Codex standards, this is no longer the case. Under the Code Manual of Procedure, where every effort to reach an agreement fails, there may be decisions taken by voting. In the event of a vote, decision is by majority of Members present at the particular session. Compliance with the adopted standard is then voluntarily under Codex principles.

Under the Statements of Principle Concerning the Role of Science in the Code Decision-Making Process, "when the situation arises that Members of the Codex agree on the necessary level of protection of public health but hold different views about other considerations, Members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex"[532].

The presumption of conformity introduced by the SPS Agreement makes the Codex and the other international standard-setting organizations "quasi-legislators"[533]. This phenomenon renders today more and more difficult to agree on the setting up of new

[529] See Procedural Manual of the Codex Alimentarius Commission, 14th edition, 2005.
[530] D. Jukes, *Codex Alimentarius – Current Status, in Food Science and Technology Today*, supra note 524, at 10.
[531] *Ibid.*
[532] CAC Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors Are Taken into Account (Decision of the 21st Session of the Commission 1995 ALINORM 95/37).
[533] Trachtman and Marceau, supra note 473.

standards. Given the incentives stemming from the presumption of conformity provided by Article 3.2 SPS, it is not surprising that Codex's Members tend to vote in a manner that would advance their trade interests. In fact, if a Member can have its standard adopted in Codex, it will not have to defend its measures under the SPS Agreement. This inevitably induces Members to rely more frequently on the use of majority voting within the organization with the effect of rendering pretty slim the consensus behind the adoption of standards. Moreover, Codex's works are increasingly influenced by the participation of commercially interested NGOs and, at the same time, by the absence of developing countries' involvement.

This increasing politicization of Codex's work inevitably leads to the adoption of standards by majority voting thus weakening their scientific authority. Being supported by a smaller number of Members, the newly adopted standards do not enjoy of international scientific consensus.

It results that the length of the approval processes for new standards combined with the diverging trade interests are likely to even prevent the adoption of numerous scientifically controversial standards.

*2. The EU's involvement in Codex: from the observer status to full membership*

The EC and its Members take into account CAC's standards, but only as long as they are compatible with EC food safety underlying principles. Thus, for instance, the EC, in adopting Commission directive 2002/82, laying down specific purity criteria on food additives other than colors and sweeteners[534], has referred to and incorporated within the directive the relevant Codex standard.

EC's reliance on these standards justifies an increasing European participation within Codex, especially since measures relying on them benefit from a presumption of conformity with WTO/SPS rules[535]. Indeed, it is in the EC interest to effectively contribute to the works of this body so as to make sure that new standards reflect as much as possible their food policy objectives.

In the light of that, the EC has recently become a full Member of Codex[536]. EC's accession to Codex resulted from an intensive lobbying activity undertaken by the EC

[534] OJ L292/1 28 October 1998.

[535] See Enhancing Participation in Codex Activities, An FAO/WHO training package, 2005, at 74.

[536] Council Decision of 17 November 2003 on the accession of the European Community to the Codex Alimentarius Commission, OJ L 309 of 26.11.2003.

Commission to modify Codex's provisions excluding from its Membership regional organizations. In the past, the EC could only benefit from an observer status. Today – thanks to the European involvement – all regional organizations can obtain full Membership[537]. It is worth noticing that while the Council has authorized the Commission to begin negotiations with Codex already in 1993, it is only in 2003, after having lost two SPS disputes involving international standards (*Hormones* and *Sardines*[538]), that the Commission acted to obtain the desired status. The EC Commission wrote to the Director-General of the UN/FAO in November 2003 to formally complete the accession process. This means that the European Commission has relinquished its observer status in Codex and now represents all EC countries on matters of EC competence.

In particular, the Commission speaks and votes in Codex on behalf of the Community on all issues of exclusive Community competence. It also speaks and votes on behalf of the Community on all issues of mixed competence where the preponderance of the competence lays with the Community. However, EC Member States are still able to contribute to the debate in Codex matters of Community and mixed competence to support and develop the Community line, by voting on issues within areas of exclusive Member State competence and also on those issues of mixed competence when the preponderance of the competence lies with the Member States.

The advantages stemming from a European Membership to Codex are self-evident. Although the EC does not accrue more votes (the principle being 'one nation, one vote') as a result of its full Membership, it certainly acquires stronger "bargaining power" within the Codex's negotiating activities. This means that not only EC draft proposals will be more willing to obtain consensus (being already supported by 25 countries)[539], but also that the EC will easily block the adoption of a standard proposed by non-European Members.

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[537] Rule VII of the Codex Statute. See Report of the 26th session of the CAC of 30 June – 7 July 2003, para 78.

[538] *EC - Description of Sardines*, Report of the Panel, WT/DS231/R decided May 29, 2002 (adopted as modified by the Appellate Body Oct. 23, 2002) and Report of the Appellate Body, WT/DS231/AB/R (decided Sept. 26, 2002) adopted Oct. 23, 2002.

[539] It is worth noticing that during the last session of the CAC, the Delegation of the European Community was acting also on behalf of Bulgaria and Romania, for which the accession Treaty to the EC has already been signed and officially published. See Joint FAO/WHO Food Standards Programme, Report of the Codex Alimentarius Commission, 28th Session, Rome, 4-9 July 2005, at 1.

The European Community and its Members regularly present joint comments on issues discussed in Codex Committees, which are within the competence of Community legislation. The procedure is described in the Council Decision of 17 November 2003 on the accession of the European Community to the Codex Alimentarius Commission. These comments are presented in the EC position papers. The Directorate General for Consumer and Health Protection acts as the contact point and co-ordinates this work.

### *3. The Role of Codex within the SPS Agreement*

At least until adoption of the WTO Agreements, the Codex has been regarded as a technical organization that operates at an epistemic level, "largely unaffected by national political interests as well as national and international law"[540]. The acceptance of standards has been very limited and mainly confined to those developing countries who were setting up new food legislations and found very practical to adopt the Codex ready made standards. Most of these countries were also expecting that reliance on Codex standards would have ensured them access into the markets of Europe and North America. This has not been the case since industrialized countries, such the European Community Members and the USA, already disposing of evolved food laws, proved unwilling to modify their legislations to adapt them to the standards.

Now, however, because of the heightened legal status of its standards under the SPS Agreement, the Codex activities are becoming more relevant and, accordingly, also more sensitive thus inevitably getting under the spotlight of politics[541]. Amongst the three organizations mentioned within the SPS Agreement, Codex is without doubt the one that has been more politicized as a result of the Uruguay Round. To support this Statement one may refer to the long and controversial debates surrounding the vote on Codex beef hormone standards[542] in 1995, which has subsequently led to the well-know Hormones disputes opposing the US to the EC.

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[540] F. Veggeland and S.O. Borgen, *Changing the Codex: The Role of International Institutions*. Norwegian Agricultural Economics Research Institute, Oslo (January 2002).

[541] For an analysis of the SPS impact on the Codex's activities, see D. Jukes, *The Codex Alimentarius Commission – Current Status*, supra note 524.

[542] On these issues, see infra Part IV.

More recently, the mounting level of Codex politicization has been shown by its failure to adopt recommended standard for recombinant bovine somatotropin (rbST), a synthetically produced version of a naturally occurring hormone intended to increase milk production. To prevent the adoption of this standard the EC invoked, for the first time ever, "other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade", as recognized in the "Statements of Principles on the Role of Science in the Codex Decision-Making Process and the Extent to Which Others Factors Are Taken into Account" as they have been incorporated within Codex Procedural Manual in 1997[543]. During the negotiations leading to the drafting of this document, the US and the EC have been confronted each other on the setting up of guidelines defining the precise role of science in risk management, thus giving a more operative meaning to the Codex Statement of Principles[544]. While the US argues that that food standard should rely solely on scientific evidence, the EC sought to introduce a "need" criterion, aimed at preserving marginal farmers against the productivity-enhancing food technologies[545].

As shown above, Codex Alimentarius Commission's mandate includes two competing goals: ensuring free movement of goods in international trade and protecting the health of consumers. This dichotomy inherent within Codex's mandate makes it ill suited to effectively safeguard consumer health.

In particular, Codex's voting rules tend to favor self-interested Members to vote for those standards promoting their respective economic interests at the expenses of public health protection. Thus, in the past, several European countries have blocked the adoption of standards that would mandate pasteurization, whereas pottery-producing countries, such as Portugal and Spain have objected to high lead standards[546].

Against this backdrop one may easily foresee that those standards that will be adopted in the future will be approved by slim majorities rather than by consensus[547]. This, as the Hormones case shows, means that all those controversial standards upon which it will be

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[543] As amended in 1998, see Second Statement of Principle included in a Appendix to the Procedural Manual entitled "General Decisions of the Commission". For an overview over this discussion, see D. Jukes, *The Role of Science in Internal Food Standards*, in Food Control, Volume 11(3), June 2000. See infra Part IV.

[544] See infra Part IV.

[545] See D. Jukes, *The Role of Science in Internal Food Standards*, in Food Control, Volume 11(3), June 2000.

[546] L. Sikes, FDA's Consideration of Codex Alimentarius Standards in Light of International Trade Agreements, 53 Food & Drug L.J. 327, at 328 (1998).

[547] This has been amply demonstrated by the recourse to votes since the 21st and 22nd sessions to the last one (the 28th held in 2005).

reached an agreement by a slim majority will be likely to trigger a move to the WTO's dispute settlement body.

Against this backdrop, it seems that the question today facing Codex is whether, when dealing with difficult and controversial issues, such as those discussed above, it would not be wiser to avoid the adoption of the standard and recognize that the parties could not reach an agreement. While it is true that Codex is increasingly acting as a sort of Food Safety World Parliament, the adoption of standards by majority vote seems to weaken rather that to strengthen its legitimacy by inevitably giving rise to further tensions which may lead to trade disputes.

In the light of the above, one may wonder to what extent Codex's inability to reach consensus on specific contentious issues will call into question its entrusted harmonizing role of SPS measures. At the moment, Codex's efforts to develop meta-standards, such a risk analysis framework for food safety risks, clearly illustrated how the newly status received by the SPS has contributed to shift its attention from standard-setting to other more ambitious agendas which that body cannot realistically and effectively carry out.

### B. International Office of Epizootics (OIE)

The French-based OIE was created in 1924 as a Member States-led organization to improve hygiene and public health by preventing the spread of diseases in animals and animal products in international trade. It is the oldest veterinary organization in the world and, similarly to Codex, has a significant record of establishing international standards. Its structures comprises an International Committee, composed of delegates from its Members States meeting annually, a central office acting as an executive and several commissions serve as deliberative organs. Among its missions, OIE develops international standards, guidelines and recommendations relating to animals and animal products. More precisely, its main commissions deal with epizootic diseases, fish diseases and standards and have developed an International Animal Health Code and an International Aquatic Animal Health Code, which are periodically updated. OIE's standards may be found in the OIE's Code, which lists standards for international trade,

and Manual, which set forth standard diagnostic procedures for animal diseases as well as vaccine standards related to international trade.

Although this 155 Members organization is not part of the UN system, it regularly cooperates with FAO and WHO in global food safety issues.

Unlike the Codex and the IPPC, the OIE has not experienced major reforms in its standards-setting process and structure since the entrance into force of the SPS Agreement.

As the establishment of international standards for animal and animal products does not raise the same concerns as do the Codex's standards relating on human health, the OIE has not experienced any significant controversies when setting standards.

Although OIE's role within the international trading system may seem to be minor when compared with Codex and IPPC, the *Australia-Salmon* case has shown the contrary. The proposes EC's ban on the use of "specified risk materials" (SRMs), which may pose risks regarding transmissible spongiform encephalopaties, had been based on a OIE's standards prohibiting the international trade of bovine brains and spinal cords originating from countries affected by BSE.

### C. International Plant Protection Convention (IPPC)

The IPPC is a treaty signed in 1952 and administered by FAO through the IPPC Secretariat. It aims at securing common and effective action to prevent the spread and introduction of pests of plants and plant products, and at promoting appropriate measures for their control[548]. The Convention deals with the protection of plant life and has therefore no direct relevance to food safety.

A Secretariat was established for the IPPC in 1989 by FAO, but it began to function only in 1993. Its main task consists in coordinating international efforts concerning plant quarantine issues, to compile information concerning plant pest outbreaks, and to provide technical assistance to the Members on phytosanitary issues. Another of the Secretariat's functions is to coordinate the implementation of the IPPC through its nine regional organizations. The Secretariat operates under the aegis of FAO and is located in Rome.

[548] See Article I of IPPC.

One of IPPC most relevant tasks is its work with FAO's pest management activities, but it also in charge of developing international standards for phytosanitary measures, centralizing and disseminating information on plant parasites that could be present in imports and providing technical assistance to developing countries.

Although the IPPC was amended in 1979 (the amended text became operative in 1991), this organization revealed to be the least prepared among the three international organizations mentioned in the SPS Agreement. On this basis, the FAO Conference decided, in 1997, to amend it as to adapt it to the new responsibilities provided for by the SPS Agreement. Among the most relevant changes introduced by this reform there is the creation of a standard-setting procedure. In fact, originally the IPPC did not contain any provision relating to the establishment of standards.

As to the voting rules, under the revised IPPC, if consensus cannot be reached on a matter that comes before the IPPC's Commission on Phytosanitary Measures, decisions have to be adopted by a two-thirds majority, not by a simple majority.

### 4.2. The standard-setting organizations' role within the SPS Agreement

This brief analysis of the three standard-setting organizations shows how the SPS Agreement has brought changes not only into their functioning but especially on the role they play within the international trade arena. In particular, the presumption of conformity introduced by the SPS Agreement makes these standard-setting organizations "satellites organizations" of the WTO[549] or "quasi-legislators"[550]. While they do not legislate in the full sense of the term the norms they lay down do produce some legal effects when such standards are adopted and respected. However, their lengthy approving systems for international standards, the increasing number of scientific controversies surrounding new technologies and also the diverging economic interests of its Members are rendering increasingly difficult the adoption of standards, notably in areas characterized by scientific uncertainty. In other words, the SPS negotiators' choice to

[549] S. Poli, *The Adoption of International Food Safety Standards*, in European Law Journal, Vol. 10, no. 5, September 2004, at 615.
[550] Marceau and Trachtman, supra note 473.

invest these organizations with the task to adopt international standards in order to keep their elaboration far from political tensions did not prove successful.

Although the possible increased politicization of the standard-setting process of these organizations is regrettable, it is inevitable today.

As the *EC - Hormones*, *Australia - Salmon* and *Japan - Agricultural Products* cases have shown, the outcome of many international trade disputes may revolve around the conformity by a WTO Member's SPS measure with international standards. This explains the increasing involvement of WTO Members in these standard-setting international organizations. Countries try to protect their current or possible future SPS measure by promoting their approaches to risk analysis throughout the work of the organization. This trend is likely to lead to less consensus within the Codex, IPPC and OIE thus inevitably harming the final objective of harmonization.

## 5. Mutual Recognition and Equivalence

Article 4.1 requires Members to accept the SPS measures of another Member as equivalent if the exporting Member "objectively demonstrates [...] that its measure achieve the importing Member's appropriate level of sanitary and phytosanitary protection".

To make this provision operational, the SPS Committee has adopted a decision in 2001 imposing an obligation on importing Members, upon the request of the exporting country, to explain the objective and rationale of the SPS measure, to identify clearly the risks that the relevant measure intends to address, and to indicate the appropriate level of protection sought[551]. Accordingly, exporting Members must also provide reasonable access, upon request, to the importing Member for inspection, testing and other relevant procedures.

Moreover, Article 4.2 encourages Members States to enter into consultations with the aim of achieving bilateral and multilateral agreement on recognition of the equivalence of specified SPS measures[552].

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[551] See document G/SPS/19.

[552] For an overview of Mutual Recognition Agreements concluded by the EC and their evolution, see, respectively, A. Alemanno, *Gli Accordi di Mutuo Riconoscimento tra esperienza europea e regole OMC*, supra note 155, at 379 ss. and A. Alemanno, *Le principe de la reconnaissance mutuelle au delà du marché intérieur. Diversité règlementaire ou 'colonialisme' règlementaire ?*, supra note 155.

## 6. INTERNAL CONSISTENCY

Article 5.5 SPS seeks to achieve consistency in the application of the appropriate level of SPS protection against health risks. It provides that WTO Members should avoid arbitrary or unjustifiable distinctions in the levels they consider to be appropriate in different situations, if such distinctions in the level of risk result in discrimination or a disguised restriction on international trade. In other words, when conducting a risk assessment, Member States should adopt similar levels of risk for similar products.

This provision constitutes a corollary of the general principle of non-discrimination prohibited by Article 2.3 SPS[553]. It aims at avoiding the situation where a Member could adopt a strict level of acceptable risk for one product and a more lenient approach for another even though the potential risk of harm is very similar for the two products.

It is worth noticing that even if a challenged measure is based on a valid risk assessment, it may be violating the SPS Agreement if all comparable products are not subject to similar regulatory measures based on equally detailed scientifically-based risk assessments.

The AB in the *EC-Hormones* case has clarified the scope of this provision by determining the level of inconsistency that a measure should reach to be struck by this provision:

"[...] the goal set [by Article 5.5] is not absolute or perfect consistency, since governments establish their own levels of protection frequently on *ad hoc* basis and over time, as different risks present themselves at different times. It is only *arbitrary or unjustifiable inconsistencies* that are to be avoided"[554].

In the same report, the AB has established that there is a violation of Article 5.5 only when the following three elements are demonstrated:

- "the first element is that the Member imposing the measure complained of has adopted its own appropriate levels of sanitary protection against risks to human life or health in several *different* situations";

[553] As stated by the AB in the *Hormones* case: "Article 5.5 may be seen to marking out and elaborating a particular route leading to the same destination set out in Article 2.3". See *EC – Hormones*, AB Report, para 212.

[554] *EC-Hormones*, AB Report, para 213.

- "the second element to be shown is that those levels of protection exhibit arbitrary or unjustifiable differences in their treatment of different situations";
- "the last element requires that the arbitrary or unjustifiable differences result in discrimination or a disguised restriction of international trade"[555].

This interpretation has been confirmed by the AB in the *Australia – Salmon* case where it held that because Australia prohibited importation of salmon and salmon products, while simultaneously allowing the importation of herring for bait and live ornamental fish (both of which posed similar risks of disease introduction), it was against Article 5.5 SPS[556] and, accordingly, of Article 2.3 SPS.

To further clarify the practical implications of the requirements of Article 5.5, WTO Members adopted some "Guidelines To Further the Practical Implementation of Article 5.5"[557].

It will be shown below that the consistency requirement by inducing panels to enquire into the validity of a Member's decision on the level of risk it may be prepared to accept in different situations it opens the door for a highly intrusive review. Notably, by checking the regulatory consistency, panels may increasingly assessed the Member States' choices about the level of protection they would like to offer to its own citizens thus inevitably reducing their "right to take SPS measures necessary for the protection of human, animal or plant life or health" expressly recognized by Article 2.1 SPS.

This outcome might in principle be contained should the AB maintain its original position, adopted in the *Hormones* case, according to which the consistency test should catch only "arbitrary or unjustifiable inconsistencies"[558]. However, notwithstanding this initial deferential approach, there are some signs showing the incoming AB's willingness to follow a stricter reading of the consistency requirement.

In particular, the *Australia – Salmon* case is quite self-telling in that sense. While assessing the Australia's quarantine measure prohibiting the import of fresh, chilled and frozen salmon in light of Article 5.5 SPS, the AB held that "warning signals" and "additional factors" may be relied upon to identify inconsistencies under this provision.

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[555] Ibid., Para 214

[556] *Australia – Salmon*, Report, para 240.

[557] See Doc. G/SPS/15 adopted on 18 July 2000.

[558] *EC - Hormones*, AB Report, para 213.

Thus, the AB considered the violation of Article 5.1 risk assessment requirements a "a strong indication" that the contested measure was not really aimed at protecting health, but rather a protectionist measure adopted "in the guise of" an SPS measure[559].
Only future cases will shown whether the AB will live up with its commitment to respect Member States' freedom in pursuing the level of protection they might consider the most appropriate vis-à-vis a certain risk. Signs show that it will rather adopt a stricter attitude to regulatory distinctions.

## 7. Permission for Precautionary Action

The idea of precautionary action is stated in a very limited form within the GATT/SPS framework[560]. Under Article 5.7, a precautionary approach to food safety risks is available to allow "provisional measures" where scientific evidence is "insufficient", where the Member State acts on the basis of "available pertinent information", and where the Member State seeks to obtain the additional information needed for "a more objective risk assessment" within a "reasonable period of time".

Reliance on precaution has been rigorously framed by these conditions as it constitutes the only way in which SPS measures, although failing to meet the scientific justifications requirements provided by Article 2.2, may survive review under the WTO discipline.

Similarly to the European's version, the ratio underlying a precautionary approach consists in recognizing Member States the ability to addressed perceived risk to public health without waiting for definitive scientific answers.

The first appearance of the precautionary principle within the WTO context may be found in the *Hormones* case where the EC, although explicitly stating that it was not invoking Article 5.7[561], tried to argue that this principle was a general principle of

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[559] *Australia-Salmon*, AB Report, para 166. For a critical analysis of the way in which the consistency test has been applied to date, see W.J. Davey, "Has the WTO Dispute Settlement System Exceeded Its Authority?", in T. Cottier and P. Mavroidis, *The Role of the Judge in International Trade Regulation: Experiences and Lessons for the WTO*, (University of Michigan Publishing, Ann Arbor, 2003) at 43.
[560] See supra Part I, Chapter I, section C. The Precautionary Principle, notably paragraph 1 on its origins in international law and Community law.
[561] *EC – Hormones*, AB Report, para 207. The EC did so because it seemed to be aware that its directive did not stand a chance of passing off as a provisional measure. This had been in force for several years already and had

international law or a rule of customary international law. Although the Appellate Body abstained from taking a position on the status of the precautionary principle[562], it has then recognized that various of its elements are reflected in several provisions of the SPS Agreement[563]. In particular, it found that:

"124. [...]. First, the principle has not been written into the SPS Agreement as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of the Member set out in particular provisions of that Agreement. Secondly, the precautionary principle, indeed, finds reflections in Article 5.7 of the SPS Agreement. We agree, at the same time, with the European Communities that there is no need to assume that Article 5.7 exhausts the relevance of the precautionary principle. It is reflected also in the sixth paragraph of the preamble and in Article 3.3. These explicitly recognize the right of Members to establish their own appropriate level of sanitary protection, which level may be higher (i.e. more cautious) than that implied in existing international standards, guidelines and recommendations. Thirdly, a panel charged with determining, for instance, whether 'sufficient scientific evidence' exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative government commonly act from perspective of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned"[564].

It results that, although Article 5.7 and 3.3 incorporates a "precautionary principle", such principle does not override the need for Members to prove they have based their measure on a proper risk assessment, as provided in Article 5.1 and 5.2 SPS[565].

In light of the above, the Appellate Body concluded in the *Hormones* case that theoretical risk, arising by virtue of the impossibility of ever providing a product or substance

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not originally be adopted in an emergency context. See on this point, T. Christoforou, *Science, Law and Precaution in Dispute Resolution on Health and Environmental Protection: What Role for Scientific Experts*, supra note 177, at 271-72; W. T. Douma, *How Safe it Safe? The EU and the WTO Codex Alimentarius Debate on Food Safety Issues*, in V. Kronenberg, *The European Union and the International Legal Order : Discord or Harmony ?*, T.M.C. Asser Press, Amsterdam, at 185.

[562] *EC – Hormones*, Appellate Body Report, para 123, where the AB merely stated that "[t]he status of the precautionary principle in international law continues to be the subject of academics, law practitioners, regulators and judges. [...] Whether it has been widely accepted by Members as a principle of general or customary international law appears less than clear. We consider, however, that it is unnecessary, and probably imprudent, for the Appellate Body in this appeal to take a position on this important, but abstract, question".

[563] *EC – Hormones*, AB Report, supra note, at para 124.

[564] *Ibid.*, para 124.

[565] *Ibid.*, para 125.

completely safe for all time, is not the kind of risk to be assumed under Article 5.1, and that accordingly food safety measures adopted pursuant to this kind of (non-ascertainable) risk cannot be considered as "based on" a risk assessment within the meaning of the SPS Agreement[566].

Following this decision, it was unclear how the SPS Agreement, notably its Article 5.7, could effectively accommodate the precautionary principle within the WTO legal system should its invocation requires the same risk assessment prescribed for situations of scientific certainty. This uncertainty was even strengthened by the circumstance that neither the Panel not the Appellate Body had the chance to interpret Article 5.7 of the SPS Agreement directly, because the EC had not invoked it to justify the measures at dispute[567].

As it has been pointed out, if this provision was meaningful the threshold for the triggering the invocation of the principle had to be lower than those prevailing elsewhere in the Agreement[568]. In other words, the "knowledge" requirement for the triggering of the principle should have not coincided with that prescribed for the adoption of any other SPS measure.

It is in the successive *Japan - Agricultural Products* and *Japan - Apples* cases that the existence of the principle has been recognized (as "a qualified exemption" of Article 2.2 SPS[569]) and, accordingly, the exact scope of Article 5.7 had been thoroughly considered.

In the first case, Japan claimed that the challenged varietal test – requiring that the efficacy of a quarantine treatment be determined on each variety of fruit – was provisional and therefore compatible with Article 5.7 SPS. The panel found that the contested measure was not only in breach of Article 2.2 but also that it could not fall

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[566] *EC – Hormones*, AB Report, at paras 123-125. The EC had until 13 May 1999 to bring its measure into conformity with its obligations under the SPS Agreement. That deadline was not met. For an account of the current status of the dispute see D. Wüger, *The Implementation Phase in the Dispute Between the EC and the United States on Hormone-Treated Beef*, supra note 177, and for the most recent developments, see A. Alemanno, *Judicial Enforcement of the WTO Hormones ruling within the European Community: Toward an EC Liability for the non-implementation of WTO Dispute Settlement Decisions*, supra note 502, at 547.

[567] The EC simply stated that the precautionary principle is already a general customary rule of international law or at least a general principle of law and that it applies not solely in the management of risk, but also in the assessment of it. In the light of the above, it claimed that the Panel erred in law in holding that the precautionary principle was only relevant for "provisional measures" under Article 5.7 SPS.

[568] Scott and Vos, supra note 43, at 279.

[569] *Japan – Agricultural Products*, AB Report, para 80.

within the scope of Article 5.7 to the extent Japan had not met the fours cumulative requirements imposed by this provision[570]. The four requirements are the following:

a) the measure has to be imposed in a situation where the relevant scientific information is insufficient;

b) the measure has to be adopted on the basis of "available pertinent information";

c) the Member which adopted the measure must seek to obtain the additional information necessary for a more objective assessment of risk; and

d) the Member which adopted the measure must review it within a reasonable period of time.

In particular, in the instant case, there was no evidence that Japan had taken the initiative to seek to obtain the necessary additional information. Moreover, the eleven year interval between the introduction of the Japanese program and the WTO claim exceeded the notion of reasonable delay for reconsidering a temporary measure[571].

This finding was later upheld by the Appellate Body, who confirmed that these four cumulative requirements have to be met in order to validly invoke the precautionary principle under Article 5.7 SPS[572]. To support this finding, the Appellate Body argued that, as an exception, Article 5.7 SPS should be given a narrow meaning and that therefore, if one of the requirements is not met, then the measure must be found to be inconsistent with the SPS Agreement. According to *a contrario* reasoning, one may argue that if Japan had not failed to carry out the affirmative duty to review its varietal testing requirement within a reasonable period of time, the AB would have upheld the Japanese precautionary measure.

Among the requirements imposed by the Appellate Body for adopting precautionary action, the first (insufficient scientific evidence), which triggers the invocation of the principle, is without doubt the most controversial. After confirming the need for those

[570] *Japan – Agricultural Products*, Panel Report.
[571] *Japan – Agricultural Products*, AB Report, para 143(b).
[572] *Ibid.*, para 89.

four cumulative requirements to validly invoke Article 5.7, the Appellate Body in the *Apples* case mainly addressed the "insufficiency" requirement.

In the *Apples* case, it was argued by Japan that its quarantine measures, being provisional, were consistent with Article 5.7 because, despite accumulated scientific evidence, "unresolved uncertainty" remained which science could not solve[573]. The Panel held that Japan could not validly invoke Article 5.7 to justify its measures because, as regard the risk of transmission of fire blight through apple fruit, one might no said that there was insufficient scientific information[574]. It observed that "scientific studies as well as practical experience have accumulated for the past 200 years"[575] on this question and that, while analyzing the respect of Article 2.2 SPS, it had come across an "important amount of relevant evidence"[576]. Stating that Article 5.7 was "designed to be invoked in situations where little, or no, evidence was available on the subject matter at issue", the Panel concluded that the measure was not imposed in respect of a situation where relevant scientific evidence is insufficient within the meaning of Article 5.7[577].

The Appellate Body endorsed this reading of Article 5.7 by confirming that the standard of sufficiency under the first requirement of the abovementioned test refers to the measure of information necessary to perform an adequate assessment of risks as provided for by Article 5.1[578]. In particular, the Panel found that, with regard to fire blight "not only a large quantity of but a high quality scientific evidence has been produced over the years"[579]. Against this backdrop, the AB concluded that this body of available scientific evidence "permitted, in quantitative and qualitative terms, the performance of an assessment of risk, as required under Article 5.1 and as defined in Annex A to the SPS Agreement, with respect to the risk of transmission of fire blight through apple fruit

[573] In reality, Japan relied on Article 5.7 only in the event that the Panel rejected Japan's view that "sufficient scientific evidence" exists to maintain the measure within the meaning of Article 2.2. This explains why the Panel assigned the burden of proof to Japan to make a prima facie case in support of its position under Article 5.7. This particular aspect has not been challenged in appeal.
[574] *Japan – Apples Panel Report*, paras 8.221 – 8.222.
[575] *Ibid.*, para 8.219.
[576] *Ibid.*, paras 8.216.
[577] *Ibid.*, paras 8.219.
[578] *Japan – Measures Affecting the Importation of Apples* WT/DS245/AB/R AB Report adopted 10 December 2003, para 179.
[579] *Japan – Apples* Panel Report, paras 8.219.

exported from the United States to Japan"[580] and therefore the "relevant scientific evidence" is not "insufficient" within the meaning of Article 5.7 SPS.

The reasoning followed by the Appellate Body in this case carries the potential of diluting the scope of the precautionary principle as it has been conceived, interpreted and applied within the EC, by dramatically obliterating its main precondition: scientific uncertainty.

In rejecting Japan's contentious, according to which Article 5.7 is intended to address also "unresolved uncertainty", i.e. uncertainty that that the scientific evidence is not able to resolve, despite accumulated scientific evidence"[581], the Appellate Body reduced the scope of precautionary action to "situations where little, or no, reliable evidence was available on the subject matter at issue". In particular, the Appellate Body stated that

> "the application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence. The text of Article 5.7 is clear: it refers to 'cases where relevant scientific evidence in insufficient', not to 'scientific uncertainty'. The two concepts are not interchangeable" [582].

This narrow reading of Article 5.7 seems to heavily constrain the margin for precautionary action within the WTO/SPS food safety framework. In fact, this interpretation would rule out from the scope of Article 5.7 all those situations in which notwithstanding the existence of a "more than little" quantity of scientific evidence, scientific uncertainty persists. Thus, for instance, the present considerable amount of scientific studies regarding the actual or potential effects of GMOs on human health and on the environment would not be regarded as justifying precautionary action under Article 5.7 of the SPS Agreement[583].

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[580] *Japan – Apples*, AB Report, para 182.
[581] *Ibid.*, para 183.
[582] *Ibid.*, para 184.
[583] This may particularly relevant in the *EC-Biotech* case pending before the WTO DSB, supra note 7, where the EC has maintained that Member States "product-specific moratoriums" (safeguards measures authorized by Article 16(1) of Directive 90/220/EC and Article 12(1) of Regulation No 258/97) are provisional measures pending a full assessment at EC level and therefore fall to be assessed under Article 5.7. As the EC has exclusive competence upon trade in goods, the action has been taken against the EC even if the allegedly wrong-doing is perpetrated by the EC Member States.

By shifting the focus of precautionary action from the "knowledge" requirement to the "insufficiency" or "unreliability" conditions, the AB seem to have considerably altered the scenarios which may justify precautionary action within the WTO.

Following the AB's interpretation of Article 5.7 in the *Apples* case, it has been argued that "contrary to popular perception, it is not Article 5.7 of the SPS Agreement that allows for a precautionary approach, but the provisions of the Agreement on risk assessment"[584]. According to this view, risk assessment, being a tool for the evaluation of risks, creates by itself tremendous scope for precaution so that Article 5.7 could have only been intended to deal with "emergency" situations, situations in which there has not yet been the time for scientific research[585].

Although this interpretation of Article 5.7 may find some support in the negotiating history of the SPS Agreement[586], there are some doubts whether it will be confirmed by the upcoming WTO judicial bodies' decisions. This is so because the AB's reasoning is so decidedly non-definitive that is not, accordingly, possible to say whether it represents a veritable, and definitive, dismissal of scientific uncertainty from the WTO/SPS legal system. The pending *Biotech* case is likely to shed some light on the interpretation of the conditions that trigger Article 5.7.

This narrow interpretation of Article 5.7 would also seem to conflict with the definition of precautionary action contained in the Cartagena protocol on Biosafety to the Convention on Biological Diversity[587]. In particular, Article 10.6 of this Protocol refers to "lack of scientific certainty due to insufficient relevant scientific information and knowledge" as the basis for taking precautionary action". According to this view, precautionary action would be justified every time "the insufficient scientific information" would give rise to "scientific uncertainty". This may, in turn, to be due to two different circumstances: either *after* having conducted a risk assessment there is still

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[584] D. A. Motaal, *Is the World Trade Organization Anti-Precaution?*, in Journal of World Trade, 39(3), at 496.
[585] Motaal, supra note, at 496.
[586] Marceau and Trachtman, supra note 473, at 848, footnote 143 reporting a discussion with G. Stanton, Secretary of the SPS Committee.
[587] Cartagena protocol on Biosafety to the Convention on Biological Diversity, signed in Montreal on 29 January 2000 and entered into force on 11 September 2003. For an analysis of "precautionary action" under the Cartagena Protocol, see R. Hill, S. Johnston and C. Sendashonga, *Risk Assessment and Precaution in the Biosafety Protocol*, in RECIEL, 13 (3), 2004. For an overview on the relationship between the Protocol and the WTO, see O. Rivera-Torres, *The Biosafety Protocol and the WTO*, in 26 Boston College International & Comparative Law Review.

a lack of scientific certainty about the potential effective stemming from a LMOs or *before* conducting a risk assessment there are not enough information to conduct a risk assessment. According to the AB's interpretation of Article 5.7, precautionary action would be allowed solely in the latter situation[588].

Although the Biosafety Protocol rules out *expressis verbis* its supremacy upon the WTO Agreements, by denying its status of *lex specialis* among international trade sources of law[589], it is not excluded that WTO judicial bodies may refer to the Protocol in order to draw inspiration for the interpretation of Article 5.7 SPS[590]. In fact, this outcome is not excluded to the extent the same Appellate Body stated in the first case it came before it that

> "[...] the General Agreement is not to be read in clinical isolation from public international law"[591]. Therefore, to the extent the disputing WTO Parties have ratified the existing Biosafety Protocol they may rely on it as a useful tool for interpreting WTO Members' obligations, for instance their right to take action in the face of scientific uncertainty under Article 5.7 SPS[592].

In conclusion, the review of allegedly precaution-based measures has shown some reticence by the WTO judicial bodies in recognizing the application of the precautionary principle within the WTO/SPS legal system. Precautionary action is not solely perceived as "a qualified exemption" to the scientific evidence regime imposed by Article 2.2 and 5.5 but it is also rigorously constrained by a set of demanding criteria. In other words, both the panels and the Appellate Body seem to privilege measures addressing "scientifically identifiable risks" rather than those facing "uncertain risks".

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[588] S. Zarrilli, *International Trade in GMOs and GM Products: National and Multilateral Legal Frameworks*, Policy Issues in International Trade and Commodities, Study Series No. 29, UNCTAD, at 33.

[589] See Preamble of the Biosafety Protocol where it is stated: "[...] this Protocol should not been interpreted as implying a change in the rights and obligations of a Party under any existing international agreements".

[590] For a more elaborated version of this argument as applicable to the pending EC-Biotech dispute, supra note 7, see L. Boisson de Chazournes and M.M. Mbengue, *GMOs and Trade: Issues at Stake in the EC Biotech Dispute*, in RECIEL, 13(3), 2004, at 298-99; see, also, S. Zarrilli, *International Trade in GMOs and GM Products: National and Multilateral Legal Frameworks*, supra note 588, at 38.

[591] *United States – Standards for Reformulated and Conventional Gasoline*, AB Report, WT/DS2/AB/R, para 19.

[592] S. Zarrilli, *International Trade in GMOs and GM Products: National and Multilateral Legal Frameworks, Policy Issues in International Trade and Commodities*, supra note 588, at 38.

The reasons explaining the WTO courts' reluctance in expressly endorsing the precautionary principle may be found in the following excerpt:

> "[...] the requirements of a risk assessment under Article 5(1), as well as of 'sufficient scientific evidence' under Article 2(2), are essential for the maintenance of the delicate and carefully negotiated balance in the SPS Agreement between the shared, but sometimes competing, interests of promoting international trade and protecting the life and health of human beings"[593].

To reconcile this Statement with the inherently uncertain circumstances underlying the invocation of the precautionary principle does not seem an easy task for any WTO expert. The challenge behind the acceptance of the precautionary principle within the WTO/SPS system is to prove that risk assessment (5.1) and precaution (5.7) are entirely compatible and that they may play complementary roles in the process of decision-making. It will be shown in part IV that the identification of a minimum scientific threshold that each scientific study must satisfy under Article 5.1 may somehow reconcile the scientific uncertainty inherent to precautionary action to the legal certainty required by a legal system.

## 8. NOTIFICATION AND TRANSPARENCY REQUIREMENTS

Article 7 and Annex B of the SPS Agreement deal with transparency of SPS measures. The objective of these provisions is to enable interested Members to become acquainted with all newly adopted SPS measures.

Under Article 7 WTO Members have a duty to notify to the SPS Committee all new SPS measures, and all modifications to existing measures that do not conform to international standards and that produce a significant effect on international trade. Notifications aim to make traders or the regulatory authorities in their countries aware of new legislation that may have a significant effect on trade so they can behave access and, if appropriate, to

[593] *EC – Hormones*, Appellate Body Report, para 177.

submit comments[594]. Between 1995 and 2001, Members submitted more than 2,400 SPS notifications to the WTO, far more than those submitted under the GATT obligations[595]. Annex B provides that WTO Members promptly publish all SPS measures that they adopt and provide an explanation of the reasons for these measures upon request. Members are then directed, except in urgent circumstances, to allow a reasonable period of time between the publication of the SPS measure and its implementation.

Paragraph 3 of Annex B specifically imposes on WTO Members to ensure that one "enquiry point" exists that provides answers to all reasonable questions from interested WTO Members as well as supplying all relevant documents[596].

A footnote to Annex B, paragraph 1, specifies that the publication requirement extends to include "SPS measures such as laws, decrees or ordinances which are applicable generally". This provision has been interpreted extensively by the *Japan-Varietal* panel who stated that: "[...] nowhere does the wording of this paragraph require such measures to mandatory or legally enforceable [...]. This context indicates that a non-mandatory government measure is also subject to WTO provisions in the event compliance with its measure is necessary to obtain an advantage from a government or, in other words, if sufficient incentives or disincentives exist for that measure to be abided by"[597]. This finding was upheld by the Appellate Body in the same case, where it also said that this publishing requirement goes beyond "[...] laws, decrees or ordinances, but also includes [...] other instruments which are applicable generally and similar in character"[598].

## 9 .THE SPS COMMITTEE

The SPS Agreement establishes a committee, the so-called SPS Committee, to monitor and review food safety measures, notably international harmonization activities by

[594] The number of notifications continues to increase. The incorporation to the SPS Agreement of China and other regional trading blocs has also led to an increase in notifications.
[595] Josling, supra note 5, at 60.
[596] Unit SANCO/E03 (International Food, Veterinary and Phytosanitary Questions) is responsible to run the obligations of both the EC SPS Notification Authority (NA) and Enquiry Point (EP).
[597] *Japan – Agricultural Products*, Panel Report, supra note, para 8.111.
[598] *Japan – Agricultural Products*, Appellate Body Report, supra note, para 105.

coordinating this effort with the "relevant international organizations", which presumably include the Codex, IPPC and OIE[599].

The Committee does not only ensure a correct implementation of the agreement by examining compliance issues, but it also provides a forum for information exchange and discussion on issues affecting trade in food. This committee, open to all WTO Members, normally meets three times a year, with informal or special meetings.

Conformingly to Article 12.4 SPS the Committee has adopted throughout the time procedures to monitor the use of international standards.

The role of this Committee heavily relies upon the Codex, IPPC and OIE's activities. The Committee is expected to work with the "relevant international organizations" to develop a list of international standards, guidelines and recommendations that affect international trade[600].

[599] Article 3.5 SPS.

[600] Article 12, paragraph 4, provides that: "[t]he Committee shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations. For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by Members of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported products conforming to these standards can enjoy access to their markets. For those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member should provide an indication of the reason therefore, and, in particular, whether it considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection. If a Member revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the Secretariat as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B".

# PART III

# JUDICIAL REVIEW OF FOOD SAFETY MEASURE WITHIN THE EC AND WTO

## Introduction

Where the previous two parts of this work provided an in-depth analysis of the food safety regulatory disciplines existing within the EC and in the WTO, this part expands on that analysis by focusing on the role played by science within their respective regime. In particular, chapter II examines how the EC and WTO food disciplines have been interpreted by their respective judicial bodies, by focusing on the issue of judicial review of science-based measures.

As seen above, at the time of SPS negotiations, rather than relying solely on discrimination to identify illegitimate health regulations, Member States decided to choose a neutral-value criterion such as scientific evidence. Similarly, also the EC courts, followed by the EC legislators, began quite soon to refer to science as the main organizing criterion allowing distinguishing between legitimate and illegitimate health measures.

As a consequence, since both the WTO and the EC require the presence of scientific justification to determine the legitimacy of national (and supranational) food safety regulations to avoid disguised forms of protectionists[601], their courts are increasingly called upon reviewing the scientific soundness (whether a scientific justification exists) of these measures while assessing their legality.

But how a judge, by definition a non scientist, may conduct an assessment on whether a measure is scientifically supported?

Which is the level of intensity of the scrutiny that this judge may exert over the risk regulation being reviewed?

[601] The broad area of public health measures is unique for the moment in its explicit invocation of scientific and quasi-scientific notions, such as the elements identifying their correctness.

These questions are currently sources of endlessly controversy in the international legal arena[602] and at the centre of some international trade disputes[603].

Their answers are relevant to the extent they determine not only the immediate outcome of some legal disputes, but also how much regulatory autonomy WTO and EC Members enjoy in regulating to protect the health of their people, notably by adopting food safety regulations. This final question is obviously more sensitive within the WTO framework than within the EC, where not only EC courts[604] have more adjudicatory power, but also Member States have transferred regulatory competences to the EC.

Chapter 1 provides an overview of the scientific justification disciplines existing within the EC and the WTO by summing up the main obligations imposed by their food safety risk regulations regimes. After having briefly introduced the issue of judicial review in both legal systems, the following chapter focuses notably on the standards of review applied by the EC and WTO courts to science-based measures. It then sketches out the level of scientific involvement required from the respective courts.

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[602] See C.D. Ehlermann, *Six Years on the Bench of the "World Trade Court": Some Personal Experiences as Member of the Appellate Body of the World Trade Organization*, in 36 J. World Trade (2002) 605, at 612-13, who, while leaving the organ, has noted that "during the last months, the question of standard of review has thus become one of the most controversial aspects of the Appellate Body's jurisprudence".

[603] See, for instance, the Biotech dispute opposing the US, Canada, and Argentina against the EC regarding its alleged general moratoria (the product specific moratoria and the national bans) on the importation of genetically modified organisms. See supra note 7 .

[604] For the purpose of this work, the term "EC courts" means the European Court of Justice (ECJ) and the Court of First Instance (CFI), both based in Luxemburg.

# CHAPTER I: RISK REGULATIONS IN EC AND WTO LAW

## 1. THE EC AND SCIENTIFIC JUSTIFICATION

As the analysis of the current food safety regime has shown, scientific evidence is becoming crucial at all stages of the drawing up of new legislation and for the execution and management of existing European and national legislation, especially for national regulations derogating European disciplines. The use of science as one of the sources of evidence to support decision-making is not limited to the food safety field, but it is relevant in a wide range of other policy areas, such as emission limits, environmental protection, fishing quotas, consumer protection and worker safety.

### 1.1 The origins

Originally, the 1957 Treaty of Rome did impose neither on the EC institutions nor on Member States a duty to justify their health, safety, environmental protection measures scientifically. Rather, its text did not contain any reference to scientific justification.
However, as Member States began invoking Article 36 (current Article 30) of the Treaty of the European Community, allowing them to adopt restrictions on trade justified on grounds of protection of health[605], they often turned in scientific evidence to the European Court of justice in order to demonstrate that their measures were covered under this exception. Thus, in the *Beer Purity case*[606], Germany, after having banned the marketing of beer containing all additives (not just some additives for which there was

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[605] See supra Part I, Chapter 1, 1. The exceptions: Article 30 EC. While Article 28 prohibits Member States to adopt quantitative restrictions on imports and all measures having an equivalent effect to a quantitative restriction, Article 30 "shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property".

[606] Case 178/84, Commission v. Germany [1987] ECR 1227.

evidence of risks)[607], tried to justify its measure by arguing not only that Germans drank a lot of beer but also that the long-term effect of additives was unknown. To support its scientific claim, Germany also cited experts' reports referring to the risk inherent in the ingestion of additives in general[608]. In the same case, not only the parties but also the Court hinted at the scientific element. The ECJ, referring to the previously decided *Sandoz*[609], *Motte* [610]and *Muller*[611] judgments, held that the possibility for a Member State to restrict the free movement of a foodstuff legally marketed in another Member States is subject to "the *findings of international research*, and in particular of the work of the Community's scientific committee for food, the *Codex alimentarius* committee of the FAO and the World Health Organization"[612]. After having deferentially referred to the scientific findings of these entities, the Court found that the additives did not present a risk to public health and also that the German policy was inconsistent to the extent it allowed the use of these same additives in other drinks.

Yet, whilst Member States must respect the findings of these scientific international organizations, the Court allows departing from them to the extent there is some scientific uncertainty[613].

Thus, without being formally introduced within the Rome Treaty, a *de facto* scientific requirement imposed itself in the regulatory practice developed around Articles 28-30 EC as applied to food regulations. While the Court recognized that the " health and the life of humans rank foremost among the property interests protected by Article 30"[614], it was suspicious of Member States' attempts to invoke health reasons as a means of affording a disguised restriction on trade. In particular, it established that, although not binding, the scientific opinions prepared by the Scientific Committee on Foodstuffs had to be taken

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[607] According to the *Reinheitgebot* (the German beer purity law), originally enacted in 1516 by the Bavarian duke Vilhelm IV, only beer containing the following ingredients could be marketed on the German territory: water, hops, barley, and yeast.

[608] Case 178/84, supra note 26, para 48.

[609] Case 174/82, Sandoz BV [1983] supra note 214. In this case, the Court had to face a Dutch refusal to grant authorization for the importation of muesli bars with added vitamins from Germany (where they were lawfully sold). For a comment of this case, see M.M. Slotboom, *Do Public Health Measures Receive Similar Treatment in European Community and World Trade Organisation Law?*, in Journal of World Trade (2003) 553, at 557.

[610] Case 247/84 Motte [1985] ECR 3887. This concerned the import of lumpfish roe prepared with colorants banned in Belgium but allowed in the country of export.

[611] Case 304/84 Ministere Public v Muller and others [1986] ECR 1511.

[612] Case 178/84, supra note 26, para 44.

[613] Case 247/84 Motte [1985] ECR 3887; Case 174/82, Sandoz BV [1983] supra note 214.

[614] Case 104/75 De Peijper [1976] ECR 613, para 15, and Case C-320/93 Ortscheit [1994] ECR 5243, para 16.

into account by Member States while considering for approval or refusal the circulation of a product on their markets.

It is only in 1999 that scientific justification has been expressly inserted in Article 95, paragraph 5, as one of the requirements Member States must satisfy in order to *introduce* a measure derogating European harmonization legislation[615]. In particular, a Member State that deems necessary to introduce a national measure aimed at the protection of the environment after the adoption of a Community measure on the matter, it must provide "new scientific evidence". It is controversial whether this evidence must have necessarily been elaborated after the adoption of the Community measure or could have merely been unknown to the Community legislator at the time of the adoption[616].
Although a similar scientific requirement is not expressly provided with reference to the situation where a Member State does *maintain* a measure derogating an harmonized measure (Article 95, par. 4)[617], it has recently been stated that a

> "Member State may, in order to justify maintaining such derogating national provisions, put forward the fact that its assessment of the risk to public health is different from that made by the Union legislature in the harmonization measure"[618].

Therefore, though the risk assessment provided by the interested party does not have to be "necessarily [...] based on new or different scientific evidence", the mere need to refer to "its assessment of the risk" is enough to constitute a scientific justification test also in this specific scenario. Indeed, the Court has stated that to comply with Article 95, par. 4,

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[615] According to Article 95, paragraph 5, "if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonization measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them".
[616] See, on this point, Commission Decision 1999/830/EC on the Danish request for derogation on the use of os sulphites, nitrites and nitrates in foodstuffs, OJ 1999 L392/1.
[617] The ECJ in Case 3/00, Denmark c. Commission, (ECR 2643) has stated that "the requirement for new scientific evidence [...] is not one of the conditions imposed for maintaining such provisions" (Article 95, par. 4 ECT).
[618] *Ibid.*, para 63.

"it falls to the applicant Member State to prove that those national provisions ensure a level of health protection which is higher than the EC harmonization measure and that they do not go beyond what is necessary to attain that objective"[619].

In conclusion, Member States must today scientifically justify their measures not only when they act outside from a harmonized area, by relying on Article 30 ECT, but also when, after the adoption of a harmonization measure, they deem it necessary to maintain or introduce a national provision derogating the European one. However, to discourage Member States from adopting diverging national standards susceptible to restrict the free movement within the internal market, the EC legislation has been setting up very high standard of health and environmental protection[620]. Accordingly, as we have seen above, should a Member States be willing to introduce a national provision setting up a stricter a higher level of protection than that attained by the EC legislation, its measure should be "based on new scientific evidence"[621].
It results that an embryonic and "de facto" scientific discipline has evolved throughout the time to resist national protectionism, thus permitting the establishment of the internal market.

In the meanwhile, the scientific justification discipline originally developed in relation to Member States measures based on public health had been extended to the acts adopted by the European institutions. In 1997, when the aim to achieve a "high level" of health and environmental protection was given the status of a general objective in the EC Treaty (Article 3(1) (p)), Article 100a (current 95 EC) was amended in order to precise that this objective should be pursued and based on "scientific facts"[622]. It must be observed that, already in the late 70s, the ECJ's case law established that the Treaty prohibitions on restriction on free trade within the Union did not apply only to Member States but also to the EC itself[623]. In other words, a Community measure enacted on the basis of one of the

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[619] *Ibid.*, para 64.
[620] Christoforou, *Science, Law and Precaution in Dispute Resolution on Health and Environmental Protection: What Role for Scientific Experts?*, supra note 177, at 239.
[621] Article 95, paragraph 5, ECT.
[622] Article 100a(3) of ECT, current Article 95, paragraph 3.
[623] Case 80-81/77 Ramel [1978] ECR 927 followed by Case 179/78 Rivoira [1979] ECR 1147; Case 218/82, Commission v. Council (rum quotas) [1983] ECR 4063;Case 15/83 Denkavit [1984] ECR 2171 and Case 216/84, Commision v. France [1988] ECR 793; Case C-47/90, Delhaize [1992] ECR I-3669; Case C-388/95, Belgium v. Spain 2000 ECR I-3123. For a systematic approach to the relationship between primary and

Treaty articles concerning the realization of the internal market, such as Article 95 EC, must be in conformity with the prohibitions concerning free movement. However, insofar as the EC health measures are non-discriminatory, these should not be prohibited and thus fall outside the scope of Article 28-30 ECT regardless of whether they have a negative effect on trade between Member States[624]. Nowdays, being the scientific requirement being expressly imposed on the Community institutions, such a privileged status of EC legislation vis-à-vis the scientific element has disappeared.

### 1.2. The codification of the scientific justification requirements: from scientific evidence to risk assessment

Thus, since 1999, when the Amsterdam Treaty entered into force, all Community's legislation concerning health, safety and environmental protection and consumer protection (including food regulations) should aim at achieving a high level of protection by "taking account in particular of any development based in scientific facts"[625]. Notably, EC policy on the environment aiming at a high level of protection should "take into account of available scientific and technical data"[626]. This is because the Commission intends "to use this advice for the benefit of the consumer in order to ensure a high level of protection of health"[627]. As the Commission has pointed out in its 1997 Communication on Consumer Health and Food Safety

> "scientific evidence is of the utmost importance at all stages of the drawing up of new legislation and for the execution and management of existing legislation"[628].

Recently, scientific justification has been expressly defined as "an essential requirement for Commission proposals, decisions and policy" relating to consumer safety, public

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secondary law in the context of the internal market, see K. Mortelmans, *The Relationship Between the Treaty Rules and Community Measures for the Establishment and Functioning of the Internal Market – Towards a Concordance Rule*, in 39 Common Market Law Review, 1303-1346, 2002.

[624] This is a controversial point since the Court has not as yet explicitly dealt with the question whether the prohibitions are more limited vis-à-vis the EC legislature as compared with the Member States. For an apparently limited interpretation see, for instance, Case C-180/96 UK v Commission [1998] supra note 112 and R. Barents, *The Agricultural Law of the EC*, 1994, at 20-21. Contra, Mortelmans, supra note 623, at 1322.

[625] Article 95, paragraph 3, ECT. See also, Articles 152 (1) and (4), 153, 174 (2).

[626] Article 174, paragraph 3, ECT.

[627] Communication from the Commission on Consumer Health and Food Safety, supra note 117.

[628] *Ibid.*

health and the environment[629]. To fulfill its function scientific advice on matters relating to consumer health must be based on the principles of excellence, independence and transparency[630].

These are the only references contained in the Treaty laying down a general duty for the EC and the national decision-makers to provide for scientific justification while adopting legislation concerning consumer safety, public health and the environment. However, as seen in the food sector, this mandatory requirement to base regulation on science has been extended to all secondary legislation regulating risk[631]. More precisely, the scientific justification requirement has developed in greater detail not only in the food safety regulations but in all risk-related secondary legislation, thus evolving into a better defined risk assessment requirement. As seen above, risk assessment represents the first step of the traditional structure approach to risk analysis and consists in a scientifically based process, which in turn, is based on four stages: hazard identification, hazard characterization, exposure assessment and risk characterization.

Nowdays, risk assessment procedures can be found not only in food safety but also in areas such as worker health and safety[632], dangerous substances[633], medicinal products, GMOs[634], biocides[635], contaminants, pesticides[636], food additives[637], water protection[638], etc.

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[629] See Commission Decision of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment, 6 recital of the Preamble.
[630] Communication from the Commission on Consumer Health and Food Safety, supra note 117, and Commission Communication on the precautionary principle, supra note 215.
[631] Christoforou, supra note 177, at 240.
[632] Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemicals, physical and biological agents; Directive 89/391/EEC on the introduction of measures to encourage the improvements in the safety and health of workers at work; Directive 90/391/EEC on the protection of workers from the risks related to exposure to carcinogens at work.
[633] Risk assessment of existing chemicals is provided by Council Regulation 793/93 and Commission Regulation 1488/94. As for new chemicals, risk assessment procedures are imposed by Commission Directive 93/67/EEC laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Directive 67/548/EEC.
[634] See Articles 4(1) and (2) of Directive 2001/18/EC on the deliberate release of GMOs,
[635] Directive 98/08/EC concerning the placing of biocides on the market.
[636] The 1998 Rotterdam PIC Convention refers to "risk evaluation" as a precondition for regulatory action.
[637] Directive 89/107/EEC concerning food additives authorized for use in foodstuffs intended for human consumption according to which the food additive must be subjected to appropriate testing and evaluation.
[638] See Article 16(2) of Directive 2000/60/EC establishing a framework for Community action in the field of water policy.

As noticed above, being the European Union a WTO Member together with its Member States, it is also subject to those further scientific constraints set forth by the WTO/SPS Agreement. Measures to protect the health and life of humans, animals and plants must be based on a scientific risk assessment and not maintained without sufficient scientific evidence. Moreover, international standards must be followed unless there is a scientific justification for a more stringent measure.

### 1.3. The use of scientific evidence within the EC

The EC institutions' effort to improve the quality and the credibility of the scientific data they rely upon in the decision-making process has not been limited to the food safety area. Thus, besides EFSA, it has been established also a risk assessment agency for medicines (EMEA)[639]. Furthermore, the whole Scientific Advisory Committee structure has been reorganized and new committees have been established[640]. Finally, policies and guidelines for the use of scientific advisors have been developed by the EC Commission. Notably, this growing scientific advice policy is contained in three main documents: the Science and Society Action Plan (2002), the Commission Communication on the Collection and Use of Expertise (2002)[641], and the Commission Decision to set up Scientific Committees in the Fields of Consumer Safety, Public Health and the Environment (2004)[642]. These documents impose "sound and timely science" as an essential requirement for risk management in the areas of consumer safety, public health and the environment and they recommend a set of guiding 'core principles' for the collection and use of scientific expertise by the Commission departments: quality, openness, effectiveness, independence, pluralism, excellence, impartiality, proportionality and transparency.

[639] Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, O. J. L 214 of 24 August 1993.
[640] The Scientific Committee on Consumer Products (SCCP); the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).
[641] European Commission, COM(2002) 713 final of 11 December 2002.
[642] European Commission, Decision 2004/210/EC of 3 March 2004, OJ L66, p. 45.

Notwithstanding these institutional and normative efforts, there is currently no common system providing scientific advice to the EC policy-makers. Scientific support is rather ensured through a range of different mechanisms depending on the relevant policy area. The most common sources of advice used to support the EC policies, legislations and regulatory decisions are the following: formal scientific committees under the control of the Commission Health and Consumer Protection Directorate General (DG SANCO), scientific committees within EFSA and EMEA; reports by advisory agencies, such as the European Environmental Agency (EEA); reports provided by external consultants (individuals, groups or companies, possibly using study contracts); national reports provided by Member States' advisory bodies; reports by ad-hoc expert groups; in-house analysis conducted by Commission officials; reports and opinions by the Joint Research Centre (JRC) and the Scientific and Technical Options Assessment group in the European Parliament (STOA).

It is in the light of the above that since 2000 some efforts have been aimed at setting up a harmonized approach to risk assessment procedures among the Scientific Committees advising the European Commission in the area of human, animal and plant health and on the environment[643]. The risk analysis sketched out by Regulation 178/2002 constitutes without doubt the main source of inspiration for the drawing up of these general guidelines. Moreover, in order to promote some consistency in the delivery of advice from so many different sources of expertise, the abovementioned Commission Communication on the Collection and Use of Expertise established a set of core principles and guidelines applicable to all expertise intervening at all stages of Commission policy-making. Thus, whenever the Commission departments collect and use advice of experts coming from outside the responsible department they should ensure quality, by seeking the advice from an appropriately high quality source (i.e. excellence, independent and pluralism), openness, by showing flexibility while looking for advice, and effectiveness, by making sure that its methods for collecting and use of expert advice are effective[644]. However, these principles and guidelines are not legally binding. Nor they do apply to the formal stages of decision-making as provided by the Treaty and in other EC legislation. Therefore, not only the formal legislative procedures but also the

[643] According to the Updated Opinion of the Scientific Steering Committee on Harmonization of Risk Assessment Procedures, adopted on 10-11 April 2003, a full Second Report on the Harmonization of Risk Assessment Procedures is currently under editing and will be published shortly.

[644] European Commission, COM(2002) 713 final of 11 December 2002, at 8-10.

formal exercise of the Commission's implementing powers through the 'comitology' committees are excluded.

### 1.4. Conclusions

While the EC case law has made clear since 1970s that, in absence of EC harmonization, any national measure purporting to regulate risk should be based on scientific evidence and respect proportionality[645], it is only in 1999 that European harmonized risk regulations have explicitly been subject to similar constraints. According to Article 95, par. 3 ECT, EC health and environmental protection regulations must take "as a base a high level of protection, taking account in particular of any new development based on scientific facts".

As to the harmonized areas, similarly to what happen within the WTO context with reference to international standards, when a Member States wants to achieve (by maintaining or by introducing a national measure) a level of protection which is higher than that ensured by the EC harmonization measure, it has to base its provision on scientific evidence. Furthermore, this mandatory requirement to base regulation on science has been extended not only to food safety regulations but also to all secondary legislations regulating risk, which contain detailed provisions on how to conduct a risk assessment in the different policy areas, such dangerous substances, medicinal products, contaminants, pesticides, GMOs, food additives, etc. As it has been argued, "in the EC legal system, regulatory action is nearly always based on a risk assessment of the highest possible quality"[646]. This is crucial not only to satisfy consumer protection interests but also to prevent Member States from systematically relying on Article 95 safeguards clauses thus disrupting the functioning of the internal market.

As for the respect of the 'core principles and guidelines' as set forth by the Communication on the collection and use of expertise by the Commission is not subject to judicial review, but it merely represents a moral commitment by the Commission departments while they rely on expertise.

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[645] Christoforou, *The Precautionary Principle, Risk Assessment, and the Comparative Role of Science in the European Community and the US Legal Systems*, supra note 207, at 31.

[646] See, on this point, Christoforou, *Science, Law and Precaution in Dispute Resolution on Health and Environmental Protection: What Role for Scientific Experts?*, supra note 177, at 222.

Finally, if the requirement that a risk analysis be conducted to show the potential danger of a certain substance has been introduced by the Court's case law in order to primarily ensure a proper functioning of the internal market, the same requirement has subsequently been codified and incorportated within both EC primary and secondary law in order to ensure also another legitimate objective: a high level of protection of health within the Community.

## 2. THE WTO AND SCIENTIFIC JUSTIFICATION

### 2.1 The origins

As the WTO's involvement with health and environmental risk regulation is of even more recent origin and by far less relevant than in the EC, its scientific justification discipline is, at least from a normative perspective, less developed. There are only two WTO agreements that make an explicit reference to "science", the Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application on Sanitary and Phytosanitary Measures (SPS). As for the GATT, although Article XX GATT - similarly to Article 30 EC - allows Member States to adopt measures restricting the free flow of goods when it is necessary to protect human, animal and plant health (Article XX (b)) or to conserve natural exhaustible resources (XX (g), it does not make any reference to science. Therefore, at least in principle, under this Article, Member States may adopt health or environmental related measures without being asked to justify them scientifically. Nonetheless, in practice, it would be difficult for the defendant to satisfy its burden of proof that its measure is "necessary" for the protection of health without resorting to scientific evidence. In fact, States in the past have often turned in scientific evidence to the WTO in order to demonstrate that their measures were covered under the exceptions provided by Article XX (i.e. not discriminatory, but truly health or environmental related). Thus, for instance, already in the *US - Gasoline* case, involving a US measure applying stricter rules on the chemical characteristics of imported gasoline than it did for domestically refined gasoline, it has been established that "inasmuch as they include the notion of "protection", the words "policies designed to protect human life or health" imply the existence of a *health risk*" and that, accordingly, the plaintiff must

determine whether the prohibited product poses a risk to human life or health[647]. In the following *Shrimp-turtle* case[648], after the US prohibited the imports of shrimps harvested with technology that may adversely affect certain sea turtles[649], it tried to justify its ban by referring to a multitude of national (mainly by the National Research Council) and international-led studies proving that all species of turtles face the danger of extinction.
In the *EC - Asbsestos* case, the panel has clearly established that the invoked health risk under Article XX must be proved[650]. Notably, in determining "how should assess the existence of a health risk"[651], it has stated that while "it is not its function to settle a scientific debate, not being composed of experts in the field", "it should base its conclusions with respect to the existence of a public health risk on the scientific evidence put forward by the parties and the comments of the experts consulted"[652].

## 2.2 The SPS discipline

Since 1995, when the the WTO came into being, two additional Agreements also apply to health regulations: the TBT and SPS. While the SPS Agreement expressly identifies itself as an elaboration of GATT Article XX (b), the TBT does not. Nevertheless, both Agreements have been designed to deal with the same kind of measures: those inspired by the protection of human, animal or plant life or health. Notably, these Agreements have been established to prevent technical legislation which is intended for the protection of the human health or safety, the protection of the health or life of humans animals or plants, consumer protection against deceptive practices and environmental protection being used to create or resulting in unjustified barriers to international trade[653].

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[647] *United States - Standards for Reformulated and Conventional Gasoline* Appellate Body report WT/DS2/AB/R and *United States - Standards for Reformulated and Conventional Gasoline* WT/DS2/R Panel report as modified by the Appellate Body report.
[648] *United States - Import Prohibition of Certain Shrimp and Shrimp Products* WT/DS58/R, paras 73-119, available at http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm#r58
[649] This unless the harvesting nation was certified to have a regulatory program and an incidental take-rate comparable to that of the US, or that the particular fishing environment of the harvesting nation did not pose a threat to sea turtles.
[650] *EC- Asbestos*, Panel Report, paras 8.170 and 8.177.
[651] *Ibid.*, para 8.180.
[652] *Ibid.*, para 8.182.
[653] Since the 1979 Tokio Round some countries feared that the lowering of border measures would be circumvented by disguised protectionist measures in the form of technical regulations, notably sanitary and phytosanitary regulations. For this reason already in that occasion it was adopted a Plurilateral Agreement on Technical Barriers to Trade, also called "Standards Code". See M. Trebilcock and R. Howse, *The Regulation of*

In order to attain this goal, the Agreements lay down a number of principles: the measures of the contracting countries should have a legitimate objective[654]; the measures adopted should be appropriate or proportionate to those objectives[655], there should be no alternatives which cause less disruption to international trade and there should be no discrimination[656]. Measures that conform to international standards are presumptively consistent with WTO obligations[657].

In particular, Article 2.2 TBT stipulates that: "technical regulations shall not be more trade restrictive than necessary to fulfill a legitimate objective, taking account of the risks that non-fulfillment would create". In other words, this Agreement asks countries to only adopt product regulations that are 'proportional' ("take into account") to the risks that are trying to address. The same Article states that

> "in assessing such risks, relevant elements of consideration are, *inter alia*: *available scientific and technical information*, related processing technology or intended end-uses of products".

While the TBT refers to science exclusively as one of the elements to be taken into account in assessing the 'proportionality' of a contested measure, the SPS requires Member States to base their measures on science, by going into what that science should entail. So, which are the requirements of the SPS Agreement with respect to science?

In particular, the primary scientific justification requirement may be found in Article 2.2 SPS. That Article requires that any Member States' sanitary and phytosanitary measure be "based on scientific principles and it is not maintained without sufficient scientific evidence".

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*International Trade*, (London-New York, Routdlege, 1999) at 145. See also Marceau and Trachtman, *The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tariff and Trade, A Map of the World Trade Organization Law of Domestic Regulation of Goods*, supra note 473, at 811-881.

[654] While Article 2.2 TBT affirms that: "[...] Such legitimate objectives are, *inter alia:* national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment", Article 2.2 SPS refers solely to the legitimate objective "to protect human, animal or plant life or health".

[655] Articles 2.2 TBT ; 2.2 SPS ("only to the extent necessary").

[656] Articles. 2.1 TBT; 2.3 SPS.

[657] Articles 3.1 TBT; 3.2 SPS.

Furthermore, Article 5 SPS translates this duty in operational terms by providing that countries should ensure that their measures be "based on an *assessment*, as appropriate to the circumstances, *of the risks* to human, animal or plant life or health". This requirement constitutes an attempt by the SPS framers to set up some common structure on the way in which WTO Members enact SPS measures.

The panels and AB have elaborated on these requirements, by interpreting them cumulatively[658] as requiring that there must be an "objective or rational relationship" between the SPS measure and the scientific evidence[659]. Therefore, these two SPS obligations focus on the capability of the measure to tackle the health concern. The WTO judicial bodies are called to determine to what extent the measure at issue is reasonably related to the public policy goal it pursues.

Furthermore, the AB offered some further clarification on how to apply this test: "whether there is a rational relationship between an SPS measure and the scientific evidence is to be determined on a case-by-case basis and will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence"[660].

The country adopting an SPS measure, therefore, is entitled to determine the appropriate level of protection[661], subject to this rational relationship constraint.

However, the meaning of "based on" risk assessment in Article 5.1 soon revealed difficult to interpret[662]. Is this a substantive and/or a procedural requirement? In other

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[658] *EC - Measures Concerning Meat Products* Appellate Body Report WT/DS26/AB/R, WT/DS48/AB/R adopted on 13 February 1998, para 160 – 168; confirmed by *Japan - Measure Affecting Agricultural Products* WT/DS76/AB/R AB Report adopted 19 March 1999, para 76 (hereinafter: *Japan - Agricultural Products*); confirmed also by where the Appellate Body has stated that "the context of the word 'sufficient' or, more generally, the phrase 'maintained without sufficient scientific evidence' in Article 2.2, includes Article 5.1, as well as Articles 3.3 and 5.7 of the SPS Agreement. See, notably, para 82.

[659] *EC - Hormones* AB Report, para 189; then confirmed in *Measure Affecting Agricultural Products* Panel Report WT/DS76 para 8.29, 8.42; *Japan - Agricultural Products* AB Report, para 82.

[660] *Japan - Agricultural Products*, para 84.

[661] This freedom has been recognized not only by Article SPS but also by the AB in *Australia – Salmon*. In its report, the AB has stated that the panel or AB should not substitute its own reasoning about the implied level of protection for that expressed consistently by Australia. See para 199.

[662] This question arose in the first SPS case that reached the DSB: the Hormones case, supra note 61. For an overview of the *Hormones* case, see Wüger, *The Implementation Phase in the Dispute Between the EC and the United States on Hormone-Treated Beef*, supra note 177 and for a follow-up of the case, see Alemanno, *Judicial Enforcement of the WTO Hormones ruling within the European Community: Toward an EC Liability for the non-implementation of WTO Dispute Settlement Decisions*, supra note 502, at 547.

words, to what extent does it impose on Members a duty to conduct a risk assessment before acting?

Although the panel in the *Hormones* case has interpreted this requirement as a "minimum procedural requirement"[663], the AB in the same dispute has rejected this interpretation, by emphasizing the 'substantive requirements' that regulate the adoption of SPS measures, notably that a SPS measure must be justified by science. Thus, the Appellate Body held that, absent national procedural requirements, a Member may rely on a risk assessment conducted by another Member State or by an international organization, and should therefore not carry out its "own risk assessment"[664]. Contrary to a procedural interpretation, this approach promotes greater convergence of Member States' regulatory measures by requiring them to be rationally linked to the results of a risk assessment. At the same time, with a substantive standard, unless a Member adopts the same regulatory measures as those recommended by international bodies, States will need have sufficient technical capability to verify that there is an objective and rational relationship between the scientific data available and the measures they wish to adopt[665].

In the same case, the Appellate Body also rejected the panel's narrow view that the measures must *conform* to the scientific conclusions reached in the risk assessment[666], by stating that this requirement mean that "the results of the risk assessment must sufficiently warrant – that is to say, reasonably support – the SPS measure at stake"[667]. As to the degree of rational relationship between the measure and the risk assessment, the AB made the following Statement:

> "We do not believe that a risk assessment has to come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure. The risk assessment could set out both the prevailing view representing the "mainstream" of

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[663] The panel found that "[...] there is a minimum procedural requirement contained in Article 5.1". It went on "In our view, the Member imposing a sanitary measure needs to submit evidence that at least it actually took into account a risk assessment when it enacted or maintained its sanitary measure in order for that measure to be considered as based on risk assessment". See *EC - Measures Concerning Meat and Meat Products (Hormones)* Panel Report WT/DS26/R 1997, at para 8.113.

[664] *Hormones*, AB Report, para 189-190.

[665] However, as shown below, the increasing demand for specific risk assessment puts a limit on the extent to which WTO Members may rely on risk assessment conducted by other countries or international bodies. See Button, supra note 196, at 67.

[666] *Hormones*, Panel Report, para 8.117.

[667] *Hormones*, AB Report, para 193-94 confirmed in *Japan-Agricultural Products* AB Report, para 76.

scientific opinion, as well as the opinions of scientists taking a divergent view. Article 5.1 does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community. In some cases, the very existence of divergent views presented by qualified scientists who have investigated the particular issue at hand may indicate a State of scientific uncertainty. Sometimes the divergence may indicate a roughly equal balance of scientific opinion, which may itself be a form of scientific uncertainty. In most cases, responsible and representative governments tend to base their legislative and administrative measures on "mainstream" scientific opinion. In other cases, equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources. By itself, this does not necessarily signal the absence of a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety. Determination of the presence or absence of that relationship *can only be done on a case-to-case basis*, after account is taken of *all considerations rationally bearing upon the issue of potential adverse health effects*[668].

To sum up, to verify whether a SPS measure satisfies the need for sufficient scientific evidence and the substantive standard required for risk assessment, respectively imposed by Article 2.2 and 5.1 SPS, panels and the Appellate Body must examine whether there is "a rational relationship" between the SPS measure and the scientific evidence. The relationship is to be assessed case-by-case and

> "will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence"[669].

In particular

> "a measure as a whole should be considered to be maintained "without sufficient scientific evidence if one or more of its elements are not justified by the relevant scientific evidence addressing the risk at issue"[670].

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[668] *EC - Hormones*, AB Report, para 194.
[669] *Japan - Agricultural Products* AB Report, para 84.
[670] *Japan - Apples*, Panel Report, para 8.180.

Annex A of the SPS Agreement defines risk assessment as: "The *evaluation of the likelihood* of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the *evaluation of the potential* for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs".

The same article lists some of the factors that should be taken into account: "available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest - or disease - free areas; relevant ecological and environmental conditions; and quarantine or other treatment" (5.2-5.4). In the *EC-Hormones* case, the AB interpreted this list a non-exhaustive[671] and as including non-scientific factors as well[672]. The scientific justification discipline is also contained in Article 3.3, which allows Members to introduce or maintain SPS measures which result in a higher level of protection than that provided for by measures based on international standards but only if they are grounded on a 'scientific justification'.

Finally, the Agreements also deals with situation of scientific uncertainty by stating that

> "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective

[671] AB Report on *EC-Hormones*, para 187 ("there is nothing to indicate that the listing factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a close list").

[672] AB Report on *EC-Hormones*, para 187 ("[...] the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die"). The interpretation of this Statement seems controversial. For a criticism see, *ex multis*, R. Quick and A. Bluthner, *Has the Appellate Body Erred? An Appraisal and Criticism of the Ruling in the WTO Hormones Case*, supra note 512, at 618-9. For a positive comment see R. Howse, *Adjudicating Legitimacy and Treaty Interpretation in International Trade Law: The Early Years of WTO Jurisprudence*, supra note 512, at 64 ss.

assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time".

## 2.3. Conclusions

This overview on the WTO requirements for scientific justification clearly shows that the SPS Agreement is the only WTO instrument that expressly imposes on its Members to base their measures on scientific evidence, regardless of whether the measures are discriminatory[673].

In an effort to eliminate protectionist and unnecessary non-tariff barriers, the SPS Agreement imposes strict scientific justification requirements. By doing so, the Agreement does not only impose a higher justificatory burden on WTO Members wishing to adopt measures aimed at protecting themselves from health risks but it also makes it easier for potential complaining parties to challenge them[674]. In line with the SPS Preamble, no Member is prevented from adopting or enforcing measures necessary to protect human, animal or plant life and health, but it is entitled to take sanitary and phytosanitary measures necessary for the protection of these values, "provided that such measures are not inconsistent with the provision of this Agreement", notably with the scientific justification discipline. However, being these requirements particularly cumbersome, all of the major SPS cases to date - the *Hormones*, *Salmon*, *Agricultural products* and *Apples* cases - have been lost by the defending Member. In particular, the risk assessment discipline sketched out by Article 5 has been pivotal in the functioning of the Agreement during its first years of operation. In all SPS cases to date, the contested national measures have been found to be inconsistent with the risk assessment requirements, i.e, not sufficiently specific or not rationally or objectively related to the

[673] This has been expressly recognized by the same Panel in the *Asbestos* case. See Panel Report, supra note 460, para 8.180. The only difference between justification under Article XX (b) and the scientific evidence requirement in the SPS text is that while under Article XX the defendant bears the burden of proof for justifying its measure, under the SPS it is the plaintiff that has to raise at least a presumption that the contested measure is not based on scientific evidence.

[674] See R. Howse and P.C. Mavroidis, *Europe's Evolving Regulatory Strategy for GMOs – The Issue of Consistency with WTO Law: of Kine and Brine*, 24 Fordham International Law Journal 317, at 320 (who notice that the complainant has to at least raise a presumption that the Member's SPS measure is not based on scientific evidence).

relevant scientific evidence to satisfy Article 5.1. However, it must be observed that in any of these cases national authorities have been found to have wrongly conducted a risk assessment, but rather they had failed to support their measures with either "specific enough" evidence (*Hormones*[675], *Apples*[676]) or with "objective evidence" (*Agricultural products*[677]; *Salmon*[678]). The pending *Biotech Products* case, in which Canada, the US and Argentina have brought an action against the EC regime concerning the approval and marketing of biotech products, is likely to raise similar difficult questions on how to apply the SPS scientific evidence discipline[679].

Before analyzing how and to what extent these scientific justification disciplines have been implemented by the competent courts, the following section provides a comparison between the WTO and EC disciplines, by looking at their respective goals.

## 3. WHY BOTH THE EC AND THE WTO RELY ON SCIENCE?

As seen above, both the WTO and the EC embraced science as the organizing principle while regulating public health measures. Rather than relying solely on non-discrimination as the main criterion enabling them to distinguish between legitimate and illegitimate barriers to trade inspired by public health protection, they introduced a new, more demanding element, with reference to those measures: scientific justification. In particular, the scientific element would ensure that SPS measures address a real, objectively established, health risk and are not protectionist measures disguised as health regulations.

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[675] *EC - Hormones*, AB Report, paras 199-201 (where the Panel rejected general studies of the carcinogenic risk of hormones and suggested that a proper risk assessment of these substances should have been undertaken on an individual basis).

[676] *Japan - Apples*, Panel Report, paras 8.127, 8.277-280 (where the Panel rejected Japan's risk assessment because it did not focus sufficiently on the risk of transmission of fire blight through apple fruit as opposed to other modes of transmission).

[677] *Agricultural products*, AB Report, para 113.

[678] *Australia - Salmon Measures Affecting the Importation of Salmon* WT/DS18/R modified Panel Report, para 8.99; *Australia* - Salmon, AB report, paras 128-135.

[679] See *EC-Measures Affecting the Approval and Marketing of Biotech Products* WT/DS291/1 (US's request for consultation dates back to 20 May 2003); WT/DS293/1 (Canada's request dates back to 20 May 2003) and WT/DS293/1 (Argentina's requests dates back to 21 May 2003). See supra note 7.

According to this vision, scientific justification would be more effective that non-discrimination in spotting protectionist measures and in dismantling sham health measures framed as de facto trade barriers.

However, the current practices of scientific risk assessment do not seem to reflect, thus confirming, this vision. In fact, despite science's promise of value-neutrality, its mechanisms of scientific assessments often rely on science policies, such as assumptions, inferences and techniques, which enable it to overcome uncertainties and fill in gaps inherent to scientific methods[680]. Thus, for example, one of the most common science policies is the presumption that positive effects in animal cancer studies indicate that the agent under study can have carcinogenic potential in humans[681]. Other examples include the use of a linear dose-response model, the assumption that absorption in animals and humans is approximately the same or the use of body weight scaling for interspecies comparisons[682].

Against this backdrop, one may legitimately wonder whether the use of these policies and assumptions may jeopardize the role of scientific justification as the organising principle in the trade-health interface. In particular, this blurred relationship existing between risk management components and scientific justification may render extremely difficult the task of the international adjudicator called to review the legality of these measures.

Apart from these inherent limits of science as determining criterion chosen to distinguish between legitimate and illegitimate measures, the scientific justification disciplines in the EC and in the WTO do not entirely respond to the same logic. While scientific justification in the SPS/WTO system is conceived as an exclusively free-trade mechanism aimed at dismantling not only deliberately discriminate protectionist SPS measures but also those genuine health regulations which are unnecessary because more

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[680] On the role of science policies in risk analysis, see Walker, *Keeping the WTO from Becoming the "World Trans-Science organization": Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute*, supra note 471, at 261-263 and the most recent work from the same Author, *The Myth of Science as a "Neutral Arbiter" for triggering Precautions*, supra note 189, at 198 ss.

[681] See T. O. McGarity, *On the Prospect of "Daubertizing" Judicial Review of Risk Assessment*, 66 Law & Contemp. Probs. 155, at 163 and by the same Author, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 Geo. L. J. 729 (1979).

[682] For an illustration of the most common risk assessment policies used by the Codex's bodies in charge of conducting many of the risk assessment leading to the adoption of the Codex standards (JECFA and JMPR), see Joint FAO/WHO Consultation Risk Management and Food Safety, (FAO Food and Nutrition Paper 65, Rome1997), p. 7-9. See also Breyer, supra note 192, at 43-44.

trade-restrictive than they need to be[683], the European scientific requirements found their origin in the European attempt to integrate into its market-oriented agenda also other interests deserving equal protection, such European citizens' consumer protection.
In short, if the WTO scientific regime, without establishing any minimum level of health protection, follows exclusively a market-opening agenda, the EC discipline answers to a more complex public demand for health protection within an increasingly integrated Union by imposing not only on Member States' measures but also on EC-wide regulations to attain a high level of protection.

We will see below, how the different objectives underpinning the two scientific justification regimes will influence the standard of review to be applied by their respective courts.

**Diagram 5.** Scientific justification requirements in the WTO and the EC.

| | |
|---|---|
| "Nothing in this agreement shall be construed to prevent the adoption or enforcement of measures":<br>"to protect human, animal or plant life or health" (Article 2.2 SPS; Article XX (b) GATT) | "[...] shall not preclude prohibitions or restrictions on imports, exports:<br>"justified on grounds of [...] the protection of health and life of humans, animals or plants" (Article 30 EC) |
| "Applied only to the extent necessary"(Article 2.2 SPS) | Proportionality principle (case law-based) |
| Based on scientific principles and not maintained without sufficient scientific evidence | (Article 30 EC: according to the case law, it requires scientific justification) |

[683] In this sense, see Button, supra note 196, at 45, who argues that the SPS agreement aims at "a broader objective": identifying and dismantling all instances in which markets are unnecessarily closed by scientifically unsupported health measures.

| | | |
|---|---|---|
| | (Article 2.2 SPS) | |
| | "not applied in a manner which should constitute a means of arbitrary or unjustifiable discrimination" (Article XX)<br>Do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail (Article 2.3 SPS) | "not constitute a means of arbitrary discrimination" (Article 30 EC) |
| | "not applied in a manner which would constitute a disguised restriction on international trade" (Article XX; Article 2.3 SPS) | "not constitute [...] a disguised restriction on trade between Member States" (Article 30 EC) |
| | Members may "introduce or maintain measures which result in a higher level of protection than would be achieved by measures based on international standards, "if there is scientific justification" (Article 3 SPS) | Members may "maintain national provisions on grounds of major needs referred to Article 30 EC" (Article 94, par. 4, EC) or "introduce" new measures derogating harmonized legislation "based on new scientific evidence" (Article 95, par. 5) |

After having seen which the EC and WTO scientific justification disciplines are, and how they are understood, there remains to be seen to what extent the respect of the relevant scientific requirements is assessed by their respective courts. That is, there remains the question as to the standard of review applicable to science-based measures.

# CHAPTER II: JUDICIAL REVIEW OF FOOD SAFETY (SCIENCE-BASED) MEASURES IN THE EC AND THE WTO

## 1. AN INTRODUCTION TO JUDICIAL REVIEW

Standard of review is a key issue for any court or tribunal, domestic or international, called upon reviewing legislation or administrative decisions.

When the examination of a regulation falls within its jurisdiction, the question arises to what extent should a court review determinations of the legislative authorities. Routinely, courts face the following questions: how intense this review should it be? To what extent should it second-guess the determinations made first by decision-makers? Does have a court the tools, experience and knowledge as to carry out a full-scale re-examination of both factual and legal issues?

While in a domestic law perspective the answers to these questions may affect the balance of powers between the legislative, executive, and judicial branches of government, in an international context the answers touch upon an even more sensitive area: the division of powers between a State and a supranational and multilateral entity, such as the WTO or the European Union. As it has been stated, here the standard of judicial review is, within an international context, relevant not only to the extent it plays a procedural function (within a system of check and balances), but also because it "is a critical element of allocating power between an international tribunal and a national government"[684].

Thus, as it is frequently argued not only in anti-global contexts, but also in legal writings, the courts should respect national governments determinations up to some point. The determination of this point is "the crucial issue that has sometimes been labeled the

[684] J. Jackson, *The Great 1994 Sovereignty Debate: United States Acceptance and Implementation of the Uruguay Round Results*, in J. Jackson, *The Jurisprudence of GATT and WTO: Insights on Treaty Law and Economic Relations*, 2002, at 367-369.

standard of review"[685]. Similarly, borrowing from the European Court of Human Rights' jargon, the notion of standard of review defines the *margin of appreciation* which the courts grant to Members' authorities in enacting and enforcing their obligations under the relevant international agreement[686].

### 1.1. Differing levels of intensity of review

If standard of review refers to the nature and intensity of a court's scrutiny of the legal validity of a legislation or administrative decision, de novo review and 'total deference' are generally referred to as the two extreme standards of review. While the former allows a judge to substitute its own findings for those of the national authority, the latter prevents a judge from reviewing in substance the investigations conducts by the decision-makers. Being both standards impracticable, the entire standard of review debate boils down to the challenge of finding a proper standard along the spectrum between these two extreme forms of standards of review. There is, in fact, no single or proper standard of review: each legal system must develop the standard that satisfies its own needs. This is because judicial review is valuable as a mechanism to discourage authorities from engaging in conduct prohibited within a legal system, which, if effective, either deter the illegal conduct or it removes it sooner than it otherwise would.

### 1.2. The specificity of reviewing science-based measures

In the specific context of reviewing science-based measures (like all food regulations), the determination of the applicable standard is particularly relevant to the extent it determines not only how much regulatory autonomy WTO and EC Member States enjoy in regulating to protect the health of their people but also the level of scientific involvement required from the judges.

Depending of the applicable standard of review, a court may be called upon to determine one or more of the following issues: whether the scientific evidence has been duly taken into account in the decision-making process, whether the scientific evidence

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[685] S. Croley and J. Jackson, *WTO Dispute Settlement Panel Deference to National Government Decision: The Misplaced Analogy to the US Chevron Standard-Of.-Review Doctrine*, in E.U. Petersmann (ed.), *International Trade Law and the GATT/WTO Dispute Settlement System*, 1997, at 188.

[686] E. Brems, *The Margin of Appreciation Doctrine in the Case-Law of the European Court of Human Rights*, in Zeitschrift für ausländisches öffentliches Recht und Völkerrecht, 1996, at 240-93.

underpinning a certain measure is reliable or plausible, whether the scientific evidence underpinning a certain measure is valid.

## 2. THE STANDARD OF REVIEW IN THE EC

### 2.1 Introduction to the general standard of review

As we have seen above, the European scientific justification discipline has emerged gradually and quite recently, being first introduced spontaneously by the Member States in order to support their measures derogating EC law, and then subsequently codified and extended to the EC action in the field of health and environmental protection, notably in the food safety area. Yet, there is a relevant and growing body of case law by the European Courts dealing with measures adopted by EC Member States and by EC institutions to address risks to health and the environment.

Lacking an expressed indication of the standard of review to be applied to those measures, it is necessary to look at this body of case law in order to determine the level of intensity of the scrutiny exercised by the EC courts.

Traditionally, the European Courts, in solving a specific legal dispute, are only required to control whether the authorities have not used in an arbitrary or unjustifiable manner their regulatory discretion. However, it is crucial to State from the outset that the ECJ's approach to Member State health regulations, such as food safety measures, is much more demanding that the approach adopted by the same court while reviewing the health claims of the EC institutions[687].

### 2.2. Reviewing EC Food Safety Regulations

While the review of EC action is limited to examining "whether the exercise of its discretion is vitiated by a manifest error or a misuse of power"[688], the review of Member States' health regulations tends to go beyond such a 'manifestly inappropriate threshold'.

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[687] See J. Peel, *Risk Regulation Under the WTO SPS Agreement: Science as an International Normative Yardstick?*, in Jean Monnet Working Paper, 02/04, NYU School of Law, p. 45; Button, supra note 196, at 204-210; Slotboom, *The Hormones Case: An Increased Risk of Illegality of Sanitary and Phytosanitary Measures*, supra note 502, at 486.

[688] This ECJ's formula is settled case law (see, in particular, Joined Cases 56/64 and 58/64 Consten and Grundig v Commission [1966] ECR 299, Case 55/75 Balkan-Import Export v Hauptzollamt Berlin-Packhof [1976] ECR 19, paragraph 8, Case 9/82 Øhrgaard and Delvaux v Commission [1983] ECR 2379, paragraph 14, Case C-

Thus, for instance, the ECJ called to determine whether the Commission lacked the competence to adopt Decision 96/239 providing for a total ban on exports of bovine animals, bovine meat and derived products from the territory of the United Kingdom to the other Member States and to third countries in the aftermath of the BSE crisis, it declared that

> "since the Commission enjoys a wide measure of discretion, particularly as to the nature and extent of the measures which it adopts, the EC judicature must, when reviewing such measures, restrict itself to examining whether the exercise of such discretion is vitiated by a manifest error or a misuse of powers or whether the Commission did not clearly exceed the bounds of its discretion"[689].

This deferential approach to judicial review of EC health measures has been further elaborated in the *Upjohn* case, where the ECJ has declared

> "where a Community authority is called upon, in the performance of its duties, to make complex assessments, it enjoys a wide measure of discretion, the exercise of which is subject to a limited judicial review in the course of which *the EC judicature may not substitute its assessment of the facts for the assessment made by the authority concerned.* Thus, in such cases, the EC judicature must restrict itself *to examining the accuracy of the findings of fact and law* made by the authority concerned and to verifying, in particular, that the action taken by that authority is not vitiated by a manifest error or a misuse of powers and that it did not clearly exceed the bounds of its discretion"[690].

Recently, this deferential standard of review has been extended specifically to those situations

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225/91 Matra v Commission [1993] ECR I-3203, paragraphs 24 and 25, and Case C-157/96 National Farmers' Union and Others [1998], supra note 179, para 39.

[689] Case C-157/96, National Farmers' Union and Others [1998], supra note 179, para 39; referring to Case 98/78 Racke v Hauptzollamt Mainz [1979] ECR 69, para 5.

[690] See Case C-120/97, Upjohn Ltd [1999] ECR 223, para 34. See, also, Case C-405/92 Mondiet [1993] ECR 6133.

"where Community institutions are required to undertake a scientific risk assessment and to evaluate highly complex scientific and technical facts"[691].

Thus, in the *Bellio* case[692], the ECJ upheld the right of the EC to pursue a policy of 'zero tolerance' in regard to the contamination of animal feed with material possibly containing the agent that causes BSE, even in circumstances where the contamination was probably accidental and there was scientific uncertainty as to the minimum amount of infected material required to lead to disease in humans[693]. The Court came to this conclusion after having considered that that policy had been adopted "on the recommendation of experts having at their disposal the relevant scientific data" and formed "part of a coherent body of legislation the purpose of which is to combat TSEs"[694]. By relying on the same deferential standard of review, the Court has recently set aside in the *CEVA* case a CFI judgement in so far as it held that there had been an inaction on the part of the Commission in the establishment of a maximum residue level for progesterone under Regulation 2377/90[695]. While the CFI established that the politically and scientifically complexity of the progesterone file "does not excuse the Commission's inaction", the ECJ confirmed that

"in delicate and controversial cases, the Commission must have a sufficiently broad discretion and enough time to submit for re-examination the scientific questions which determine its decision"[696].

It must also be noted that the assessment made by the EC institutions can be contested only

"if it appears incorrect in the light of the elements of fact and law which were available to them at the time when the contested regulation was adopted"[697].

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[691] See Pfizer, supra note 161, paras 168-69 and 323.
[692] Case C-286/02 Bellio F.lli Srl v Prefettura di Treviso, [2004] not yet reported.
[693] See A. Alemanno, *Protection des consommateurs : Bellio*, in Revue du Droit de l'Union Européenne, 2/04, at 319-323.
[694] Case C-286/02 Bellio F.lli Srl v Prefettura di Treviso, para 61.
[695] Case C-198/03 P, Commission v. Ceva/Pfizer, [2005], not reported yet.
[696] Ib., para 75.
[697] Pfizer, supra note 161, para 324 and Crispoltoni, supra note 232, para 43.

It follows that

> "subject to that condition, the information in question cannot be taken into account for the purposes of the review of the legality of the contested regulation"[698].

Furtermore, after the *Artegodan* judgments, the Court may also may called to control the respect of the procedural requirements prescribed for the adoption of a decision based upon the precautionary principle[699], notably to review the formal legality of any scientific committee's opinion.

In general, In all these cases, the Court, after having relentlessly recalled the limited scope of review applicable to science-based measures, has always refrained from addressing the merits of the scientific findings brought by the parties, thus showing great deference to the EC scientific bodies.

### 2.3. Reviewing Science-Based National Food Safety Regulations

While the EC judiciary shows to be quite deferential in examining EC's efforts to attain a high level of protection of health, through the adoption of food (and feed) safety regulations, when it comes to the Members States' use of science in pursuing health protection goals, it adopts a rather different approach.

As we have seen above, Member States' health regulations come to the ECJ when they are challenged as inconsistent with Article 28 ECT (prohibiting all national measures which are capable of hindering intra-Community trade) and Member States try to justify them on public health grounds by traditionally invoking Article 30 ECT. In doing so, States have quite soon began making reference to scientific studies proving the existence of a health threat. In the meanwhile, the ECJ has imposed on Member States relying on Article 30 the duty to prove harm by reference to credible evidence.

Thus, for instance, in the *Greek Butter* case, a Greek measure requiring imported butter to be accompanied by a health certificate was not only found inconsistent with Article 28 but also not justifiable on public health grounds because Greece fails to substantiate its

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[698] Ibid.

[699] Joined Cases T-144/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00 and T-141/00 Artegodan a.o. v. Commission [2002] ECR 4945, supra note 253, para 199. Upheld by Case C-39/03 P Commission v Artegodan c.o. [2003] ECR.

health claims[700]. Similarly, Italy was condemned by the Court for not having substantiated alleged health threat imposed by gelatine[701]. Here the Court clearly stated that "the Italian Government has not produced, in support of its contention, any evidence or information showing that public health was actually threatened by the use of animal gelatine"[702].

In an infringement proceeding against Belgium[703], the Court, by building upon the *German Purity Beer* case[704], affirmed that "the (claimed health) risk must be measured, not according to the yardstick of general conjecture, but on the basis of relevant scientific research"[705]. It therefore concluded that "in neglecting to produce scientific data on the basis of which the Belgian law (limiting the maximum salt content in bread to 2 %) would have been justified in enacting and retaining the measures at issue, the Belgian authorities have failed to demonstrate the risk to public health of a salt content in excess of 2%"[706]. More recently, the ECJ has been called to examine the compatibility with EC law (Article 28) of a Danish regulatory practice under which enriched foodstuffs lawfully produced or marketed in other Member States could not be marketed in Denmark unless shown to meet a nutritional need in the Danish population. Although the Court recognized that Member States enjoy the right to choose their own level of protection in the absence of harmonization, it established that any claim that a risk to health existed had to be sufficiently established on the basis of

> "a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research"[707].

In sum, the EC Courts' scrutiny of science-based measures is quite intrusive and scientifically demanding. Although never engaging in the scientific debates underlying the contested measures, by usually showing deference to the scientific findings brought by the parties, the Court is rather demanding in assessing whether the contested measure

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[700] Case 205/89 Commission v Greece [1991] ECR 1361, para 12.
[701] Case 51/83 Commission v. Italy [1986].
[702] Case 51/83 Commission v. Italy [1986], para 17.
[703] Case C-17/93 Criminal Proceedings against JJJ Van der Veldt [1994] ECR 3537.
[704] Case 178/84 Commission v Germany [1987] ECR 1227.
[705] Case C-17/93 Criminal Proceedings against JJJ Van der Veldt [1994] ECR 3537, para 17.
[706] *Ibid.*, para 18.
[707] Case 192/01 Commission v Denmark, supra note 271, para 52, referring to EFTA Surveillance Authority v Norway, para 30, and Monsanto Agricoltura Italia and Others, para 113.

is adequately backed up by credible scientific evidence. Thus, for instance, a national measure prohibiting the use of a specific additive which is authorized in the State of destination violates Article 28 and cannot be justified under Article 30 to the extent the additive in question, on the basis of the findings of international scientific research and in particular the work of the EC's competent scientific committees, does not present a risk to public health. Finally, as it has been correctly underlined, not only science but also "pragmatism and common-sense reasoning form a prominent part of the ECJ's approach to health claims"[708].

### 2.4. Why diverging standards of control?

This brief comparison between the EC courts' approach to EC's health regulations and their approach when they review Member State health claims clearly shows that the EC courts tend to be less deferential vis-à-vis the latter.

This distinction seems to be firstly due to the specific normative framework within which Member States must act when adopting national health regulation, such as a food safety measure. As we have seen, either in the absence or in presence of harmonization, in order to take advantage of respectively Article 30 or Article 95, paragraphs 4 or 5, ECT Member States must show that the measure in question is a genuine health measure[709]. This implies that the existence of a threat to health must be shown in both situations, thus inevitably opening this issue to the scrutiny of the judiciary. To the contrary, as we have seen above, EC action is not subject to such a detailed set of scientific constraints. Article 95, paragraph 3, merely imposes the Commission, in its proposals concerning health, safety, environmental protection and consumer protection, to take

> "as a base a high level of protection, taking into account in particular of any new development based on scientific facts".

As to the duty imposed on both EC Institutions and Member States to base a food safety measure on the risk analysis scheme provided by Article 6 of Regulation 178/2002, it is

[708] Button, supra note 196, at 205.

[709] For another example of Member States' failure to provide credible evidence demonstrating the alleged risk, see and Case 123/00 Criminal Proceedings against Christina Bellamy and English Shop Wholesale [2001] ECR 2795, para 12.

probably too early to foresee whether it will be interpreted as imposing on them a procedural obligation.

Secondly, this more intrusive approach into the Member States' determinations as to the adoptions of those measures may be explained when contextualized within the internal market mechanisms, notably within the dialectic existing between the EC Treaty's positive and negative integration tools. Taken from this perspective, the reasons for this distinction in reviewing EC and national health measures are not difficult to spot. In fact, the introduction by a Member State of a health measure inevitably carries the risk of balkanizing the functioning of the internal market, and this regardless of whether it is guided by protectionist considerations or not. In fact, unlike an EC's health regulation, a national measure does not take usually into account and reflect the views of the other Member States on that specific matter. As the Court has stated, the objective a Community measure is different: it is not

> "prescribed by each Member State in order to protect some interest of its own but by the Community legislature in the general interest of the Community"[710].

Finally, the EC courts different approaches to the review of science-based measures fully reflect the objectives underlying the European construction. As the free circulation of goods lies at the heart of the EC integration model, all Member States measures potentially restricting that freedom are subject to a strict scrutiny by the Court. To the contrary, since any action by the EC institutions presumptively contribute to the realization of the internal market and to the achievement of other goals deserving equal protection, their measures deserve very light review. This idea has been enlightening the the case law of the Court developed on the relationship between primary law and secondary law according to which the Community is bound by the Treaty rules on the free movement but not in the same way as the Member States.

In conclusion, though the EC courts have developed different standards of review depending on the EC or Member States' origin of the health claim, they have generally tended, under both standards, not to get involved in the scientific issues underlying the

[710] Case 46/76, Bauhuis, [1977] ECR 5.

contested measure, by refraining from examining the merits and the methodologies of the scientific findings advanced by the parties.

## 2.5 Toward a More Intrusive Scrutiny of Food Safety (science-based) Measures within the EC?

The recent *Pfizer* judgment seems to cast some doubts not only on the traditional EC Courts' deferential approach in reviewing EC's science-based measures[711], but also on its traditional reticence in addressing the scientific basis of the contested regulations. This judgment, which it has already been examined above for its findings on the precautionary principle, it has been recently followed by a line of cases where the ECJ would seemed to have showed some willingness to get more involved in scientific matters while judicially reviewing science-based regulations.

### A. The *Pfizer* Judgment

In this recent judgment[712], the CFI seems to have shown some readiness to become more involved into the exam of the scientific evidence brought by the parties to the dispute and this even when the contested measure had a EC origin[713]. Immediately after the adoption of an EC Regulation banning the use of four antibiotics as additives in animal feeding-stuffs[714], Pfizer, producer of one of these antibiotics (virginiamycin), challenged this EC

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[711] Case Pfizer, supra note 161.

[712] See also the parallel case that concerned the same revocation of the authorization of some antibiotics as growth promoters: T-70/99, Alpharma Inc. v Council [2002] ECR II-3495. For a comment on these cases, see *ex multis*, Walker, *The Myth of Science as a "Neutral Arbiter" for triggering Precautions*, supra note 189, at 207-208; E. Vos, *The Precautionary Principle Reviewed: the Judgements of the Court of First Instance of 11 September 2002 Concerning the EU Ban of Two Antibiotics*, in Journal of Risk Research 7, 2004; F. Mariatte, *Commentaire n. 362 - Principe de precaution*, Europe, Novembre 2002, p. 12; L. Gonzalez Vaqué, *El Principio de Precaucion en la jurisprudencia comunitaria: la sentencia "virginiamicina" (asunto T-13/99)*, in Revista de Derecho Comunitario Europeo, 2002, n. 13, p. 925 and Alemanno, *Protection des consommateurs - Arrêts Alpharma/Pfizer*, supra note 259, at 842.

[713] Contra, see Peel, supra note 687, at 43 who argues that "Although the Court stressed that regulatory authorities must have at their disposal scientific information which is sufficiently reliable and cogent to allow them to understand the ramifications of the scientific questions raised and to make a decision on policy measures in full knowledge of the facts, the CFI displayed a "strongly deferential attitude when reviewing the institutions' interpretation of the scientific material and their judgments as to the existence of genuine scientific uncertainty".

[714] These antibiotics were used as growth promoters and they also had the useful side effect of preventing certain animal diseases.

measure by alleging manifest errors of risk assessment and a misapplication of the precautionary principle.

Although the CFI clearly stated from the outset that it was not for it "to assess the merits of either of the scientific points of view argued before it and to substitute its assessment for that of the Community institutions", it could not prevent itself from discussing the scientific validity and merits of the scientific evidence advanced by the parties. This inevitably led the Court to engage in a quasi-scientific debate on the main scientific controversy underlying the legal dispute: whether there is a link between the use of virgiamycin as an additive in feeding-stuffs and the development of streptogramin resistance in humans. In particular, the Court expressly decided to consider whether, as sustained by Pfizer, the contested regulation was unlawful "because of the inadequate nature of the scientific data" provided by the parties. In other words, the Court went so far, in its judicial-scientific involvement, as to directly ask itself whether the scientific evidence available to the EC institutions was "sufficiently reliable and cogent for them to conclude that there was a risk associated with the use of virgiamycin as a growth promoter"[715].

For the first time, a EC Court felt the need to make an express reference to the quality of the scientific evidence the EC institutions should rely upon. This must be "sufficiently reliable and cogent"[716].

Before starting its analysis, the CFI recalled the purpose and scope of judicial review of a Community measure by helding that in a situation where the EC institutions are required to make complex assessments of a scientific and technical nature and the parties to the dispute have submitted for review by the Court a large number of arguments of a scientific and technical nature, based on a large number of studies and scientific opinions from eminent scientists,

> "judicial review is restricted and does not imply that the Community judicature can substitute its assessment for that of the Community institutions"[717].

[715] Pfizer, supra note 161, para 322.
[716] *Ibid.*, para 162.
[717] *Ibid.*, para 323.

Notwithstanding this declared commitment, the CFI carried out a detailed review of the scientific findings brought by the parties to determine whether the EC institutions erred when they concluded, "on the basis of the scientific knowledge available at the time of the adoption of the contested regulation", that the use of virginiamycin as an additive in feeding stuffs entailed a risk to human health. By engaging into a quasi-scientific analysis of the scientific studies advanced by the parties to the dispute, the Court found that

> "the Community institutions could *reasonably* take the view that they had a *proper scientific basis* for a possible link between the use of virginiamycin as an additive in feeding-stuffs and the development of streptogramin resistance in humans".

In other words, the Community was right to take the view that

> "the various experiments and observations [...] were *not mere conjecture* but amounted to *sufficiently reliable and cogent scientific evidence* ".

### B. The *Vitamins* Line of Cases

A trend towards more scientifical involvement by the EC Courts, inaugurated in the Pfizer case, may seem to have been followed up by a recent line of cases decided by the ECJ.

In this line of cases involving fortified foods, the Court had been called to examine four infringement proceedings brought against Denmark[718], France[719], Italy[720] and the Netherlands[721]. In particular, the Commission contested, on one side, the Danish and Dutch practices entailing that enriched foodstuffs lawfully produced and marketed in other Member States may be marketed in their territories only if its shown that such enrichment with nutrients meets a need in the Danish and Dutch populations and, on the other side, the French and Italian systems of prior approval for fortified foods lawfully produced and marketed in other Member States.

In all these cases, the Court has established that in order to show that the national measures are necessary to give effective protection to public health the competent

[718] Case 192/01 Commission v Denmark [2003] ECR 9693.
[719] Case C-24/00 Commission v France [2004] not yet reported.
[720] Case C-270/02 Commission v Italy [2004] not yet reported.
[721] Case C-41/02 Commission v Netherlands [2004] not yet reported.

authorities must base their decisions "on a *detailed assessment* of the risk alleged by the Member State invoking Article 30 EC". This detailed scientific requirement has been originally sketched out by the EFTA Court in the *Kellog's* case, where it was established, although within the EEE context, the need that Member States, while invoking the precautionary principle, conduct a "comprehensive evaluation of the risk to health"[722]. While in the Italian case the Court directly found that the government failed to show "any alleged risk to public health" and to "explain on what scientific data or medical reports" it relied[723], in the case brought against France, the Court found that the scientific opinions cited by the government were not specific enough to prove the alleged risk since they refer

> "*vaguely* to the possibility of a general risk of excessive intake, without specifying the vitamins concerned, the extent to which those limits would be exceeded or the risk incurred"[724].

Moreover, always in the French case, the Court found that, contrary to the studies focusing on L-tarrate and L-carnitine, the studies it relied upon concerning drinks such as *Redbull* fulfilled the requested scientific requirement ("detailed assessment") and proved that excessive caffeine content and the presence of taurine was harmful to human health. On this basis, it concluded that the Commission failed to explain or to adduce evidence to rebut those studies. But, who is going to decide whether the scientific opinion a State relies upon in the adoption of public health measure is a "detailed assessment" within the meaning of the ECJ's case law?

This line of cases clearly shows that the Court by imposing a stricter scientific discipline (a "detailed assessment") seems to be willing to get increasingly involved in scientific matters. Not only the CFI (in Alpharma/Pfizer), but also the ECJ would seem eager to play with science by weighing the merits and assessing the validity of scientific opinions set forth by the parties to the dispute. Both the CFI and the ECJ have thus inaugurated a new approach to scientific issues allowing them to 'pick and choose' those scientific

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[722] EFTA Court of 5 April 2001, Case E-3/00 Efta Surveillance Authority v Norway, in EFTA Court Report 2000/2001, 73, para 30. For a comment of this case, see Alemanno, *Le principe de precaution* ..., supra note 187, at 947-50.

[723] Case C-270/02 Commission v Italy, supra note 117, para 24.

[724] Case C-24/00 Commission v France, supra note 116, para 61.

opinions they believe better fulfilling the minimum scientific requirements they would require in order to consider a measure "based on a detailed risk assessment".

## 3. THE STANDARD OF REVIEW IN THE WTO DISPUTE SETTLEMENT SYSTEM

### 3.1. An introduction to the general standard of review

As it is often the case in international dispute resolution, the issue of standard of review has not been explicitly settled by the WTO's negotiators[725]. This left panels and the Appellate Body free to identify a proper standard of review. The only guide offered to them is the vague and open-textured formulation of Article 11 DSU which provides that "a panel should make an *objective assessment* of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements, and make such other findings as will assist the DSB in making the recommendations or in giving the rulings provided for in the covered agreements".

However, the 'objective assessment', by itself, does not seem to disclose a meaningful standard of review, notably it does not say how intense the scrutiny should it be[726]. In fact, any assessment of the facts, whether (it is) inspired by 'total deference', by 'reasonable deference' or by *de novo review*, can virtually be 'objective'. The objective standard rather hints at the panel's obligation to exercise in good faith its responsibilities under the DSU[727].

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[725] See M. Oesch, *Standards of Review in WTO Dispute Resolution* (Oxford University Press, 2003), at 16. According to Christoforou this general lack of attention paid to procedural rules should be seen as a result of greater Members' efforts to improving the substantive rules on trade and health regulations. See T. Christoforou, *Settlement of Science-Based Trade Disputes in the WTO: A Critical Review of the Developing Case Law in the Face of Scientific Uncertainty*, in NYU Environmental Law Journal (2000) 622, at 625-26.

[726] Several commentators have expressed some suspicion about the possibility that this expression may disclose a meaningful standard of review. See, *ex multis*, C.D. Ehlermann, *Standard of Review in WTO Law*, in 7 *Journal of International Economic Law* 3, p. 498 and Button, supra note 196, at 173, who after having stated that 'objective assessment' only provides a "minimum standard for its review" defines it as "a guarantee of due process or fairness in panel proceedings", rather than "a particular standard of review".

[727] See Article 11 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), *in* Annex 2 to the Agreement Establishing the World Trade Organization, Apr. 15, 1994, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Article 2(2), Apr. 15, 1994, Legal Instruments -- Results of the Uruguay Round vol. 1 (1994), 33 I.L.M. 1125 (1994) reprinted in World Trade Organization, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 161 (1994).

A European attempt to regard the DSU's 'objective standard' as tantamount to the 'deferential reasonable standard" expressed by Article 17.6(i) of the Anti-Dumping Agreement was rejected by the Appellate Body's in the first SPS case it had to face[728]. In the *Hormones* case, the Appellate Body stated that

> "In our view, Article 11 of the DSU bears directly on this matter and, in effect, articulates with great succinctness but with sufficient clarity the appropriate standard of review for panels in respect both the ascertainment of facts and the legal characterization of such facts under the relevant agreements [...] So far as fact-finding by panels is concerned, their activities are always constrained by the mandate of Article 11 of the DSU: the applicable standard is neither *de novo* review, nor 'total deference', but rather the 'objective assessment of the facts' ".

In other words, the Appellate Body refused to accept that, as provided in the Antidumping Agreement

> "if the [authorities'] establishment of the facts was proper and their evaluation was unbiased and objective, even thought the panel may have reached a different conclusion, the evaluation should not be overturned"[729].

Although clearly refusing to interpret the objective assessment standard as *de novo review* (panels are 'poorly suited' to engage in it[730]), the AB has not made clear to what extent panels are allowed to establish for themselves the facts underlying the national authority's assessment or the deductions that the national authority drew from those facts. By hinting to the fact that the proper standard of review should lie somewhere between de *novo review* and 'total deference" review, the AB has not in reality identified such a standard.

However, by taking a negative approach in defining the proper standard of review, it has clarified what a panel cannot do by defining what it envisages as *de novo review*: "a

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[728] The European Community argued for the adoption of this standard by stressing the fact that it was already applicable in all highly complex factual situations. See *Hormones* AB Report, paras 112-13, citing paras 128-29 of the EC's Appellant submission.

[729] Article 17.6(i) of the Agreement on implementation of Article VI of the General Agreement on Tariffs and Trade 1994.

[730] *Hormones*, AB Report, para 117.

situation where the panel redoes the investigation into the facts that has been done by a national authority"[731].

Instead of performing a *de novo review*, the AB has stated that a panel

> "must put itself in the place of the [national authority] at the time it made its determinations"[732].

Although this statement may seem to indicate that panels should accord a considerable degree of discretion to national authorities, we will see below that it has not always been the case in the case law.

This uncertainty about the applicable standard of review means that in every case, panels and the Appellate Body must decide how intensively a measure should be reviewed and how much deference should be granted to national decision makers. As the same AB has implicitly recognized[733], the requirement for an 'objective assessment' must operate with another, more precise, underlying standard of review.

It follows that, although panels perform an 'objective assessment', the scope of and the intensity of their assessment is not the same for every issue, in every dispute.

The four SPS disputes decided to date – *Hormones*, *Australia Salmon*, *Japan Varietals* and *Japan Apples* – have involved quite different SPS measures. While the *Hormones* cases concerned the complaints submitted by the US and Canada against the EC ban on the importation of meat and meat products from cattle treated with six particular hormones for growth promotion purposes, the three latter disputes related to the challenges to quarantine regulations imposed by particular WTO Members. To determine the standard of review adopted vis-à-vis (food safety) science-based measures we must therefore look at these cases. We will see that panels have closely scrutinized the scientific evidence advanced by the parties. However, although this trend towards an

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[731] *Hormones*, Panel Report, para 111.

[732] *United States - Transitional Safeguard Measure on Combed Cotton Yarn from Pakistan* ('US Cotton Yarn'), Appellate Body Report, WT/DS192/AB/R, adopted on 5 November 2001, para 78.

[733] In the *US-Hot-Rolled Steel*, the AB stated that "it is inconceivable that Article 17.6(i) should require anything other than panels make an objective "assessment of the facts of the matter". See, *United States - Anti-Dumping Measures on Certain Hot-Rolled Steel Products from Japan* Appellate Body Report WT/DS184/AB/R, adopted on 23 August 2001, para 55.

intrusive review was already visible in the *Hormones* and *Salmon* cases, it is in the *Apples* case where the panel went so far as adopting a *de novo review* involving an assessment of the quality of the scientific information brought by the parties, thus totally ignoring the previous AB's veto on the adoption of this standard.

### 3.2 The Standard of Review under the SPS Agreement

A WTO's Member health measure may not survive review under the SPS Agreement, unless it is grounded on science. In other words, according to the SPS Agreement, a Member State measure, although not discriminatory, may be struck for being scientifically flawed. Similarly, a EC Member State health measure, or a EC Institution's health measure, may not survive a ECJ's review should it be lacking of a solid scientific justification.

The scientific justification discipline governing in the WTO raises questions of what "sufficient scientific evidence" is, and when a measure is based on "scientific principles" and "on risk assessment", according to Article 2.2 and 5.1 SPS. As we have seen above, these requirements have been interpreted as meaning that there must be an "objective or rational relationship" between the SPS measure and the available scientific evidence[734].
By focusing solely on the existence of a rational relationship between the evidence and the measure, this criterion *per se* does not seem to be excessively intrusive into the Member States' regulatory autonomy. In principle, by virtue of this interpretation of the WTO scientific discipline, Members would remain free to adopt risk regulations based on what *they* consider to be "sufficient evidence", provided that there is a rational relationship between the evidence and the measure[735]. Thus, for instance, the panel in the *Japan - Agricultural Products* case has stated that in determining whether "the varietal testing requirement (the contested measure) is maintained without sufficient scientific evidence (i.e., whether there is a lack of an objective or rational relationship between the measure at issue and the scientific evidence before the Panel)", neither the panel is "empowered, nor are the experts advising the Panel, to conduct [their] own risk

[734] For a synthesis of the case on this point, see *Agricultural Products*, Panel Report, paras 8.28, 8.42.
[735] This freedom has been recognized not only by the text of the SPS Agreement but also by the AB in *Australia - Salmon*, para 199. In its report, the AB has stated that the panel or AB should not substitute its own reasoning about the implied level of protection for that expressed consistently by Australia.

assessment"[736]. This approach seems to have been confirmed in the most recent SPS case report issued to date, *Japan - Apples*, where the panel has stated: "we are mindful that we are not supposed to conduct our own risk assessment or to impose any scientific opinion on Japan. Like the panels in *Australia - Salmon* and *Japan - Agricultural products II*, we will only examine and evaluate the evidence, including the information we have received from the experts advising the Panel, and the arguments put before us in light of the relevant WTO provisions"[737].

However, contrary to what it may appear from these relentless Statements of principle, panels in applying the "rational relationship" test to verify the conformity of SPS measures to the WTO scientific justification discipline have adopted a rather intrusive approach[738]. By traditionally relying on advice from independent experts, panels tend to determine whether the scientific theory or risk assessment outcome put forward by a defending Member is properly backed up by the available scientific evidence. In doing this, the panels have increasingly engaged with scientific controversies, especially after the AB offered the following interpretation of the rational relationship test

> "whether there is a rational relationship between an SPS measure and the scientific evidence is to be determined on a case-by case basis, and will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the *quality and quantity of the scientific evidence*"[739].

This AB's elaboration of the rational relationship test, by referring to "the quality and quantity of the scientific evidence", inevitably opened up the Pandora's box of scientific discussion to the WTO judicial bodies, thus legitimizing their involvement in controversial scientific matters.

In the same case, the panel had already invested itself with the task

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[736] Panel Report, *Agricultural Products*, para. 8.32.

[737] *Japan - Measures Affecting the Importation of Apples* - Recourse to Article 21.5 of the DSU by the United States, WT/DS245/RW Report of the Panel, para 8.137.

[738] See A. Guzman, *Food Fears: Health and Safety at the WTO*, in Boalt Working Papers in Public Law, 2004, who after criticizing such an intrusive approach makes a claim for a more deferential WTO review of SPS measures.

[739] *Japan - Agricultural Products* AB Report, para 84.

"to *examine and weigh* all the evidence validly submitted to us, including the opinions we received from the experts advising the Panel in accordance with Article 13 of the DSU"[740].

The existence of such a non-deferential standard of review of science-based measures has recently been expressly admitted by the AB in the *Apples* case. In this case the WTO judicial bodies had to verify the compatibility of the quarantine restrictions applied since 1994 by Japan on US apples to protect against the introduction of fire blight. Called to clarify the issue of the standard of review that a panel must apply in the assessment of scientific evidence submitted in proceedings under the SPS Agreement, the AB has declared

"total deference to the findings of the national authorities would not ensure an objective assessment as required by Article 11 of the DSU"[741].

On this basis, it rejected Japan's contention according to which, under Article 2.2, a panel would be obliged to give precedence to the importing Member's approach to scientific evidence and risk when analyzing and assessing scientific evidence[742].

In determining whether the Japanese measure was supported by sufficient scientific evidence (rational relationship test), the panel had to face numerous specific scientific issues boiling down to the question as to whether mature and apparently symptomless apple fruit could nevertheless be infected and thus capable of transmitting the fire blight disease.

In evaluating this question, the panel engaged in a quasi-scientific debate on the merits of the data advanced by the parties before reaching its own conclusion, thus acting as a real arbiter of a scientific controversy. For instance, on the specific scientific issue of whether a mature, symptomless apple could harbor endophytic bacteria[743], as the scientific opinions brought by the US and Japan were divergent, the panel turned to the opinion of its experts to reach its own conclusion. In doing so, it dismissed the scientific validity of

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[740] *Japan - Agricultural Products*, Panel Report, para 7.10.
[741] *EC - Hormones*, AB Report, para 117.
[742] *Japan - Apples* AB Report, para 165, where it stated that "Japan's submission that the Panel was obliged to favor Japan's approach to risk and scientific evidence over the views of the experts conflicts with the Appellate Body's articulation of the standard of objective assessment of facts".
[743] In other words, whether a mature, symptomless apple could harbor bacteria inside the fruit without itself being infected.

some studies, by criticizing not only their methodology ( a study "did not specify the degree of maturity of the fruit") but also the results they reached ("this made its conclusions confused, difficult to interpret or even unconvincing")[744]. After having fully engaged in such a scientific debate, the panel concluded by stating that

> "on the basis of the elements before us, there was not sufficient scientific evidence to support the view that apples are likely to serve as a pathway for the entry, establishment or spread of fire blight within Japan".

This conclusion was reached notwithstanding that fact that "some slight risk of contamination cannot be totally excluded". In other words, as "the experts all categorized the risk *as negligible*", the panel denied the scientific evidence brought by Japan the qualification of "sufficient" within the meaning of Article 2.2 SPS, thus condemning the Japanese measures at stake.

In light of the above, it is clear that, contrary to what expressly stated by the Panel in the *Asbestos* case, the Panel, though heavily relying on its experts' opinions, undoubtedly acted as "an arbiter of the opinions expressed by the scientific community"[745], by assessing not only the quality of the scientific studies brought before it but also setting up a "minimal" level of risk justifying the adoption of an SPS measure.

One may observed that this deliberate intrusive approach has been adopted in a case where for the first time the panel has assessed the sufficiency of the scientific underpinnings of a Member's risk regulatory measures directly, rather than coming to this question mainly through an analysis of its role as part of the process of risk assessment supporting the Member's regulation[746]. In other words, the panel instead of looking at scientific evidence as a part of the process of risk assessment it focused on what might

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[744] It is worth noticing that on that specific controversial scientific issue, only one of the Panel's experts (Dr. Smith) expressly criticized the study (as "not convincing in several aspects"), cited by Japan, by van der Zwet. See paras 6.72-6.75.

[745] *EC - Asbestos*, Panel Report, para 8.181. In this case, the panel before analyzing whether the French ban on asbestos products could be justified under Article XX GATT, declared that "its role [...] is to determine whether there is sufficient scientific evidence to conclude that there exists a risk for human life or health" and not to "set itself up as an arbiter of the opinions expressed by the scientific community".

[746] As panels may choose to commence its analysis with any of the breaches alleged by the complainant, they traditionally examine whether the studies supporting the contested measure amount to a 'risk assessment' under Article 5 SPS. In doing so, they verify whether "available scientific evidence" has been taken into account in the risk assessment to integrate the "sufficient evidence" requirement imposed by Article 2.2 SPS.

count as science within the meaning of Article 2.2 SPS[747]. It is argued that the adoption of this way of proceeding intrinsically induces a panel to explore more deeply into the scientific evidence gathered by the parties and thus might somehow explained the particularly in-depth scientific scrutiny adopted by the panel[748].

### A. Toward a 'Minimum Scientific Threshold'?

There are mainly two consequences stemming from the adoption of such an intrusive standard of review of SPS measures, both imposing significant limits on the scope of risk assessment undertaken by Members to support their science-based measures. In particular, the rigorous approach taken by WTO courts to the scientific material that Members have taken into account in assessing risk leads to the introduction of a sort of a *minimum scientific threshold* this material has to comply with in order to qualify as "sufficient". As we have seen, by insisting that the scientific evidence advanced by the parties must meet a specificity-threshold, the WTO judicial bodies seem willing and ready to assess the scientific 'validity', or at least adequacy, of the scientific studies cited by the parties in a particular dispute[749]. Thus, for instance, in the *Apples* case, the panel dismissed the risk assessment conducted by Japan to the extent it did not focus sufficiently on the risk of transmission of fire blight through apple fruit, as opposed to other modes of transmission[750]. While this trend is particular visible in this case, it is possible to interpret some findings of the Appellate Body in the *Hormones* case as similarly establishing a *minimum scientific threshold* for evidence to be "sufficiently specific" to satisfy Article 5.1. In such a case, the AB dismissed not only the opinion by Dr. Lucier for not being "the result of scientific studies carried out by him or under his supervision" but also the scientific studies relied on by the EC because "they do not focus and do not address the particular risk kind of risk here at stake"[751]. In other words, these

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[747] *Apples*, Panel Report, para 8.92.

[748] Contra, see Peel, supra note 687, at 20 who argues that "in both cases where the parties to an SPS dispute disagree over the interpretation of the available science and its relevance in determining the significance of the risk at issue, WTO decision-makers are likely to encounter complex questions which lie at interface between law and science".

[749] See See R. Howse and P.C. Mavroidis, *Europe's Evolving Regulatory Strategy for GMOs – The Issue of Consistency with WTO Law: of Kine and Brine*, supra note 674, at 326.

[750] *Apples*, Panel report, paras 8.277-280. This finding was subsequently upheld by the AB Report, para 206.

[751] They dealt only with the general association between exposure to increased hormone levels and the development of cancer, rather than specific situation of cancer posed by consuming hormone residues in beef. See *Hormones*, AB Report, paras 198-200.

studies are "relevant but do not appear to be sufficiently specific to the case". Whether this AB judgment was correct or not it clearly represents an evaluation of the 'validity', or adequacy, of scientific evidence. Since Dr. Lucier's opinion and the other EC scientific studies did not meet a (undetermined) scientific evidence threshold, they have been rejected by the Appellate Body.

Always on the same note, the Panel in the *Apples* case after having stated that "direct" or "indirect" evidence may be equally considered, it clearly stated that, though scientifically equivalent, the latter is of greater probative value. Here again the panel did not hesitate in assigning a specific scientific value to a certain study in order to make it qualify as "sufficient" within the meaning of Article 2.2 SPS.

One may wonder if such a trend to evaluate the 'scientific adequacy' of the evidence advanced by the parties may somehow find a *raison d'être* in the fact that WTO procedures do not set out restrictions on the admissibility of evidence, thus virtually allowing parties to put junk science on the panel record[752]. What is sure today is that the WTO dispute settlement bodies increasingly require a highly specialized risk assessment addressing the particular circumstances of the case[753].

### B. Toward a 'Minimum Risk Threshold'?

The adoption of such an intrusive standard of review of science-based measures limits even further the scope of risk assessment undertaken by Members to support their regulations. As egregiously illustrated by the *Apples* case, once the AB has turned the "rational relationship test" into an assessment of the "quality and quantity of the scientific evidence", this has immediately led to the introduction of a further requirement that the scientific evidence brought by the parties must fulfill to justify the adoption of an SPS measure. Thus, to be "sufficient" within the meaning of Article 2.2 SPS, the scientific evidence supporting a Member State measure does not only have to satisfy a "minimum

[752] To the contrary, in the United States, there exist strict rules on the admissibility of scientific evidence and most of the law and science debate revolves around this specific procedural issue. See K. Foster and P.W. Huber, *Judging Science. Scientific Knowledge and the Federal Courts* (MIT Press, 1999). This *ex ante* control may perhaps explain the traditional deference shown by US Federal Courts while reviewing agencies' science-based measures. Thus, for instance, the D.C. Circuit stated: "It is not our function to resolve disagreement among the experts or to judge the merits of competing expert views. Our task is the limited one ascertaining that the choices made by the Administrator [notably, EPA] were reasonable and supported by the record". See Am. Trucking Associations v. EPA, 283 F.3D 355, 362 (D.C.Cir.2002).

[753] Button, supra note 196, at 66.

scientific threshold", but it also has to integrate a "minimum risk threshold" justifying the adoption of an SPS measure.

In fact, if one looks at the way in which the panel analyzed the scientific evidence in the *Apples* case, it appears that it came to the conclusion that the Japanese measures were not supported by scientific evidence (proving the risk of contamination) notwithstanding the fact that "some slight risk of contamination cannot be totally excluded". Through an assessment of the quality and quantity of the scientific evidence supporting the contested measure, the panel concluded that this evidence showed a risk that it was too low to qualify as "sufficient scientific evidence" justifying the adoption of a Member State's SPS measure. In other words, as "the experts all categorized the risk as *negligible*", the panel denied the scientific evidence advanced by Japan the qualification of "sufficient" within the meaning of Article 2.2 SPS, thus condemning the Japanese measures at stake.

The introduction of such a "minimum risk threshold" that the scientific evidence brought by a party must satisfy to comply with the SPS requirements seems to contradict the accepted view according to which WTO Member States enjoy complete freedom in deciding the level of risk they can accept, provided that they are able to show that the claimed risk exists. Thus, for instance, relying on this line of thought, the AB, in the *Salmon* case, went so far as to admit that a Member can choose 'zero risk' as its appropriate level of protection[754]. However, after the *Apples* case, it seems that a WTO panel while reviewing a Member's chosen level of protection could strike down a measure simply because it considers the risk involved too low for justifying the adoption of that measure.

It remains to be seen how this new approach may be reconciled with Article 5.7 SPS which expressly recognized the possibility to adopt SPS measures on the basis of available pertinent information where "relevant scientific evidence is insufficient", albeit on a provisional basis.

[754] *Salmon*, AB Report, para 125.

## C. Conclusions

This analysis of the standard of review applicable to SPS measures within the WTO context shows a growing trend towards an increasingly intrusive role of panels and the AB in reviewing (food safety) science-based risk regulations adopted by WTO Members. As closer attention has been paid to the "quality and quantity" of the scientific evidence underlying SPS measure, the panels and the AB have began imposing not only a "minimum scientific threshold" but also a minimum risk criterion (yet to be quantified) that the scientific evidence brought by the parties must satisfy. The adoption of such an intrusive standard of review carries with it the clear implication that panels and the AB are increasingly called to engaging in complex scientific debates by not only assessing the quality of the scientific studies brought before it but also by setting up a minimum level of risks justifying the adoption of science-based measures.

Such growing engagement with scientific evidence raises the question of whether WTO panelists and AB's Members and, more in general, international courts are adequately equipped to make such scientific judgments.

# PART IV

# DIVERGENCE OR CONVERGENCE BETWEEN EC AND WTO FOOD REGIMES?

Part IV, by building upon the previous parts, ventures a comparison between the EC and WTO food safety regimes in order to show the main points of tension existing between them.

In particular, Chapter 1 provides for a comparison between the EC and WTO food disciplines, by looking at their respective goals and at their instruments. Chapter 2 furthers this exam by notably comparing their food safety risk analysis models thus identifying the main points of tensions existing between the two regimes: the role of "other legitimate factors" in risk analysis and the status of the "precautionary principle". Due to the lack of risk management policy within the WTO/SPS risk analysis model, the analysis expands, when appropriate, on the Codex' principles for risk analysis. Chapter 3 offers a comparison of the standards of review applied by the EC courts and the WTO judicial bodies, by focusing notably on the respective level of scientific involvement required from them. After having analyzed the WTO expert consultation practice, it lastly formulates some proposals aimed at reorienting the role of the WTO and EU judicial bodies in order to make them less involved with science while reviewing science-based measures.

## CHAPTER I: COMPARING FOOD SAFETY REGULATORY FRAMEWORKS

This chapter provides for a comparison between the WTO and EC food disciplines, by looking at their respective goals and also at their instruments.

### 1. THE GOALS: FOOD SAFETY AS AN EXCEPTION (WTO) AND AS A GOAL PER SE (EC)

As it stems from their historical evolution, the WTO and EC food regimes do not entirely respond to the same logic. Although both disciplines impose a number of significant constraints on the ability of their Member States to regulate the safety of food, they aim at very different objectives.

While both the EC and WTO food safety disciplines have originally been conceived as exclusively free-trade mechanisms allowing public health regulations as an exception (Article XX GATT and 30 EC, respectively) to their main prohibitions, the European regime acquired throughout the time an additional and autonomous objective: the protection of human health and consumer interests. Accordingly, where under the WTO/SPS framework food safety regulations are tackled as potential obstacles to trade that may exceptionally (when all scientific requirements are met) be authorized, - within the EC - food safety is an autonomous goal to be pursued together with the objective of ensuring an effective functioning of the internal market.

This is proved by Regulation 178/2002 where it says that the overriding principles of the EC food safety policy are not only to ensure the free movement of foodstuffs within the internal market, but also "to seek to achieve a high level of protection of human health and consumers' interest"[755]. This Regulation, by focusing specifically on the food safety objective per se, may be seen as the founding act establishing for the first time food law as an autonomous branch of EC law. Food legislation ceases to be nothing more than a spill-over effect of the internal market construction to become an independent and particularly relevant EC policy.

This increasing focus of the EC on food safety has to be contextualized within a more general European attempt to integrate into its market-oriented agenda also other interests

[755] Article 1, Regulation 178/2002.

deserving equal protection, such as European citizens' public health protection. Since 1992, EC health, safety, environmental and consumer protection regulations must take "as a base a high level of protection" (Article 95, par. 3 ECT). The introduction of such a minimum level of health protection clearly shows how the public health objective pursued by food safety regulations has become autonomous from their original focus on trade[756].

In short, if the WTO scientific regime, without establishing any minimum level of health protection, follows exclusively a market-opening agenda, the EC discipline answers to a more complex public demand for health protection within an increasingly integrated Union by imposing not only on Member States' measures but also on EC-wide regulations to attain a high level of protection of protection.

It has been shown above how the different objectives underpinning the two food regimes have influenced the standard of review to be applied by their respective courts. Now, it will be illustrated how the different logics underlying the two regimes also find reflection in their different instruments of integration.

### 1.2 The instruments: Negative Integration & Positive Integration Tools

Both the EC and the GATT/WTO food regimes have originally developed by relying on the negative integration provisions existing in their respective legal systems[757]. Thus, similarly to what happened in the EC context with Article 28 EC, Articles III and XI GATT have been used to tackle all those regulations aimed at protecting public health. As a consequence of such a negative integration approach, their respective food regimes began developing in a rather piecemeal fashion, by exclusively addressing those measures giving rise to a dispute[758]. While doing so, both the EC and the GATT focused on the free movement of foodstuffs throughout the internal market and the international world trade, respectively, rather than on the food safety goal.

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[756] Preamble (8) of Regulation 178/2002 states that: "The Community has chosen a high level of protection as appropriate to the development of food law, which it applies in a non-discriminatory manner whether food or feed is traded on the internal market or internationally".

[757] As seen above, for the purpose of this study we employ the terms negative and positive integration as conceived and elaborated by J. Tinbergen back in the 1950s. While "negative integration" refers to those instruments prohibiting the use or requiring the phasing out of a particular type of trade-restrictive measure, such as quantitative restrictions or tariffs, "positive integration" refers to those normative standards that Members must follow in exercising their regulatory prerogatives. See supra note 18.

[758] However, it is worth noticing that, in contrast with the EC, the WTO cannot initiate legal proceedings against a Member State for an alleged violation of its Agreements.

As a result, the ECJ handed down a number of landmark judgments relating to food products which laid down the foundations of the free movement of goods case law. These judgments, by defining the scope of Article 28 EC, paved the way for the development of a food law and policy within the Union. In fact, in parallel to the ECJ's activity, the Commission began to rely on the positive integration instruments offered by the Treaty (Article 100; current Article 94 EC) in order to adopt a number of legislative initiatives specifically aimed at promoting the free movement of foodstuffs within the EC. Thus, for instance, the EC adopted its first food legislative act: the 1962 food colors directive; it then prepared two Communications, one in 1985 entitled "The Completion of the Internal Market: Community Legislation on Foodstuffs" and another in 1989, entitled "The Free Movement of Foodstuffs within the Community". As it emerges from this brief historical excursus, EC food law began developing on the two parallel paths of negative and positive integration, with the ECJ ensuring the application of the Treaty provisions and the Commission proposing the adoption of legislative and policy initiatives.

It is common place to argue that, unlike the EC, the WTO does not dispose of positive integration tools. While it is true that its Member States did not transfer any regulatory powers to the WTO, the signature of the Uruguay Round Agreements has partly changed this exclusive 'negative integration' vision of the GATT/WTO legal system. The following paragraph tries to explain how the conventional negative-integration's vision of the GATT/WTO no longer depicts reality.

### A. Positive Integration in the WTO: internationals standards as WTO "de facto" food legislations

The adoption of the TBT and SPS Agreements represents one of the most innovative features of this Round. As seen above, these agreements, building upon the previous plurilateral 1979 Agreement on the Technical Barriers to Trade, deal with the growing problem of non-tariff barriers to trade consisting in health and safety standards regulations.

In order to ensure that these regulations genuinely pursue their declared public policy objectives and do not constitute disguised restrictions on trade, the TBT and the SPS have adopted an approach which goes far beyond the basic principles of GATT 1947. These

agreements provide for a set of rules addressed to WTO Members that, instead of constraining their regulatory powers through prohibitions, it requires them to adopt a positive behavior[759]. Among these positive obligations, the most significant are the harmonization requirements.

As seen above within the SPS framework, WTO Member States must base their sanitary and phytosanitary measures on international standards, guidelines or recommendations, where they exist. Although not directly establishing these standards but referring to some specific standard-setting organizations, the SPS Agreement, by encouraging the adoption of harmonized food measures in order to minimize the negative effects on trade stemming from diverging national regulations, pursues a positive integration agenda.

In particular, by presuming the conformity with the WTO of all food safety measures based on international standards, the SPS Agreement has delegated to these standard-setting bodies some quasi-legislative powers they did not have for themselves.

For this reason, WTO Members are encouraged to play a full part in the relevant international organizations and their subsidiary bodies, in particular in the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention.

As illustrated above[760], as soon as they became fully aware of the indirect 'quasi-legislative' power given to these organizations, Member States have invested an increasing amount of resources in order to effectively participate within these bodies' activities.

Although they do not legislate in the full sense of the term, these organizations lay down rules that, as long as they are adopted and respected, may produce some legal effects.

The SPS drafters' choice to set up this quasi-legislative system outside of the WTO offers several advantages. The 'outsourcing' of the harmonization system to some external organizations does not only facilitate the negotiations leading to the adoption of a

[759] Although also the TRIPS may seem to impose similar 'positive' constraints on WTO Members, it is worth noticing the difference existing between these TRIPS' requirements and those contained in the TBT/SPS. Contrary to the latter, the former merely refers to pre-existing norms developed in WIPO Treaties, rather than turning a "mass of normative material that never before had the status of international law into international legal obligation". See on this point, R. Howse, *A New Evidence For Creating International Legal Normativity: the WTO Technical Barriers to Trade Agreement and "International Standards* (on file with the Author), at 3.

[760] See supra Part II, chapter 1, section 4.1, entitled Relevant International Standards Organizations.

standard by skipping the need for unanimity, but it might also be capable of insulating the WTO from any criticism it may be formulated about a particular standard.

In fact, the previous analysis of the operation of CAC, OIE and IPPC has shown the existence of increasingly politicized debates surrounding the adoption of international standards within these organizations. As a result, most of the standards tend to be adopted today by slim majority rather than by unanimity. However, this outcome does not change the normative values of the adopted standards. In fact, once a standard is adopted, the Dispute Settlement Body does not consider it to be of any importance to take into account of the institutional context in which the standards arise. In particular, as the *Sardines* case clearly shows[761], a WTO Member may be bound to apply an international standard that it voted against even if it is only a voluntary norm. Although the AB came to this conclusion in a case involving the application of an international standard under the TBT, there are good reasons to be believed that this answer could be extended to the interpretation of the SPS Agreement. Therefore, now, after this ruling in *Sardines*, international standards are binding through the SPS and the TBT Agreements regardless of whether they are made by consensus.

Last but not least, it may be noticed that the SPS indirect harmonization structure may guarantee that the international standards be negotiated by scientists, experts in the relevant subject-matter, rather than by trade negotiators.

To support our finding according to which the SPS harmonization requirements do represent an innovative, though peculiar, instrument of positive integration within the WTO framework, one should look at the consequences stemming from a food safety national measure relying on an international standard.

Similarly to what happen when a EC Member State conforms to a EC regulation, when a WTO Member relies on an international standard, it has not to defend its food safety measure under the SPS Agreement. In particular, the soundness of the scientific evidence supporting that particular standard is unreviewable even though it may restrict the trading opportunities of other Member States. Furthermore, in that circumstance, it is not given the opportunity for other Members to challenge the regulation based on an international standard by alleging that a less trade restrictive measure would have been available.

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[761] *EC - Trade Description of Sardines*, WTO Appellate Body Report WT/DS231/AB/R, adopted on 23 October 2002. European Communities, Appellant; Peru, Appellee; Canada, Chile, Ecuador, United States and Venezuela.

Thus, following international standards could provide some protection for domestic regulatory autonomy against the growing judicial intrusion shown by the WTO judicial bodies.

In the light of the above, it may be argued that, contrary to conventional wisdom, the WTO/SPS food framework relies not solely on negative integration instruments but also, and especially, on some specific instrument of positive integration.
Although representing a legislative tool much less developed than those available within the EC, the SPS "harmonization" requirements allow the WTO food regime to rely, though indirectly, also on some form of harmonizing power.
The choice of the SPS negotiators to refer to standard-setting international organizations outside the WTO framework has inevitably invested them of a quasi-legislative power. Although their standards remain not legally binding, but merely advisory in nature, the consequences stemming from their adoption by a Member State render them "de facto" WTO food legislations.

However, in drawing a parallel between EC food legislations and this "de facto" WTO food regulations, one should insist on their different normative nature.
While it is true that the SPS's "harmonization" requirements do represent an emerging and innovative form of positive integration within the WTO legal system, they do not entirely fit into the traditional dichotomy existing between negative and positive integration.
This conceptual scheme of integration traditional implies also a distinction between free trade and the pursuit of other non-trade public policy objectives. Accordingly, while the reduction of tariff barriers and the elimination of quantitative restrictions might be perceived as instruments exclusively aimed at liberalizing trade, the adoption of harmonizing measures might be seen as a tool used to promote other non-trade objectives, such as other legitimate public policy goals[762]. If one applies this additional meaning of the positive/negative integration dichotomy to the SPS indirect harmonizing power, it discovers that, unlike the EC food regulations, the international standards do not

[762] See F. Ortino, *Basic Legal Instruments for the Liberalization of Trade*, supra note 10, at 21; J. Scott, *GATT and Community Law: Rethinking the 'Regulatory Gap'*, in Shaw and More (eds.), New Legal Dynamics of EU, 1995, at 147.

pursue other legitimate public policy objectives, but rather mere free trade. In other words, while EC regulations and directives differ from the negative prohibitions contained in the Treaty to the extent they are not only trade liberalization instruments but also tools to safeguard and further other legitimate policies, the international standards cannot be seen as promoting other values but trade.

This finding seems to be confirmed by the stated goal of the Codex where one reads

> "to guide and promote the elaboration and establishment of definitions and requirements for foods, to assist in their harmonization and, in doing so, *to facilitate international trade*"[763].

The ultimate goal pursued by these standard-setting organizations is clearly related to trade rather than to other public policy legitimate goals, such as food safety.

However, it has been argued that, although trade-oriented, the international regulatory processes led by these organizations, as long as they are open to a greater variety of stake-holders than many domestic processes, may actually enhance democracy[764]. Thus, for instance, the NGOs' participation in Codex, though imperfect, shows much greater openness than in the WTO itself[765]. The recent *Biotech* negotiations have clearly shown the impact that growing public interest participation may produce within Codex[766].

Notwithstanding these positive developments, it remains that traditionally the CAC standard-setting practice has shown a big pro-industry bias, by not making it easier for consumer associations to participate to the highly technical debates in the CAC working groups and committees[767].

Lastly, while comparing the instruments of both the EC and the WTO, one may not pass under silence their respective enforcing capacities. Although the DSU stresses that

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[763] See Codex Alimentarius Commission, *This is Codex Alimentarius*, 2nd edition.

[764] J. Braithwaite, *Prospects for Win-Win International Rapprochement of Regulation in Organization for Economic Corporation and Development, Regulatory Co-operation for an Interdependent World*, Paris; OECD, 1994.

[765] The EC Member States strongly support the NGOs' participation, such as, for instance, the European Consumers' Organisation (BEUC) within Codex. See Agenda item 14, ALINORM 05/28/9E.

[766] For an overview of the current debate on GMO food within Codex, see EC comments to Circular Letter 2005/2-FBT, Request for proposals for new work to be undertaken by the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology, 9 June 2005.

[767] C. Joerges and J. Neyer, *Politics, Risk Management, World Trade Organisation Governance and the Limits of Legalisation*, in Science and Public Policy, June 2003, at 222.

"prompt compliance with the recommendations or rulings of the DSB is essential in order to ensure effective resolution of disputes to the benefit of all Members", no mechanism of enforcement is available. As it has been stated

> "The WTO's enforcement mechanisms function neither as a deterrent nor as a punishment, but merely have an offsetting effect, which leaves the non-compliant party at liberty to choose between complying with WTO law or accepting the cancellation of proportionate concessions"[768].

Moreover, in contrast with the EC, the WTO does not have the competence for introducing legal proceedings nor the option of imposing administrative fines against a non-compliant Member.

### B. The lack of a Risk Analysis scheme within the WTO/SPS food regime

There is a further important consequence stemming from the WTO/SPS's choice to refer to the standards elaborated by other international organizations as the benchmark international standards for WTO Members. Since neither the WTO nor the SPS Committee are in charge of developing these "de facto" food regulations, it results that the WTO/SPS framework is almost silent on the modalities through which these standards should be established and, more in general, on how (food) risks should be analyzed by WTO Members' decision-makers.

In other words, the WTO food regulatory framework, by relying on this 'outsourced' harmonization system, does not provide for a complete risk analysis framework that Member States should follow while adopting food safety measures. Yet, as long as WTO "de facto" food safety measures are adopted by Codex and not by the WTO itself, it is at Codex's approach to risk analysis that one must look at in order to compare the EC risk analysis schemes with the WTO ones.

[768] *Ibid.*, at 223.

Against this backdrop, the next chapter will venture a comparison between the risk analysis schemes underlying the WTO and EC food regimes, respectively, by thoroughly analyzing the Codex's emerging food safety risk analysis model.

## CHAPTER II: COMPARING FOOD SAFETY RISK ANALYSIS SCHEMES

This chapter provides for a comparison between the WTO and the EC food safety risk analysis models, by looking at their respective structures. In particular, due to the lack of risk management policy within the WTO risk analysis model, the focus will shift, when appropriate, to the Codex' principles for risk analysis.

### 1. COMPARING EC AND WTO FOOD SAFETY RISK ANALYSIS: WHAT RISK ANALYSIS MODEL FOR THE WTO?

Similarly to the EC food Regulation, also the SPS agreement makes an attempt to impose some common structure on the way in which WTO Members arrive at and adopt food safety measures.

However, while the EC has established its risk analysis by heavily relying on the traditional scheme originally developed on the other side of the Atlantic by the US National Research Council[769], and subsequently adopted by several international organizations dealing with risk analysis[770], the WTO preferred not to endorse any particular form of risk analysis.

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[769] The NRC has conducted a series of studies on how society can understand and cope with those risks. In particular, the distinction between risk assessment and risk management has been originally conceived in *Risk Assessment in the Federal Government* (supra note 159) a study that sought "institutional mechanisms that best foster a constructive partnership between science and government". Subsequently, this distinction played a crucial role in the development of an organizational separation of risk assessment and risk management in many US regulatory agencies. However, as we will see further, later publications of the NRC recognized the difficulties of maintaining a sharp dividing line between the two processes and emphasized the importance of ensuring interaction and communication between risk assessors and risk managers. See P. Stern and H. Fineberg (eds), *Understanding Risk: Informing Decisions in a Democratic Society*, supra note 158, and for a brief account of this development also Ingrid Suezenauer, M. Tamplin, B. Buchanan, S. Dennis, L. Tollefson, A. Hart, *Briefing Paper: US Experience*", European Workshop on the interface between Risk Assessment and Risk Management, 2003, supra note 158.

[770] See, within the U.S., *NRC Science and Judgment*, supra note 159, at 4; see, within the OECD, Descriptions of selected key generic terms used in chemical hazard/risk assessment; OECD/IPCS, October 2003, available at http://www.oecd.org; see within FAO and WHO, Joint FAO/WHO Expert Consultation, Application of Risk Analysis to Food Standards Issues (WHO/FNU/FOS/95.3, 13-17 March, 1995, Geneva 1995), p. 6; Joint FAO/WHO Expert Consultation, Risk Management and Food Safety, (27-31 January, 1997), FAO Food and

Accordingly, from a reading of the WTO/SPS text does not emerge any specific model of risk analysis that Members should follow when adopting SPS measures within their own legal systems. However, some signs of the conventional approach to risk, incorporating the three distinct but closely linked components of risk analysis, become visible throughout the SPS text.

As seen above, both the WTO and the EC embraced science as the organizing principle while regulating public health measures. Rather than relying solely on non-discrimination as the main criterion enabling them to distinguish between legitimate and illegitimate barriers to trade inspired by public health protection, they introduced a new, more demanding element, with reference to those measures: scientific justification. In particular, the scientific element would ensure that SPS measures address a real, objectively established, health risk and are not protectionist measures disguised as health regulations.

According to the traditional structured risk analysis scheme, this scientific requirement is procedurally translated into the risk assessment stage as opposed to the risk management stage.

As it has been shown above, the only requirements imposed by the SPS Agreement relating to risk analysis boil down into a detailed risk assessment obligation that Member States should satisfy while adopting SPS measures. In other words, risk assessment is the only formalized risk analysis step expressly recognized and defined by the SPS Agreement. Annex A of the SPS defines it as "the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary and phytosanitary measures which might be applied" or as "the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants toxins or disease-causing organisms in food beverages or feedstuffs". Thus, while expressly recognizing and regulating in great detail the risk assessment stage of risk analysis[771], the SPS does not even mention the risk

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Nutrition Paper 65, 1997; Joint FAO/WHO Expert Consultation, The Application of Risk Communication to Food Standards and Safety Matters, Rome, 2-6 February 1998, FAO Food and Nutrition Paper 70, 1999.

[771] As to the risk assessment procedural obligations, Article 5 tells Member States to rely on the risk assessment techniques developed by the "relevant international organizations", which presumably include the Codex, IPPC and OIE, and also to take in due account the following factors: available scientific evidence, relevant process and production methods; relevant inspections, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine and other treatment.

management stage, i.e the process, distinct from risk assessment, of weighing policy alternatives and selecting appropriate measures and control options[772].

Accordingly, WTO Members are free to adopt all measures they deem necessary to protect food safety, provided there is a demonstrable scientific basis for their measures. The SPS Agreement expressly recognizes WTO Members' right to determine the level of sanitary and phytosanitary protection they consider appropriate[773]. However, the acknowledgement of Member States' freedom in managing food safety risk is accompanied by some constraints and, any case, "it does not represent a carte blanche for legitimizing SPS measures"[774].

In determining the level of protection they consider appropriate[775] and in selecting the measures that are instrumental in achieving this chosen level protection[776], Members must take into account the objective of minimizing negative trade effects. Moreover, they have also to avoid arbitrary or unjustifiable distinctions in the levels of protection they consider to be appropriate in different situations, if such distinctions result in discrimination or disguised restrictions on international trade[777]. These provisions, by imposing the respect of the 'proportionality'[778] and 'consistency' principles, they sketch out a really basic risk management policy, whose sole objective is to prevent food safety measures from producing unnecessary negative effects on international trade and being misused for protectionist purposes.

More in general, the risk analysis promoted by the WTO/SPS prescribes its Members to respond to food safety crisis by further centralizing risk assessment. Although this supposedly simplifies the free movement of foodstuffs in international trade, it does not answer to any other non-economic interests at stake.

By not fully shaping a risk management policy of food safety risks, the WTO regime diverges from the EC discipline which lays down strict procedural requirements for both

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[772] It may be recalled that in the *Hormones* case the AB explicitly rejected Panel's effort to distinguish between risk assessment and risk management within the SPS Agreement, by stating that "Article 5 and Annex A of the SPS Agreement speak of "risk assessment" only and that the term "risk management" is not to be found either in Article 5 or in any other provision of the SPS Agreement". See *EC – Hormones*, AB Report, at para 181.

[773] Article 2 SPS provides that: "Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement".

[774] A. Desmedt, *Proportionality in WTO law*, 5 JIEL (2001) 441 at 458.

[775] See Article 5.4 SPS.

[776] See Artile 5.6 SPS.

[777] See Article 5.5 SPS.

[778] On the interpretation of this requirement in WTO law and in particular the SPS and TBT Agreements, see Ortino, supra note 10, at 445 ss, notably at 464.

the risk assessment and risk management phases of the food risk analysis scheme that the EC and its Member States must follow.

Accordingly, WTO Members, although instructed on how to conduct a risk assessment of a food product for the purposes of the SPS Agreement, they are left alone when it comes to decide about how to regulate the entry of that particular food into the market.

In particular, this vacuum in the WTO/SPS risk regulatory discipline gives rise to the following questions:

a) How Member States, once they have conducted the risk assessment of a particular foodstuff, should manage the risk stemming from its consumption? Which factors should they take into account? (2.)

b) What Member States should decide in case of scientific uncertainty about the safety of a certain product? (3.)

These questions, relating to the risk management stage of risk analysis, do not find a direct answer into the SPS text. In fact, as SPS negotiators considered it inappropriate for the WTO to be more prescriptive about risk management, they considered Codex as a better forum for the elaboration of guidelines for regulatory action.

Therefore, given the status of Codex standards as international reference points in the framework of the SPS, one should look at Codex' risk analysis scheme in order to obtain an answer to these questions. As Codex international standards represent "de facto" WTO food regulations, likewise Codex risk analysis techniques contribute to shape the WTO risk analysis model. This is confirmed by the same SPS Agreement, whose Article 5, paragraph 1, tells Members to take into account *risk assessment techniques* developed by the relevant international organizations.

Before addressing the abovementioned risk management issues, it might be useful to briefly introduce the main features of the risk analysis scheme developed within Codex.

### 1.1. Risk Analysis in the framework of Codex

Risk analysis evolved within the Codex Alimentarius Commission during the 1990s as a result of the imminent entry into force of the WTO Agreements.

Although the SPS Agreement placed no obligations on Codex itself, it was inevitable that Codex would determine what changes were needed to adapt itself to the new tasks. The implications stemming from the new acquired status were recognized well before the

entry into force of the WTO Agreements. Thus, in 1991, an FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade, was convened in Rome to discuss the likely implications of the proposed SPS Agreement on Codex operation. This conference stressed the importance of scientific committees such as the Joint FAO/WHO Meeting on Pesticides Residues (JMPR) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in providing evaluations based on sound science and risk assessment principles.

There was general consensus that the expected adoption of the WTO Agreements meant that Codex needed to develop new practices and procedures, notably with respect to the use of science. In the light of the above, with respect to the role of science, the Conference recommended the importance of

> "[e]stablishing a review programme to examine all Codex standards as to their current relevance and sound scientific basis, with a view to facilitating international trade. This should include prioritization of standards to be examined" and "Requesting all Codex Committees, as well as JECFA and JMPR, to continue to base their evaluations on suitable scientific principles and to ensure necessary consistency in their risk assessment determinations"[779].

In particular, the SPS obligation on WTO Members to base their food safety measures on scientific evidence required Codex to further develop the methods it relied upon to elaborate and adopt standards. Most of Codex techniques were vague and subject to diverging interpretation and application from meeting to meeting. Since most of the Codex Members had an obligation, stemming from their WTO Membership, to use scientific principles, it was incumbent upon Codex Members to make full use of science when adopting Codex standards relating to food safety. In light of the above, FAO and WHO promoted additional consultations to address the three components of risk analysis: risk assessment, risk management and risk communication[780].

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[779] Report of the FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade, Rome, 18-27 March 1991, FAO/WHO Programme (ALICOM 91/22).

[780] Thus, for instance, in 1999, the Codex Committee on Food Hygiene has also developed the Principles and Guidelines for the Conduct of Microbiological Risk Assessment and is currently developing Principles and Guidelines for the Conduct of Microbiological Risk Management.

The matter was further discussed at the 10th Session of the CCGP in September 1992 which asked the Secretariat to draft a paper on the issue. The following year, during the 20th CAC meeting, the Commission, after having experienced a difficult debate on hormones for beef, asked the CCGP to develop some guidance on how science and other factors should be taken into account into its standard-setting procedures. A paper was subsequently presented at the 11th Session of the CCGP in April 1994 entitled: "Consideration on the Role of Science in the Codex Decision-Making Process"[781]. The most controversial point was whether these Statements should have been incorporated into the rules of procedures or merely in the General Principles of Codex Alimentarius, which, unlike the former, do not constitute binding rules for the CAC work. After some lengthy and difficult debate, the Committee established a Working Group that finally indicated which sections of the Procedural Manual might have needed some revision. On that basis, during the 41st Session of the Executive Committee in June 1994, the Committee elaborated four 'Statements of Principle', that eventually became, at the 21st CAC meeting in July 1995, the "Statements of Principle concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Legitimate Factors are Taken into Account". After some discussions, these Statements have been finally incorporated as an Appendix into the Procedural Manual entitled "General Decisions of the Commission"[782].

Risk analysis is since then considered an integral part of the standard-setting process within Codex. For that purpose, the Commission has established not only the "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius"[783] but also the "Definitions for the Purposes of the Codex Alimentarius" of risk analysis terms related to food safety[784]. These principles for risk analysis are intended for application in the framework of the Codex Alimentarius. They provide guidance to the Codex Alimentarius Commission and the Joint FAO/WHO expert bodies so that food safety and health aspects of Codex standards are based on risk analysis.

The model of risk analysis chosen by Codex Members reflects the main features of the structured approach comprising the three distinct but closely linked components of risk

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[781] CX/GP 94/4.

[782] See the 10th Edition of the Procedural Manual published in 1997.

[783] The "Working Principles for Risk Analysis" are contained in Section III of the CAC Procedural Manual, Fourteenth edition, 2005, at 101 ss.

[784] The "Definitions" are listed in Section I of the CAC Procedural Manual, Fourteenth edition, 2005, at 43 ss.

analysis originally elaborated on the other side of the Atlantic by the National Research Council.

According to the definition given by Codex, risk analysis provides

> "a process to collect, analyze and evaluate, systematically and transparently, relevant scientific and non-scientific information about a chemical, biological or physical hazard possibly associated with food, in order to select the best option to manage that risk based on the various alternatives identified"[785].

A fundamental principle of all Codex standards stems directly from this vision of risk analysis: the food standards must be based on science.

As WTO Members are obliged to base their SPS measures on an assessment of the risk taking into account all available scientific information, the usefulness of Codex standards to the WTO/SPS Agreement is evident.

In particular, the risk analysis used in Codex, as provided for by the "Working Principles for Risk Analysis", must be "conducted in accordance" with two important texts annexed to the Codex Procedural Manual[786]:

- The Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account[787]; and
- the Statements of Principle Relating to the Role of Food Safety Risk Assessment[788].

In particular, the first text states that:

> "(1) The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that standards assure the quality and safety of the food supply".

The importance of science is then tempered by two further points which state:

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[785] Section I of the CAC Procedural Manual, Fourteenth edition, 2005, at 43 ss.

[786] See Article 4, point 3, of the Working Principles for Risk Analysis" are contained in Section III of the CAC Procedural Manual, Fourteenth edition, 2005, at 101 ss.

[787] Originally adopted during the CAC 21st session. See Report of the 21st Session, at 61.

[788] See Appendix of the CAC Procedural Manual, Fourteenth edition, 2005, at 188 ss.

"(2) When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade"
(3) In this regard it is noted that food labeling plays an important role in furthering both objectives".

As to the Statements of Principle Relating to the Role of Food Safety Risk Assessment, this document provides that:

"Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances", and "Food safety risk assessment should be soundly based in science, should incorporate the four steps of the risk assessment process, and should be documented in a transparent manner".

As it will shown in the following pages, these documents combined with the Working Principles have shaped the Codex risk analysis scheme. It is argued that this model of risk analysis is gradually becoming, through the bridge of the SPS harmonization requirements, a "de facto" WTO risk analysis model.

## 2. The Integration of "other legitimate factors" into the EC and WTO/SPS Risk Analysis Models

In an effort to eliminate protectionist barriers to trade, both the EC and the WTO regimes impose strict scientific justification requirements, notably a duty to conduct a risk assessment while adopting food safety measures. However, risk assessment does not provide the decision-makers with a definitive regulatory answer, but rather it offers them some information upon which to take regulatory action.
While both food safety risk analysis schemes require to satisfy this scientific requirement, it is only the EC risk analysis model which tells regulators how to take the subsequent risk management decision, by listing the 'other (non-scientific) factors' to be taken into account in the risk management stage of the regulatory process.

According to the EC food safety risk analysis model, besides scientific findings, "other factors legitimate to the matter under consideration", such as societal, economic,

traditional, ethical and environmental considerations may play a role in the decision to take protective action[789]. Although science plays the major role at the risk management stage, the EC Food Regulation reserves expressly the right of risk assessors to take these "other factors" into consideration when reaching a final decision[790]. This is because

> "it is recognized that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decisions should be based"[791].

It is indeed settled case law that a decision taken at Communiy level within the context of risk management may depart from the findings of a scientific assessment.[792] The perceived need to consider also non science-based factors within the decision-making process characterizes the European approach to risk analysis by differentiating it greatly from the one adopted by the WTO/SPS legal frameworks.

In fact, contrary to this risk analysis model, the WTO food safety risk analysis does not specify the extent to which 'other factors', such as social values and consumer preferences, may be taken into account in national regulatory decision-making processes. As shown above, the WTO does not endorse any particular risk analysis model, by mainly focusing on the risk assessment stage of risk analysis. Yet, this exclusively scientific-oriented approach would seem to suggest that the risk management phase should focus solely on the rational, scientific-driven data stemming from risk assessment, by thus ruling out all 'other factors' from consideration. That basis for law-making would seem to exclude, or at least marginalize, other public concerns or other forms of knowledge from consideration as part of the process of regulating food safety risk. By exalting the role of science, the SPS Agreement tends to rule out all non-scientific factors from standard setting[793].

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[789] See Preamble (19) of Regulation 178/2002 and its Article 6, paragraph 3. See also the broader list of 'other factors' contained within the White Paper (see supra note 133, para 4), which mentions "environmental considerations, animal welfare, sustainable agriculture, consumers' expectation regarding product quality, fair information and definition of the essential characteristics of products and their process and production methods". However, containing both lists mere examples, their differences do not carry any particular value and should not be overemphasised.

[790] The regulation states several times that risk management decisions may consider not only risk assessment but also "other legitimate factors". See preamble (19), Article 3 (12) and Article 6 (3).

[791] *See* Regulation 178/2002, preamble (19).

[792] Commission v. Denmark, supra note 271, para 144.

[793] J. Cameron, *The Precautionary Principle, in Trade, Environment and the Millenium*, supra note 182, at 261.

This clear divergence between the food safety risk analysis schemes of the EC and the WTO deserves great attention as it carries the potential to bring the EC food regime at odds with WTO law.

### 2.1 "Other legitimate factors" in the EC Food Safety Risk Analysis: a potential incompatibility issue under WTO law?

There are several interesting questions that may arise from the role of these 'other factors' in regulation-making. In particular, there is an emerging debate as to whether the EC risk analysis model, by explicitly acknowledging the importance of non-scientific factors may be considered compatible with the SPS risk assessment requirements imposed by Article 5.1 SPS. The issue is whether a EC food safety measure taking into account 'other factors' could still be considered as "based on" risk assessment within the meaning of the SPS Agreement.

But, before, can WTO judicial bodies review a Member's reliance on such factors? To what extent should the WTO recognize such factors as having a legitimate role in decision-making?

Members' reliance on 'other factors' would not seem directly reviewable under Article 5.1 SPS to the extent that provision does not empower the WTO judicial bodies to determine the legitimacy of any of the 'other factors' considered in the risk management stage, but merely the scientific basis of the adopted measure. However, in determining whether there is a rational relationship between the adopted food safety measure and the risk assessment, it is inevitable that panels will be influenced by their perception of the legitimacy of the 'other factors' taken into account by the national authorities while adopting the contested measure. Thus, on the one hand, should the panel share the consumer fears related to the consumption of a certain product, it is likely that it will be particularly willing to endorse the adoption of a conservative regulation. On the other hand, if a panel were not so favorably disposed toward a certain 'other factor', it would be keener on looking at the relevant measure as no longer enjoying that logical relationship.

By entrusting WTO judicial bodies with a great dose of subjectivity in their assessment, this situation gives rise to a relevant amount of legal uncertainty in the international food

trade arena. Which 'other factors' may be accommodated into the SPS risk analysis scheme?

As shown above, the current SPS Agreement, by merely listing those factors that may be taken into account in the risk assessment stage, does not provide a definitive answer to that question.

For this reason, it is suggested to look at the food safety risk analysis scheme provided by the Codex Alimentarius Commission as the relevant benchmark for predicting which 'other factors' may, or may not, play a legitimate role in the risk analysis of food products within the WTO/SPS Agreement. Indeed, it is likely that also the WTO judicial bodies, in establishing whether a national food safety measure is "based on risk assessment", will be influenced by the risk analysis model, notably by the risk management policy, developed by Codex.

### A. The Role of 'Other Factors' in Codex's Risk Analysis

In 1995, Codex adopted the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors Are Taken into Account. These were adopted at the 21st session of the CAC meeting and subsequently incorporated into the Codex Procedural Manual[794].

While Principle 1 states that Codex "food standards, guidelines and other recommendations shall be based on the principle of sound scientific analysis and evidence", Principle 2 states that "when elaborating and deciding upon food standards, Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade". This last statement reveals quite obscure since it does not indicate which other factors may be taken into account and to what extent they can legitimately be invoked in the adoption of food standards. Furthermore, similarly to what happen in the application of the SPS Agreement, one may wonder to what extent a food safety standard

[794] CAC Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors Are Taken into Account (Decision of the 21st Session of the Commission 1995 ALINORM 95/37).

justified by 'other legitimate factors' may still be considered 'based on the principle of sound scientific analysis and evidence" under Principle 1.

An opportunity to launch a debate on the revision of these Statements of principle arose in 1998 during the negotiations that should have led to the adoption of Maximum Level of Residues (MRLs) for Bovine Somatropin (BST) within Codex[795]. This was the first occasion ever in which a Codex Member, notably the EC, invoked 'other factors', as quoted in Principle 2, in order to prevent the adoption of the relevant standard.

While the US was in favor of adopting the MRLs for the BST, the EC Members opposed it strongly by invoking the need to consider 'legitimate factors other than science' in determining the relevant standard. In fact, the adoption of a limit would have implied that a scientific evidence could allow the setting of a safe level, contrary to the position in the EC where the use of the substance had been banned. In particular the EC stressed the need to give consideration to the technological justification for using the hormone concerned, animal welfare and consumers' concerns for BST.

Lacking consensus on the use of 'other factors' in the standard-setting process, the EC enacted a moratorium on the use of BST within the European Community until 1999.

It is against this backdrop that the Codex Alimentarius Commission gave mandate to the Codex Committee of General Principles (CCGP) to identify which 'other factors' may be considered in the risk management of food safety standards[796].

Accordingly, in 1998, the CCGP began revising the Statements of Principle on the Role of Science and the Extent to Which Other factors may be taken into account[797]. Some delegations noted the difficulties of determining the relevance and legitimacy of other factors, the need to base them on objective criteria, especially to prevent their use as a barrier to trade. The Joint FAO/WHO Expert Consultation on Risk Management and Food Safety recommended that the Commission should clarify the application of the Second Statement of Principle. In particular, the Consultation indicated that

[795] BST is a synthetically produced version of a natural occurring hormone intended to increase milk production. The Codex Committee for the Residues of Veterinary Drugs in Food (CCRVDF) had discussed the definition of MRLs for this substance for many years, but without never reaching an agreement.

[796] See the 22nd Report of the CAC, para 67-68.

[797] Report of the 13th Meeting of the CCGP, 1998, para 59-70.

"[...] this clarification should include explicit description of the factors which may be considered, the extent to which these factors should be taken into account and the procedures to be used in this regard"[798].

For that purpose, the Codex Secretariat predisposed a paper revealing that there were several categories of 'other factors' that had previously been used in Codex standard-setting activities, mainly relating to technological, economic and safety factors[799]. While the EC argued that these categories of factors combined with other specific factors, such as consumer concerns, environmental risks and ethical and cultural elements, were essential in assuring a general acceptance of Codex international standards, other Members stated that giving consideration to these factors "could open a Pandora's box"[800]. In fact, the same Codex paper clarified that

"these recommendations should not be interpreted as allowing for the consideration of elements which are not related to health protection, such as consumer preference, because they differ significantly from one country or one region to another"[801].

This debate led to the launch of a general discussion on the role of 'other legitimate factors' in the Codex risk analysis model within the 14th meeting of the Committee on General Principles held in 1999. After two years of fervid discussion, notably between the European countries and the US, the Codex Commission adopted a Statement entitled "Criteria for Consideration of the Other Factors Referred to in the Second Statement of Principle"[802]. These criteria have been incorporated as an appendix into the Procedural Manual and read as follow:

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[798] Risk Management and Food Safety – Report of a Joint Committee FAO/WHO Consultation, 1997.
[799] See Review of the Statements of Principle on the Role of Science and the Extent to Which Other Factors should be Taken into Account (1) Role of Science and Other Factors in Relation to Risk Analysis (CX/GP 99/9). These elements are: economic implications in trade; feasibility from the technological point of view; food security; good agricultural practice in relation to pesticide MRLs; good veterinary practive in relation to veterinary drugs MRLs; technological justification in the case of food additives; the nature of the production or processing methods and their particular constraints; the availability of methods and analysis and sampling plans and the feasibility of control and inspection measures. For a comment on this paper, see Jukes, *The Role of science*, supra note 543, at 29.
[800] See Poli, supra note 525, at 624 citing OECD, Food Safety and Quality: Trade Considerations (2000), at 34.
[801] Paper prepared for the Codex Committee on General Principles (14th session), CX/GP99/09, at para 9.
[802] Decision of the 24th CAC Session, 2001.

- when health and safety matters are concerned, the Statements of Principle Concerning the Role of Science and the Statements of Principle Relating to the Role of Food Safety Risk Assessment should be followed;

- *other legitimate factors* relevant for health protection and fair trade practices *may be identified in the risk management process*, and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related texts;

- *consideration of other factors should not affect the scientific basis of risk analysis*; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;

- it should be recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant world-wide; (*Confusion should be avoided between justification of national measures under the SPS and TBT Agreements and their validity at the international level.*)

- only those other factors which can be accepted on a world-wide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex;

- the consideration of specific other factors in the development of risk management recommendations of the Codex Alimentarius Commission and its subsidiary bodies should be clearly documented, including the rationale for their integration, on a case-by-case basis;

- the feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;

- the integration of other legitimate factors in risk management should not create unjustified barriers to trade (*According to the WTO principles, and taking into account the particular provisions of the SPS and TBT*); particular attention should be given to the impact on developing countries of the inclusion of such other factors.

Although not a model of clarity, the *Criteria* seem to make it possible to invoke, on a case-by-case basis, also non-scientific factors in the risk management phase of risk analysis.

This outcome has clearly represented a success for the EC and a defeat for the US, who had constantly argued that risk management be exclusively "grounded on science-based risk assessment".

However, the possibility that other legitimate factors relevant for the health protection and fair trade practices may be identified in the risk management process is severely constrained by the same *Criteria*. In fact, such a possibility is made subject to four conditions.

First,

> "[c]onsideration of other factors should not affect the scientific basis of risk analysis".

This scientific constrain to reliance on other factors is likely to rule out the invocation of 'other factors' every time these factors may conflict with scientific evidence.

Second,

> "only those factors which can be accepted on a world-wide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account".

This means that factors recognized solely at national level may not be validly invoked by Codex countries. Thus, if the EC would like to invoke some 'other factors', it should be demonstrated that these factors are accepted in the whole Community.

Third, in taking into account 'other legitimate factors', Codex Members should also consider the impact that their measure may produce on developing countries.

Forth, the integration of other legitimate factors in risk management should not create unjustified barriers to trade. In evaluating the trade impact of the 'other factors'-based measures Codex Members must take into account "the particular provisions of the SPS and TBT Agreements"[803].

From the above it results that, although the possibility of relying also on non-scientific factors has been explicitly recognized by the model of risk analysis developed by Codex, the constraints surrounding such a possibility render almost impossible to validly invoke these factors. As a result, notwithstanding some countries' attempts to invoke them, these

[803] Footnote 38 of the Codex Procedural Manual, supra note 529 at 189.

'other legitimate factors' have never been taken into account in the elaboration of a Codex standard.

In particular, it must be noticed that neither the general acknowledgement that 'other factors' may be taken into account contained in the "Working Principles"[804] nor the *Criteria* list *which* factors may be "relevant for the health protection of consumers and for the promotion of fair practices in food trade". The CCGP's proposal to consider only those 'other factors' that had been explicitly recognized in the recommendations of the relevant multilateral international organizations was rejected.

Although further debate on the need to identify "other legitimate factors" has taken place within the Codex Ad-Hoc Intergovernmental Task Force on Food Derived from Biotechnology (IGTF), its work does not seem to have brought any progress on the matter. In fact, the "Principles for the Risk of Food Derived from Modern Biotechnologies", after having referred to the Codex Working Principles for Risk Analysis, they merely rephrase the conventional risk management formula, by stating

> "Risk management measures for foods derived from modern biotechnology should be proportional to the risk, based on the outcome of the risk assessment, and, where relevant, taking into account other legitimate factors in accordance with the general decisions of the Codex Alimentarius Commission"[805].

Recently, the CAC has requested for comments on proposals for new work to be undertaken by the IGTF[806]. The EC has proposed several subjects for the new work to be covered by the taskforce[807].

### B. Conclusions on the role of "Other Factors" in Codex

The heated discussion taking place within Codex on the role of "other legitimate factors" have led to a rather disappointing result. Although the possibility to invoke these factors

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[804] Working Principles, para 28.
[805] Principles for the Risk of Food Derived from Modern Biotechnologies (CAC/GL 44-2003). See also Fourth Report of the IGTF, 2003, para 82.
[806] Circular Letter 2005/2 – FBT.
[807] EC comments to Circular Letter 2005/02-FBT, Request for proposals for new work to be undertaken by the Codex Ad-Hoc Intergovernmental Task Force on Foods Derived from Biotechnology.

has been explicitly recognized, no consensus has been reached on a list of factors relevant for health protection and fair trade practices. At the same time, being the use of "other legitimate factors" in Codex's standard-setting activities severely constrained, a valid reliance on these factors is almost ruled out under the current Codex food safety risk analysis frame. Accordingly, notwithstanding some countries' attempts to invoke 'other legitimate factors', such factors have, at least so far, never been taken into account in the elaboration of a Codex standard.

Thus, although the Codex Statements of Principle are now supposed to define the risk analysis adopted by Codex, reliance on "other legitimate factors" continues to cause uncertainty.

On one side, it is constantly argued that Codex, after having conducted a risk assessment, should set up a standard on the basis of that result without taking into account any other factors which may potentially disguise the scientific factor. On the other, it is stated that exclusive reliance on the scientific element may not suffice in managing the risk stemming from a certain product. Although the acceptable level of risk may be difficult to define, where the use of the product confers little benefit, even a low risk may be considered unacceptable by many consumers.

### 2.2. Conclusions: "Other Factors" as an open question

The current discussion on the importance of non-scientific factors in determining the outcome of legislative and regulatory decisions is becoming increasingly complex. The issue is about how to ensure that science retains is central role in the decision-making process, whilst taking appropriate account of other legitimate factors that may play a role in the risk management phase of risk analysis. In fact, while science constitutes a valid constraint on protectionist non-tariff barriers, if let alone it may go too far in limiting countries' ability to regulate food safety in a way which is satisfactory for its own constituencies.

The EC model of risk analysis incorporating "other legitimate factors" seems to start from the assumption according to which policy-makers must let citizens choose between different potential risks if they are to retain public trust in the event of a crisis. For this reason, the EC approach to risk is more open to non scientific factors than the one developed within the WTO/SPS framework. While science makes many futures possible,

whether these are acceptable or not should be a social, economic or ethical issue, and not a scientific one.

Scientific evidence, although crucial, is therefore only one of the elements to be taken into account into the European risk analysis. This means that the risk management stage must integrate into the scientific data other factors such as economic feasibility, the desired.level of protection and other consumers' preferences. This model of risk analysis has recently been endorsed by the European Court of First Instance who stated that science is necessary but not sufficient to authorize regulatory action[808]. Against this backdrop, it concluded that the decision to ban a product is not a matter for the scientists to decide, but rather is one for the public authority to whom political responsibility has been entrusted.

But why, contrary to the SPS/WTO model of risk analysis, the European model reserves to science such a limited role?

As illustrated above, while scientific justification has been initially introduced to attain a similar anti-protectionist goal - as within the SPS/WTO system -, by requiring Members to base their derogating measures on science, it has subsequently acquired another objective: making sure that EC legislation would attain a high level of protection of health. Again, science is necessary but not sufficient to support the adoption of food safety measures.

The risk analysis model contained in the SPS/WTO lays on different premises. Contrary to the European model, the scientific evidence is exclusively required to make sure that Member States do not adopt protectionist measures. The role of science is therefore limited to an anti-protectionism mechanism and it is not motivated by consumer protection grounds. In fact, the SPS model does not set up minimum standard of protection at world-wide level, but rather it aims at making sure that the adopted SPS measure be the least-trade restrictive amongst the various management options available.

The SPS' negotiators choice to refer the "other factors" matter to Codex, by renouncing to define a clear cut risk management policy did not prove successful so far. Despite some progress on the definition of the role of other factors having been made in Codex, the extent to which consumer concerns, cultural and other social factors may be taken

[808] In the *Pfizer* case, supra note 161, at para 201 the CFI has clearly stated that "[s]cientific legitimacy is not a sufficient basis for the exercise of public authority".

into account in food safety risk management policy is not clear. Thus, the debate over the use of "other factors" is still open within Codex and does not seem to be ready to give rise to an agreement among its Members. At the same time, from the cases decided so far by the WTO judicial bodies it is not clear to what extent a measure motivated also by "other (non-scientific) factors" may still be considered "based on" risk assessment as provided by Article 5.1. Lacking a clear risk management policy within the SPS Agreement, the WTO judicial bodies tend to exalt the scientific element by applying a rather demanding standard of review thus inevitably disfavoring Member States' reliance on non-scientific factors.

Until this debate is resolved, what must countries do to be allowed to rely on "other factors" while developing their food safety policies?

This question remains particular actual within the European context where consumer concerns continue to be heightened by various real issues, such as the risk of contamination between bird flu-affected animals and humans[809] and the continuing uncertainty over the possible long-term effect of GMOs.

The current tensions existing within Codex and between the EC and other WTO Members on the 'other factors' issues show how urgent it is to develop a clearer conceptual framework that indicated which and where in the WTO/Codex risk analysis process such factors may be appropriately weighed. This issue has to be contextualized within the larger discussion, ongoing within Codex, on the definition of food safety risk analysis processes. The development of a clearer, transparent risk analysis scheme within Codex is a prerequisite for the accomplishment of Codex's dual missions: to promote harmonization and to prevent trade disputes. In fact, failure to develop a clear and consistent "other factors" policy within Codex is likely to give rise to some trade disputes before the WTO DSB.

### 3. What a Role for the Precautionary Principle?

The analysis of EC and WTO food safety disciplines has shown that both regimes recognize the idea, whether is called principle or not, according to which authorities may

[809] See Avian Influenza FAQs, available at the WHO website: http://www.who.int/csr/disease/avian_influenza/avian_faqs/en/#present

adopt a precautionary approach to uncertain food risks. More specifically, both regimes seem to allow regulatory authorities to take action to protect health before there is conclusive scientific evidence that harm is occurring.

However, in order to understand the exact scope of such a recognition it necessary comparing the conditions upon which precaution may be invoked within the EC and WTO regimes.

While in the WTO the circumstances in which precaution may be used are listed within Article 5.7 of the SPS Agreement, in the EC Article 174 of the Treaty merely mentions the precautionary principle as a basis for the Community environmental policy. The exact conditions upon which this principle may be validly invoked within the EC have been set forth by the 2000 European Commission's Communication on the Precautionary Principle[810], which has also extended the principle outside the environment to make it applicable within the field of health protection and food safety[811].

It may be recalled that, on the one hand, Article 5.7 states that

> "[i]n cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary and phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary and phytosanitary measure accordingly within a reasonable period of time".

On the other hand, according to the Commission Communication, the precautionary principle may be invoked where

> "scientific information is insufficient, inconclusive or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant

[810] European Commission, Communication from the Commission on the Precautionary Principle, supra note 215.

[811] In reality, already Article 174 acknowledged that protection of public health is one of the objectives to which environmental policy contributes.

health may be potentially dangerous and inconsistent with the chosen level of protection"[812].

A similar description is provided in the general food law regulation which provides that

"[i]n specific circumstances where, *following an assessment of available information*, the possibility of harmful effects on health is identified but *scientific uncertainty persists*, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment".

As previously established in the abovementioned Communication, the measures adopted on the basis of the precautionary principle "must be proportionate" and "no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community", having regard to "technical and economic feasibility and other factors regarded as legitimate in the matter under consideration"[813]. These measures are to be ("shall be") reviewed within a reasonable period of time, "depending on the nature of the risk to life and health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive assessment".

From a *prima facie* reading of these provisions it emerges a common *raison d'être* of the precautionary principle: a method which permits protective action in circumstances of uncertainty. Not surprisingly then the first requirement triggering the invocation of the principle is common to the two regimes: scientific uncertainty.

While comparing the conditions for its invocation, the EC version of the precautionary principle seems in many ways to be consistent with Article 5.7 SPS. Like Article 5.7, those precautionary measures adopted in the absence of proper scientific basis are subject to review as scientific knowledge develops.

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[812] European Commission, Communication from the Commission on the Precautionary Principle, supra note 215.

[813] Article 7.2 reads as follow: "Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment".

However, while this duty of review under Article 5.7 does not enjoy any flexibility, the same duty imposed by the general food regulation is tempered by the particular nature of the risk to life or health identified and the type of scientific uncertainty.

Therefore, where Article 5.7 SPS takes the view that uncertainty may (and therefore could) always be solved by further scientific studies, the EC expressly recognizes that invocation of the precautionary principle may also accommodate measures taken in situation of lasting uncertainty.

Despite this significant difference, the precautionary models elaborated within the two systems are in many ways similar, being notably structured upon the same conditions of application.

Both the EC and the WTO/SPS precautionary action models, by subjecting reliance on precaution on a set of cumulative and rather strict conditions, aim at avoiding unwarranted recourse to the principle serving to justifying disguised protectionist. The effort is to make sure that reliance on precaution may not depart from the science-based risk analysis schemes supporting both food safety regimes. According to this shared view, precautionary action should not been perceived as an alternative model of regulation to the traditional structured approach of risk analysis, but rather as fitting within this model and providing a valid risk management tool where risk assessment cannot be completed because of uncertainty[814].

Hence, the set of principles sketched out in both regimes give rise to very similar interpretative problems. In particular, the problem begins when we want to define more precisely the concepts of "scientific insufficiency" (Article 5.7 SPS) or "scientific uncertainty" (Article 7 General food law regulation). Neither the EC nor the WTO frames regulating precautionary action specify what is scientific uncertainty, notably *how* much science is needed to trigger the application of the precautionary principle.

However, both the EC and WTO courts have made an attempt at defining a minimum scientific threshold that should be met by decision-makers before adopting a precautionary measure. What is becoming increasingly clear in both systems is that countries could not validly act under the precautionary action by basing their measures

[814] For a study proving the scientific soundness of the precautionary principle, see A. Arcuri, *The Case for a Procedural Version of the Precautionary Principle Erring on the Side of Environmental Preservation*, Global Law Working Paper 09/04, NYU School of Law.

solely on unscientifically concerns about possible, merely hypothetical, negative health effects.

Thus, for instance, the AB in the *Hormones* case has stated that

> "the principle has not been written into the SPS Agreement as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of the Member set out in particular provisions of that Agreement"[815].

It results that, although Articles 5.7 and 3.3 incorporate a "precautionary principle", such principle does not override the need for Members to prove they have based their measure on a proper risk assessment, as provided in Article 5.1 and 5.2 SPS. In particular, Article 5.1 must be construed as requiring that "the results of risk assessment must sufficiently warrant – that is to say reasonably support – the SPS measure at stake"[816].

Similarly, the CFI has emphasized, according to a language clearly resonant with the WTO AB's, that a precautionary measure cannot properly be based on a purely hypothetical approach to the risk, funded on mere conjecture that has not been scientifically verified[817]. Rather, it follows from Community Courts' interpretation of the precautionary principle, that a precautionary measure may be taken only if the risk, although the reality and extent thereof have not been fully demonstrated by conclusive scientific evidence, appears nevertheless to be adequately back up by the scientific data available at the time when the measure is taken. In other words, the precautionary principle may be validly invoked within the EC only in situations where there is a risk, notably to human health, that, although it has not yet been fully demonstrated, is not based on mere hypothesis that have not been scientifically confirmed.

Thus, for instance, the ECJ took the view that precautionary measures "presuppose, in particular, that the risk assessment available to the national authorities provides specific evidence which, without precluding scientific uncertainty, makes it possible reasonably to conclude on the basis of the most reliable scientific evidence available and the most recent results of international research that the implementation of those measures is

[815] *EC-Hormones*, AB Report, para 124.
[816] *EC-Hormones*, AB Report, para 193.
[817] Pfizer, supra note 161, para 143.

necessary in order to avoid novel foods which pose potential risks to human health being offered on the market"[818]. In particular, the Court has held that "those measures can be adopted only if the Member State has first carried out a risk assessment which is as complete as possible given the particular circumstances of the individual case"[819].
Although there seems to be some consensus on the fact that precautionary action must be based on some sort of empirical evidence of risk ("ascertainable risk"[820]), there does not seem to be a similar consensus how this (minor) scientific basis should look like.
This conundrum lies at the center of the current debate on how to reconcile the traditional demanding risk assessment procedures, required by both the WTO/SPS Agreement and the EC, and the ability of Member States to act on the basis of the precautionary principle.

The primary condition upon which precautionary action may be taken ("available pertinent information") under the WTO seems to have become even further obscure following the *Apples* case.
Here, after endorsing the Panel's reading of Article 5.7 according to which this provision is "designed to be invoked in situations where little, or no, evidence was available on the subject matter at issue"[821], the Appellate Body held that "the application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence" [822]. By rejecting Japan's contentious, according to which Article 5.7 is intended to address also "unresolved uncertainty", i.e. uncertainty that that the scientific evidence is not able to resolve, despite accumulated scientific evidence"[823], the Appellate Body reduced the scope of precautionary action to "situations where little, or no, reliable evidence was available on the subject matter at issue".

The reasoning followed by the Appellate Body in this case carries the potential of diluting the scope of the precautionary principle as it has been conceived, interpreted and applied within the EC, by putting the European's version of the precautionary principle at odds with the WTO legal system.

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[818] Case C-236/01, Monsanto Agricoltura Italia, para 113.
[819] *Ibid.*, para 114.
[820] *Australia – Salmon*, AB Report.
[821] *Japan – Apples*, Panel Report, paras 8.219.
[822] *Japan – Apples*, AB Report, para 184.
[823] *Ibid.*, para 183.

This narrow reading of Article 5.7 seems to heavily constraining the margin for precautionary action within the WTO/SPS food safety framework. In particular, this interpretation seems to rule out from precautionary action all those situations in which, notwithstanding the existence of a "more than little" quantity of scientific evidence, scientific uncertainty persists. Thus, for instance, the present considerable amount of scientific studies regarding the actual or potential effects of GMOs on human health and on the environment would not be regarded as justifying precautionary action under Article 5.7 of the SPS Agreement. This may be relevant in the dispute on the EC moratorium on GMOs pending before the WTO DSB to the extent the EC is defending the "product-specific moratoriums" implemented by some Member States by relying expressly on Article 5.7[824].

Although this interpretation of Article 5.7 may find some support in the negotiating history of the SPS Agreement[825], there are some doubts whether it will be confirmed by the upcoming WTO judicial bodies' decisions. This is so because the AB's reasoning is so decidedly non-definitive that, accordingly, is not possible to say whether it represents a veritable paradigm shift in the application of the precautionary principle within the WTO legal system.

Another question that remains open after the interpretation given to Article 5.7 in the *Apples* case by the Appellate Body is whether a Member may rely on this provision to support an import ban merely because, due to lack of resources, it has not yet conducted a risk assessment of that product. Would this situation fall within the notion of "scientific insufficiency" held by the Appellate Body as triggering the invocation of precautionary action?[826] In other words, may a situation of "little evidence" be determined by a "lack of resources"?

Australia would be particularly interested in receiving an affirmative answer to this question as it is currently trying to justify its quarantine systems, which came under the

[824] *EC-Measures Affecting the Approval and Marketing of Biotech Products*, First Written Submission by the EC, DS/291, DS/292, DS/293, para 595-609. See also supra note 7.
[825] Marceau and Trachtman, supra note 473, at 848, footnote 143 reporting a discussion with G. Stanton, former Secretary of the SPS Committee.
[826] *Japan – Apples*, AB Report, para 184.

exam of the WTO[827], on the basis of Article 5.7. Australia is relying on this provision because due to resource constraint and the ordering of domestic priorities, it has not yet conducted a proper risk assessment of the products interested by its quarantine measures.

As illustrated above in relation to the "other factors" issue, it might be useful to look at the food safety risk analysis scheme provided by the Codex Alimentarius Commission as the relevant benchmark for predicting the role the precautionary principle may play in the risk analysis of food products within the WTO/SPS Agreement. Indeed, it is likely that also the WTO judicial bodies, in establishing whether a national food safety measure is validly based upon Article 5.7 SPS, will be influenced by the risk analysis model, notably by the precautionary action policy, developed by Codex.

In the light of the above, the following section will illustrate the approach which has been developed vis-à-vis the precautionary principle within the framework of Codex.

### 3.1 The Role of the Precautionary Principle within Codex

The Codex's discussion on the role of the precautionary principle has developed along the negotiations that have led to the adoption of the Working Principles for Risk Analysis in 2003.

As seen above, in 1997 the Codex Committee on General Principles received the mandate to develop a set of Principles offering guidance in the conduct of risk analysis not only to Codex committees but also to Member Governments.

Within that broad discussion, the role of the precautionary principle as legitimate basis for food safety decisions has been thoroughly debated.

The discussion was primarily motivated by the need to determine how Codex should have addressed uncertainty within its scientific evaluation activities. More precisely, the question facing the CCGP was whether Codex, when it has insufficient information, should adopt standards or leave the matter to its Members' competent authorities.

During the CCGP of 1999 the whole debate started off and immediately showed the ideological rift opposing the USA and the EC on all the issues related to precautionary

[827] *Australia – Quarantine Regime for Imports*, WT/DS287 (brought by the EC) and *Australia – Certain Measures Affecting the Importations of Fresh Fruits and Vegetables* WT/DS270 (brought by the Philippines).

action[828]. While the European Members promoted the recognition of the precautionary principle within Codex risk management policy, the US delegation strongly opposed the inclusion of the principle within Codex Working principles by arguing that not only lacked a reliable definition of precaution but also that "a precautionary approach was already built in risk assessment" and that, in any event, Article 5.7 SPS already dealt with scientific uncertainty[829].

At the end of the meeting, the following working definition was proposed

> "Lack of full scientific certainty shall not be used as a reason to delay measures intended to prevent adverse effects on human health from a hazard present in food. When a preliminary risk assessment indicates a threat of adverse effects on human health from a hazard present in food, it is justifiable to take measures to prevent such effects without awaiting additional scientific data and a full risk assessment. Such measures should be proportionate to the potential health risk and should be kept under review".

Although the objective should be to base food safety measures on science, there are situations where there is a lack of scientific evidence. But, does this recognition make the precautionary principle a "other legitimate factor"?

While discussing the "other legitimate factors" issue, the Secretariat prepared a paper addressed to the 1999 CCGP meeting and took position on this point. It made clear that, according to its view, the precautionary principle applies when the prescribed scientific foundation is still being developed and that, subsequently, it fits within the first Statement of Principle imposing the use of science rather than to the second addressing the "other legitimate factors"[830].

During the following CCGP meeting in 2000, a new text describing the use of precaution in taking risk management measures was proposed

> "When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food, and there is reasonable evidence to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature an extent, it may

[828] See Report of the 14th Session of the CCGP, 1999, para 30.
[829] See Report of the 14th Session of the CCGP, 1999, para 30.
[830] Paper prepared for the 14th Session of the CCGP, CX/GP 99/09.

be appropriate fro risk managers to apply precaution through interim measures to protect the health of consumers without awaiting additional scientific data and a full risk assessment. However, additional information for a more objective risk assessment should be sought and the measures taken reviewed accordingly"[831].

After long discussion, no agreement was reached on this new text. In order to modify it, a working group was established[832].

As the debate on the role of the precautionary principle became increasingly more contentious during the 16th CCGP meeting held in 2001, the Codex Commission decided to intervene in the matter by stating that "precaution was and should remain an essential element of risk analysis in the formulation of national and international standards"[833].

Following this Statement in support of the principle, an agreement was reached on the following compromise text

"Where there is evidence that a risk to human health exists but scientific data is insufficient or incomplete, the Commission should not proceed to elaborate a standard, but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence"[834].

Notwithstanding some attempts to put in discussion the agreed compromised, the 2002 meeting of CCGP decided to retain the text in order to submit it to the following meeting of CAC[835]. During the 2003 CAC meeting the Draft Working Principles for Risk Analysis, containing recognition of precaution were finally adopted. In particular, paragraphs 10 and 11 of the approved text read:

"10. When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.

[831] Report of the 15th meeting of the CCGP, 2000.
[832] Report of the 16th meeting of the CCGP, 2001.
[833] Report of the 24th meeting of CAC, 2001, para 77.
[834] Report of the 24th meeting of CAC, 2001.
[835] Report of the 17th meeting of CCGP, 2002.

11. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. Where there is sufficient scientific evidence to allow to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard".

It is difficult to fully understand the meaning of these two paragraphs. Paragraph 10 reflects the US' vision of risk analysis favoring a risk management policy where only scientific evidence may be taken into account. In fact, it prevents Codex standard-setting activities in presence of scientific uncertainty, by allowing, at best, the adoption of a code of practice.

The following paragraph is characterized by the kind of deep vagueness which is often the hallmark of consensus-based drafting. Although recognizing precaution as an important element of risk analysis, it does not offer any clear guidance on when and how to use it.

### 3.2 Conclusions on the role of precaution in the EC, WTO/Codex Food Safety Risk Analysis regimes

While the EC food safety risk analysis has evolved steadily toward the recognition of the precautionary principle at the same time as this principle has developed in the domestic laws of Member States, the WTO incomplete risk analysis model has been more reluctant in recognizing this principle as a risk management tool allowing Member States to take action in situation of scientific uncertainty.

In particular, if the EC pioneered reliance on the precautionary principle through the Commission Communication and the European Courts' case law, the WTO jurisprudence has shown great wariness in explicitly endorsing this principle. In particular, by narrowly reading the risk assessment requirements and by subverting the main condition triggering the invocation of Article 5.7 SPS, the WTO courts are currently limiting the ability of Member States' authorities to take precautionary measure.

The Codex Alimentarius Committee, on its side, has made an attempt at developing some further guidance on how and when to use the principle by trying to reconcile very

different positions amongst its Members. It results that, although it is true that "few legal concepts have achieved the notoriety of the precautionary principle"[836], its scope is still far from been clear in the international trade arena. As we have anticipated, at least the outcomes of two pending disputes will depend on the role that will be recognized to Article 5.7 SPS[837].

## 4. Conclusions on the comparison between the EC and the WTO Food Safety Risk Analysis models: toward a common food safety risk analysis regime within Codex?

A comparison between the EC and WTO food safety risk analysis regimes clearly shows that the two most significant points of tension between these disciplines relate to the "other factors" that may be taken into account in risk management and to the role of the precautionary principle, respectively.

It is not surprising that both issues belong to the risk management phase of risk analysis. As shown above, the risk analysis model developed within the WTO/SPS framework does not contain any meaningful provision dealing with risk management. The Panel's genuine efforts in the *Hormones* case to introduce the traditional structured approach to risk analysis by establishing a distinction between risk assessment and risk management has expressly been rejected by the Appellate Body who noticed that there was no textual basis in the SPS Agreement that would justify such an insertion.

Therefore, the SPS Agreement leaves, at least in principle, WTO Members free to determine how to address and to regulate risks, provided they satisfy the risk assessment requirements imposed by the SPS Agreement. The consequent prioritization of scientific and technical evidence makes more political decision-making problematic, especially when inspired by precautionary action or by other non-scientific factors.

The lack of any risk management guidance to WTO Members stems directly from the SPS negotiators' choice to "delegate" to Codex all harmonization activities. Since it was not the WTO, but a third entity, to do 'positive integration' by elaborating substantive rules and standards, it was not necessary to shape a complete risk analysis model for the

[836] Scott and Vos, supra note 43, at 250.

[837] *EC – Biotech case*, supra note 7, and *Australia – Quarantine Regime for Imports* WT/DS287 and Australia – Certain Measures Affecting the Importations of Fresh Fruits and Vegetables WT/DS270.

WTO. Accordingly, Codex has become not only a "quasi-legislator" in charge of elaborating international standards but, gradually, also a unique forum for the elaboration of guidelines for regulatory action in the food safety sector, including both the risk assessment and risk management stages of risk analysis.

Being invested of the regulatory task of developing international standards, Codex, unlike any other WTO Committee, had no choice but to sketch out a risk analysis model guiding the work not only of the Joint FAO/WHO expert bodies and consultations (risk assessors) but also that of the Commission and its subsidiary bodies (risk managers). Although this risk analysis model, notably represented by the "Working Principles for Risk Analysis", has been intended for application in the framework of Codex Alimentarius[838], it provides the most relevant commonly-agreed food safety risk analysis model in the world.

In the light of the above, it has been expressed the need to explore the approach adopted by Codex Alimentarius vis-à-vis these two controversial issues.

It has been argued that, given WTO reliance on Codex's international standards, the risk analysis model developed within Codex to elaborate these standards is likely to produce a significant influence on international food safety trade disputes, notably on the interpretation of the key SPS provisions dealing with risk analysis.

Lacking a full risk analysis scheme within the WTO/SPS framework, it is foreseeable that the WTO judicial bodies, when called upon reviewing the conformity with the SPS Agreement of food safety measures based not solely on risk assessment but also on 'other factors' will turn to the Codex activities in order to find some guidance. Similarly, WTO judicial bodies called to determine the legitimacy of national food safety measure based on a precaution approach may be tempted to read Article 5.7 through the lenses of the Codex risk analysis' reference to the precautionary principle.

This outcome is not excluded to the extent the same Appellate Body stated in the first case it came before it that

> "[...] the General Agreement is not to be read in clinical isolation from public international law"[839].

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[838] It is worth noticing that Article 1 of the Proposed Draft Working Principles for Risk Analysis stated that "The principles for risk analysis are intended for application in the framework of Codex Alimentarius and *are also intended to provide advice to governments when applicable*".

[839] *United States – Standards for Reformulated and Conventional Gasoline*, AB Report, WT/DS2/AB/R, para 19.

This is not to argue that Codex's activities may qualify as public international law, but simply to show the judicial openness proved by the Appellate Body since its inception. The value of Codex's risk analysis as a benchmark for WTO/SPS compatibility, or at least as an important source of inspiration for WTO courts, would be further strengthened by Codex's current efforts to draft specific "Working Principles for Risk Analysis for Food Safety". In fact, unlike the previous Codex documents on risk analysis, these working principles expressly aim at providing guidance not solely to its own bodies but also to "governments" on food safety risk analysis.
According to the first paragraph of the Proposed Draft Principles,

> "[t]he purpose of these Principles is to provide a framework for the conduct of risk analysis applied to food safety issues, as guidance to governments, in light of the purpose of the Codex Alimentarius Commission".

Furthermore, according to the second paragraph,

> "the objective of these principles is to provide guidance to Codex Members so that food safety aspects of their decisions and recommendations are based on risk analysis".

In particular, according to the EC, the development of these principles will help the governments to develop a risk analysis policy aimed not solely at protecting consumer health but also at "fulfill[ing] their obligations arising from Article 5(1) of the SPS Agreement"[840].

In the light of the above, it is believed that agreement on this additional Codex meta-standard on how the principles of risk analysis for food safety should be applied is crucial for the future development of a harmonized food safety risk analysis model. The development of a common food safety risk analysis scheme within Codex would be capable of filling up the current gap existing within the WTO risk analysis, notably

[840] EC Comments on Proposed Draft Working Principles for Risk Analysis for Food Safety, Codex Circular Letter CL 2004/34-GP.

regarding its risk management policy. In particular, both points of tensions existing between the EC and the WTO food regimes would be attenuated.

However, the whole issue, mainly because of the disagreement on both 'other factors' and the precautionary principle, is still under debate. A revised draft was circulated in July 2005 with a request for proposals on the objective and scope of the Working Principles from governments[841]. The draft consists of 37 paragraphs and the Working Group, established in November 2004 to look at comments on the first draft, only had the time to consider the first 22 of these, thus leaving aside for the moment those dealing with the most controversial issues: the "other legitimate factors" issue and also the precautionary principles (at paragraphs 32 and 33). At the 22nd Session of the CCGP, it has been agreed to return the Proposed Draft Working Principles to step 2/3 for redrafting and further comments[842].

In conclusion, Codex's present inability to solve at the regulatory level the long-standing issues of the role of the precautionary principle and that of "other factors" in risk management makes the relationship between the EC food safety regime and WTO law increasingly difficult today, notably by bringing the EC regime at odds with WTO law.

As we have shown above, these controversial aspects are currently dealt with by Codex because of the SPS negotiators' choice to "delegate" to this body the elaboration of de facto WTO food legislations. However, despite some progress on the definition of the role of the precautionary principle and other factors in risk analysis having been made in Codex, the extent to which Members may rely on this principle and the other factors in food safety risk management policy is not clear yet. Thus, the debate over the use of "other factors" is still open within Codex and does not seem to be ready to give rise to an agreement among its Members. Until this debate is resolved, what if countries invoke the precautionary principle or rely on "other factors" while developing their food safety policies?

Only part of these questions are expected to find an answear in the currently pending *Biotech* dispute opposing the US, Canada and Argentina to the EC and, accordingly, are likely to give rise to further disputes in the near future.

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[841] CL 2005/17-GP, 27 July 2005. Deadline for comments was 30 July 2005.
[842] Report of the 22nd Session of the CCGP, CL 2005/17-GP, April 2005.

This shows how the original decision not to define a well-defined management policy within the SPS Agreement is producing the effect of transferring the responsibility to shape a WTO risk analysis model from the decision-making dimension to the dispute-settlement level; in other words, from the 'executive-legislative' powers to the 'judiciary'. By borrowing the words of the Appellate Body, it is up the WTO judicial bodies to find an appropriate

> "balance in the SPS Agreement between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings"[843].

Notwithstanding their well-know commitment to textual fidelity, the WTO judicial bodies will be inevitably obliged to develop answers that rather than stemming from the texts of the WTO Agreements will flow from their understanding of the risk management policies developed in national and international contexts, such as Codex. This excess of discretion impliedly recognized to the WTO courts, if not appropriately offset, is likely to harm the WTO system by diminishing the level of legitimacy and social acceptability of its decisions.

[843] *EC - Hormones*, AB Report, para 177.

# CHAPTER III: COMPARING STANDARDS OF REVIEW

## 1. COMPARING THE EC AND WTO COURTS' STANDARDS OF JUDICIAL REVIEW OF FOOD SAFETY MEASURES

Although partly motivated by different goals, both food safety scientific justification disciplines impose the respect of similar scientific requirements: all measures addressing food safety risks must be based on science.

It follows that, even though in different institutional settings, the EC and the WTO Courts are called to a very similar legal task: examining whether the contested risk regulations pursue legitimate, as opposed to false, health concerns, in light of scientific risk assessments performed by agencies with superior technical expertise. Therefore, they both centre their review on the need for objective scientific reasons to support the contested measures. However, it must be observed that, contrary to EC courts, WTO judicial bodies are called to examine solely national food safety measures departing from de facto WTO harmonized legislations, such as Codex international standards. National food legislations conforming to those standards benefit from a presumption of conformity and, accordingly, cannot be subject to the WTO court' scrutiny[844].

In particular, both courts encounter very similar questions when called upon reviewing the legitimacy of science-based measures supposedly aimed at protecting food safety. They both wonder how intensely the scientific justification for a Member's measure must be reviewed, and the extent to which Members should be allowed to pursue their own level of protection by taking into account "non-scientific factors" or the precautionary principle.

The analysis of the standards of review applied in the two systems has revealed that the WTO's scrutiny of science-based measures tends to be more intrusive than the one

[844] It would follow than a meaningful comparison of the standards of review adopted applicable by the WTO and EC courts should focus solely on food safety national measures. However, since this would exclude a crucial part of the EC courts' scrutiny of food safety measures, the present comparison refer also to the EC's review of harmonized food safety legislations.

exercised by EC Courts. Although the EC Courts' review of Member States' measures becomes less deferential when it exercised over EC measures, it never attains the level of WTO's intrusiveness into the scientific basis of the measure at dispute.

While the approach taken by EC courts is generally one which defers to the judgment of the legislator about the existence of risk and the regulatory response, particularly in circumstances of scientific uncertainty, the WTO judicial approach is rather intrusive and scientifically demanding. Thus, for instance, the panel, in *Japan – Agricultural Products*, has stated that the DSU requires them to examine, weigh and resolve all the evidence validly submitted to them, including the opinions received from the experts advising the panel[845]. Furthermore, the Appellate Body tends to prescribe some demanding criteria for risk assessment. Since the *Hormones* case[846] the risk assessment requirement is interpreted as imposing the defending party to carry out a *specific* risk assessment capable of addressing the particular circumstances of the case at issue. On this basis, in the recent *Apples* case, the panel dismissed the scientific studies cited by Japan because they did not focus sufficiently on the risk of transmission of fire blight apple fruit as opposed to other modes of transmission[847].

To the contrary, EC courts have always appeared more reluctant in addressing the scientific basis of the contested measures, by thus showing deference to both EC and Member States' scientific bodies. Contrary to the WTO courts, the EC judiciary has managed not to get involved into the scientific validity of the arguments advanced by the parties, by refusing to engage into the scientific controversies underlying the disputes. However, not only the recent *Alpharma/Pfizer* cases but also the *Vitamins* line of cases seems today to somehow challenge the traditional EC courts' deferential attitude *vis-à-vis* scientific evidence, thus exposing the EC courts to challenges similar to those faced by the WTO courts. As it has been stated,

> "the language used by the CFI in *Pfizer* reminds one very much of the language the WTO dispute settlement organs used in EC-*Hormones* and Japan-*Agricultural Products*"[848].

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[845] *Japan – Agricultural Products*, para 7.10. Then confirmed by the AB, para 127.
[846] *Hormones*, AB report, para 199.
[847] *Japan - Apples*, Panel report, paras 8.277-280.
[848] Slotboom, *Do Public Health Measures Receive Similar Treatment in European Community and World Trade Organization Law?*, supra note 609, at 594.

Leaving aside for a moment this recent trend, it might be interesting to analyze the reasons leading the WTO legal system to be stricter in the analysis of SPS measures than its European counterpArticle

As it has been argued[849], a more intrusive scrutiny by the WTO over national measures than the review by EC courts may appear a paradox to the extent the former organization pursues a lesser integration goal. However, it is argued that this apparently paradoxical finding reflect the different normative and institutional contexts in which these courts are called upon exercising their duties. In particular, the different standards of review taken by WTO courts when compared to that followed by its EC counterparts may be explained by the following factors:

- different normative (WTO scientific discipline is more detailed than the EC regime) and institutional contexts (WTO does not dispose of its own scientific advice); (1.3.1.1)

- different risk analysis schemes (contrary to the EC, the only factor to be taken into account in the WTO risk analysis scheme is science). (1.3.1.2)

In the following paragraphs, it will be illustrated how these factors may somehow explain the strict scrutiny, notably scientific demanding, exercised by WTO Courts on Member States' science-based regulations. Notwithstanding some general Statements by the Appellate Body allowing flexibility in domestic risk management procedures and recognizing Members' right to establish their own level of protection, it has always privileged the scientific element, and the views of scientists, in reviewing the legitimacy of food safety risk regulation.

[849] See Slotboom, *Do Public Health Measures Receive Similar Treatment in European Community and World Trade Organization Law?*, supra note 609, at 553 and 594. This Author in an interesting series of articles has shown that although "in view of the different objects and purposes of the WTO Agreements and the EC Treaty" one may expect that where the WTO and the EU have rules on the same subjects, the EU law is stricter than WTO law, the "legal reality does not always correspond to this expectations". Thus, he has reached the following findings: EC law is not stricter to EU Member States that WTO law is to WTO Members with regard to discriminatory internal taxes; WTO subsidy rules seem to be stricter to WTO Members than EC rules on State Aid in EU law and, finally, that WTO law is stricter (or at least as strict as) to SPS measures than the EU legal system.

### 1.1. Different Normative and Institutional Contexts

Although imposing similar scientific requirement, the WTO and EC operate in different normative and institutional contexts[850]. It is common place to argue that while the EC integration agenda relies on both negative and positive integration tools, the WTO's agenda relies solely on negative integration provisions. In reality, as we have pointed out above, also the WTO, by referring to the Codex standard-setting activities, promotes positive integration amongst its Members.

However, unlike the EC, the WTO has no general authority to directly set health and food safety policies for its Members. Acting in such a context of lesser integration, the WTO's courts do not dispose and, accordingly, cannot rely on their own sources of scientific advice, but rather rely on external ad hoc advice. Therefore, contrary to what happened in the EC - which disposes of its own scientific committees -, the panels and the AB cannot make reference to previous studies made within a sort of WTO legislative process. Unless the contested measure draws on an international standard, the WTO judges must somehow get involved with scientific data. An integrated and institutionalized food safety dimension simply lacks to the WTO. In fact, it is by relying on scientific external experts that panels and AB assess factual matters of a scientific nature. And these experts are not themselves a WTO institution.

Furthermore, as seen above, the WTO set of scientific requirements, notably those imposed by the SPS, are particularly detailed compared to those imposed by the EC regime. It may be recalled, for instance, that Article 5 SPS, after having required WTO Members to conduct a risk assessment "as appropriate to the circumstances", it lists the scientific, technological and economical factors that should be taken into account, together with the risk assessment techniques developed by the relevant international organizations. It is argued that the standard of review developed by WTO courts inevitably reflect this normative framework. This framework, in turn, contributes to legitimizing this standard of review by thus strengthening the increasing scientific involvement of WTO judicial bodies.

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[850] For a comparative analysis of EC and WTO law, see F. Ortino, *Basic Legal Instruments for the Liberalization of Trade*, supra note 10.

### 1.2. Different Risk Analysis Schemes

The different standards of review adopted by the EC and the WTO Courts may also be explained in relation to their respective approaches to risk analysis. While the EC has embraced the generally-accepted risk analysis scheme based on a clear-cut distinction between risk assessment and risk management, the WTO/SPS texts have never tied their scientific discipline to any particular mode of risk analysis[851]. In particular, the SPS does provide little elaboration of risk management principles to guide resolution of disputes, by solely providing a definition of risk assessment[852]. By emphasizing the rational, science-based stage of risk assessment this ambiguous model of risk analysis inevitably leads the judge to mainly focus on the scientific element.

In other words, while in the EC risk analysis scheme science is necessary but not sufficient to authorize regulatory action[853], in the WTO imprecise risk analysis model science seems to be both necessary and sufficient to validate a national health measure.

This approach to risk analysis, by focusing solely on the rational, scientific basis of risk regulation, legitimizes a standard of review which is fully in line with the SPS scientific justification regime, where there is no room, at least formally, for non-scientific factors, such as the social dimension of risk. The adoption of a particularly intrusive standard of review, by allowing placing science in a privileged position, permits the panel to avoid the problem of giving recognition to policy concerns that are neither neutral-value as the scientific element nor common among Member States. To the contrary, the adoption of a standard of review focusing solely on the rational relationship between science and the measure would be more permeable to non-scientific factors. Thus, despite the initial attempts made by the Appellate Body to leave the door open for "others legitimate factors" within risk assessment in order to preserve the Member States' right to determine their own level of protection[854], the adoption of such an intrusive standard of review allowing the judge to assess the quality of the scientific information supporting a measure

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[851] See on this point Button, supra note 196, at 66 and 231 (who argues that the AB has been careful not to link the SPS system to any particular model of risk assessment and that it refused to draw a firm distinction between risk assessment and risk management under the SPS Agreement).

[852] On this point, see Josfling, supra note 5, at 48 who argues that SPS negotiators considered it inappropriate for the WTO to be more prescriptive about risk management, seeing the standard-setting organizations as the better forum for the elaboration of guidelines for regulatory action.

[853] In the *Pfizer* case, supra note 161, at para 201 the CFI has clearly stated that "Scientific legitimacy is not a sufficient basis for the exercise of public authority".

[854] *EC- Hormones*, AB Report, para. 187

tends to emphasize the role of science over other factors, thus rendering more difficult for Member States to justify their measures on non-scientific grounds.

As this trend entrusts the international judge - not only the panels and the AB but also, after the recent trend adopted in *Pfizer* and the *Vitamins* case, the EC Courts -, with a scientific-based task, the role of expertise might become crucial.

### 1.3. Conclusions

The comparison between the EC and WTO courts' standards of review developed vis-à-vis food safety science-based measures showed an increasing intrusiveness in the WTO judicial approach, notably regarding the scientific foundation of the contested measures.

Although a more intrusive scrutiny by the WTO courts than that conducted by the EC courts over national measures may appear a paradox to the extent the former organization pursues a lesser integration goal, several reasons seem to render this paradox only apparent.

In particular, the WTO judicial approach to science-based measures takes place in very different normative and institutional contexts than in the EC. Unlike EC courts, WTO judicial bodies not only do not dispose of their own sources of scientific information, but they cannot rely on clear risk management principles guiding the resolution of disputes. They rather rely exclusively on a set of extremely detailed risk assessment requirements[855]. By emphasizing the rational, science-based stage of risk assessment, this emerging ambiguous model of risk analysis inevitably lead WTO courts to mainly focus on the scientific element of the contested measure.

In other words, while in the EC risk analysis science is necessary but not sufficient to authorize regulatory action[856], in the WTO imprecise risk analysis model science seems to be both necessary and sufficient to validate a national health measure.

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such as the social dimension of risk. The adoption of a particularly intrusive standard of review, by allowing placing science in a privileged position, permits the panel to avoid the problem of giving recognition to policy concerns that are neither neutral-value as the scientific element nor common among Member States.

## 2. The Role of Experts in Judicial Review

The previous analysis of the WTO and EC risk regulation disciplines and of the standards of judicial review of science-based measures, such as interpreted and applied by their respective courts, clearly showed the struggle incurred by WTO and EC judges when they are called to play with science in their activity of *dicere legem*.

Though developed in a domestic law context, the most authoritative formulation of this struggle belongs to the US Supreme Court Chief Justice Rehnquist. In his dissenting opinion in the *Daubert* case, he noted that

> "the various briefs filed in this case are markedly different from typical briefs ... they deal with definitions of scientific knowledge, scientific method, scientific validity, and peer review – in short, matters far afield from the expertise of judges ..."[857].

It is indeed true that, also in international legal *fora*, most of legal opinions and judgments do not ordinarily rest on this kind of intellectual foundation, but rather privilege other sources of knowledge which are closer to the educational background of the judges. However, given the specificity of certain subject matters, it may happen that most of the scientific sources cited in a legal decision could not be easily read and understood by the majority of the judges composing the court.

As we have seen above, not solely the intrusive standard of review adopted by WTO panel, but also that followed by EC courts (a sort of 'reasonable deference standard') when reviewing science-based national measures may seem to require these judges some

[857] Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), paras 598-599.

scientific expertise. As seen above, this seems particularly true after the adoption of the *Pfizer* and *Vitamins* line of cases.

Even if the EC courts and the WTO judicial bodies are not directly being asked to establish whether a certain risk exists or, more in general, to settle a scientific debate, they tend to evaluate the competing scientific claims made by the parties in order to determine whether the contested measures conform to the scientific discipline in force within their legal system. However, one would not expect any AB Member or panelists or any European Courts' judge called to decide a science-based case to have any specific scientific knowledge in the field. The Members of these courts are typically staffed by individuals without scientific knowledge expertise and operate under time constraints. Moreover, these judicial bodies lack the resources to carry out a more informed and independent evaluation of the risk assessment outcomes brought by the parties. In the light of that, it is of no surprise that both EC and WTO courts, being poorly equipped to evaluate scientific evidence, struggle in accomplishing this task. Nevertheless, notwithstanding the lack of scientific knowledge and appropriate resources, under the applicable standards of review, both WTO and EC Courts tend to carry out their own investigation of the quality of the scientific data advanced by the parties.

These factors raise the question how the judiciary, notably the WTO and EC Courts, may deal with scientific evidence.

### 2.1 The External Expert Consultation in the WTO

To somehow mitigate such difficulties the WTO panels, unlike the EC judiciary, tend to rely on external advisors[858]. According to the Dispute Settlement Understanding, a panel may consult "experts", either individually, or by convening an "expert review group", to obtain their opinion in dispute settlement on scientific and technical matters[859]. Similar

[858] Such consultations have taken place in most of the health and environmental disputes that have been settled by the WTO DSB.

[859] Article 13 DSU (*Right to Seek Information)* reads as follow: "1. Each panel shall have the right to seek information and technical advice from any individual or body which it deems appropriate. However, before a panel seeks such information or advice from any individual or body within the jurisdiction of a Member it shall inform the authorities of that Member. A Member should respond promptly and fully to any request by a panel for such information as the panel considers necessary and appropriate. Confidential information which is provided shall not be revealed without formal authorization from the individual, body, or authorities of the Member providing the information. 2. Panels may seek information from any relevant source and may consult experts to obtain their opinion on certain aspects of the matter. With respect to a factual issue concerning a scientific or other technical matter raised by a party to a dispute, a panel *may* request an advisory report in writing from an expert review group. Rules for the establishment of such a group and its procedures are set

provisions already existed under the GATT system[860]. Both the SPS and TBT Agreements contain some additional provisions relating to the expert assistance procedure and encourage the panels to rely on this opportunity for external help[861].

Generally, the selection process of experts and the operation of an expert consultation procedure take places according to the following steps[862]. However, it must be noticed from the outset that any WTO Agreements provides for detailed rules and procedures for the appointment and the operation of experts acting on an individual basis, but they only do for expert review groups[863].

The Panel requests relevant international bodies (such as the WHO, IOE or the IPPC) and the parties to indicate the names of suitably qualified scientific experts and asks for their CVs. After having circulated all CVs to the parties for comments, the panel then appoints

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forth in Appendix 4". It seems that while panels may ask experts their views on the matter, they cannot dispose any new risk assessment. On the scope of WTO external expertise, see infra 4.1.2.

[860] Christoforou notices that the 1966 Conciliation-Procedures Under Article XXIII (in Decisions and Conclusions of the Contracting Parties, 5 April 1966, GATT B.I.S.D, 14TH Suppl., 1966, at 18) contained virtually the same provisions as those of Article 13.1 and the first sentence of paragraph 2 of the same article. See Christoforou, supra note 177, at 254.

[861] Article 11.2 SPS provides that a panel should seek advice from experts chosen by the panel in consultation with parties. To this end, the panel may, when it deems appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative. Article 14.2 TBT states that, at the request of a party to a dispute or at its own initiative, the panel may establish a technical assistance expert group.

[862] The following detailed description of the general expert consultation procedure builds upon the previous cases in which the panels have selected and consulted scientific experts. For an analysis of these modalities see J. Pauwelyn, *The use of Experts in WTO Dispute Settlement*, in 51 ICQL (2002) 328.
339-340; D.A. Motaal, *Is the World Trade Organization Anti-Precaution?*, in Journal of World Trade 39 (3), at 499 and Christoforou, supra note 177, at 258-259.

[863] Appendix 4 of the DSU, entitled Expert Review Groups, states: "The following rules and procedures shall apply to expert review groups established in accordance with the provisions of paragraph 2 of Article 13. 1. Expert review groups are under the panel's authority. Their terms of reference and detailed working procedures shall be decided by the panel, and they shall report to the panel. 2. Participation in expert review groups shall be restricted to persons of professional standing and experience in the field in question. 3. Citizens of parties to the dispute shall not serve on an expert review group without the joint agreement of the parties to the dispute, except in exceptional circumstances when the panel considers that the need for specialized scientific expertise cannot be fulfilled otherwise. Government officials of parties to the dispute shall not serve on an expert review group. Members of expert review groups shall serve in their individual capacities and not as government representatives, nor as representatives of any organization. Governments or organizations shall therefore not give them instructions with regard to matters before an expert review group. 4. Expert review groups may consult and seek information and technical advice from any source they deem appropriate. Before an expert review group seeks such information or advice from a source within the jurisdiction of a Member, it shall inform the government of that Member. Any Member shall respond promptly and fully to any request by an expert review group for such information as the expert review group considers necessary and appropriate. 5. The parties to a dispute shall have access to all relevant information provided to an expert review group, unless it is of a confidential nature. Confidential information provided to the expert review group shall not be released without formal authorization from the government, organization or person providing the information. Where such information is requested from the expert review group but release of such information by the expert review group is not authorized, a non-confidential summary of the information will be provided by the government, organization or person supplying the information. 6. The expert review group shall submit a draft report to the parties to the dispute with a view to obtaining their comments, and taking them into account, as appropriate, in the final report, which shall also be issued to the parties to the dispute when it is submitted to the panel. The final report of the expert review group shall be advisory only".

the best experts, generally in a number between 3 and 5. In general, panels do not select experts that are national of the parties to the dispute, unless they are expressly authorized by the parties to do that[864].

Before the appointment of the experts, the panel prepares specific questions to be addressed to the experts. To the extent possible, these will provided to the parties as well. The parties then have the possibility not only to express their objections to any particular expert but also to comment on the proposed questions before these are sent to the experts. At this stage, the panel will appoint the experts by informing the parties of its selection.

The experts are required to answer in writing to the questions and their answers will be provided to the parties. Moreover, should the panel decide it necessary, or on a party's request, a meeting with expert may take place in which the panel, parties and experts gather just before the second substantive meeting with the parties.

Finally, the panels' practice in expert consultation shows that panels may have recourse to scientific experts even if none of the parties to the dispute requests it or if a party objects to it[865].

In all the health cases in which expert consultations have taken place to date – the *Hormones*, *Salmon*, *Agricultural product*, *Asbestos* and *Apples* cases – the panels have consulted more than one experts, but always on an individual basis. In other words, to date not a single panel has set up an expert review group.

The issue whether the panels, in a dispute involving scientific or technical matters, are limited to seek advice from an expert review group or whether they may consult experts on an individual basis is controversial. Unfortunately, neither the relevant DSU and SPS provisions nor the panels/AB case law contribute to solve the matter.

As it will be shown below, though it might appear a mere procedural question, the choice of appointing an expert review group or individual scientists is pivotal in determining the level of scientific involvement requested from the WTO judicial bodies.

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[864] This exclusion rule is expressly provided by Appendix 4 of the DSU establishing rules and procedures applicable to expert review groups.

[865] Thus, for instance, neither in the *Salmon* case nor in the *Agricultural products* the parties to the dispute have requested expert advice.

### A. Individual Experts vs. Expert Review Group

Each time a party expressly asked for the appointment of an expert review group (typically the EC), the panel appointed individual experts instead[866]. The Appellate Body has endorsed this preference by interpreting Article 13 DSU as referring to expert review group as a mere option (a panel *may* request). This constant practice raises several procedural and substantive questions which deserve a closer scrutiny.

Although rendered controversial by the wording of the WTO texts, this preference for the appointment of individual experts tends to be justified on practical grounds[867]. It is argued that expert individual consultation is not only less time-consuming than group review (not having to generate a common written report) but it would also ensure more flexibility to the consultation process. In an expert individual consultation – the argument goes - a panel by asking specific questions to each expert and by adding questions during the process it would obtain the individual opinion of each expert rather than a common and monolithical consensus position. This would help the panel in better assessing the scientific evidence brought by the parties. However, contrary to conventional wisdom, the provision of expertise by individual experts within the judicial review context is not necessarily more efficient than the setting up of an expert review group.

While reliance on individual experts may appear to render the expertise consultation process more expedite and flexible than the expert advisory group scheme, past cases have clearly shown how these expectations cannot realistically be met. In fact, the provision of various opinions by individual experts inevitably produces the effect of providing the judge with further scientific material to consider and evaluate. This has been expressly recognized by the panel in *Japan – Agricultural Products*, which stated that

> "we are called to examine and to weigh all the evidence [...] including the opinions we received from the experts advising the panel"[868].

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[866] This has happened notwithstanding the expressed request of the complaining party to appoint an expert review group in the *Shrimps-Turtles* case and notwithstanding the complainant and defendant common request in the *Hormones* case. See for a criticism of this position, T. Christoforou, *Settlement of Science-Based Trade Disputes in the WTO: A Critical Review of the Developing Case Law in the Face of Scientific Uncertainty*, supra note 725, at 622, 630-1 and Christoforou, supra note 177, at 255.

[867] For an excellent description of the practical arguments generally invoked to justify the panels' preference for individual expert consultation, see J. Pauwelyn, *The use of Experts in WTO Dispute Settlement*, supra note 862, at 328.

[868] Panel Report in *Japan – Agricultural Products*, para 7.408.

In particular, being these opinions elaborated on an individual basis and according to different methodologies, they lead the panel to engage in a complex quasi-scientific analysis aimed at verifying whether there is a common ground among these opinions. This evaluation becomes even more complex when individual experts hold divergent views.

While the main objective of the expert consultation procedure should be to prevent the panelist from getting involved in scientific issues by providing them with an assessment of the plausibility of the scientific evidence advanced by the parties to the dispute, the described individual consultation practice seems to achieve the exactly opposite result. Indeed, by introducing into the review process additional (often conflicting) scientific materials to be assessed together with the competing scientific claims brought by the parties, reliance on individual experts renders, paradoxically, the task of the judges even more (scientifically) cumbersome. How judges may be epistemically capable to assess the possibly conflicting individual scientific opinions expressed by the experts?

In the light of the above, it is argued here that the appointment of an expert review group, though apparently more time-consuming, may potentially simplify the scientific task that judges are increasingly called to accomplish. Being entrusted with the duty to come up with a written report, the expert group would be forced to either find common grounds on the different specific scientific issues at stake or, at least, to genuinely represent the whole range of scientific opinions (i.e. majority and minority) existing in the current scientific state-of-the-art research on that controversial issues. In fact, adherents to different school of thought should be represented among the experts. By borrowing the AB's language, the expert review group may set out

> "both the prevailing view representing the mainstream opinion, as well as the opinions of scientists taking a divergent view"[869].

Furthermore, besides these arguments of merit, there are also some textual reasons for privileging reliance on expert review group over that on individual expert. As it has been

[869] *Hormones*, AB Report, para 194.

observed, although the wording of the relevant WTO texts does not help in identifying the appropriate form of expert consultation in a scientific-based controversy, it is undisputed that they do provide for detailed rules and procedures solely for an expert review group[870]. This has meant that the panels' current practice of appointing individual experts has taken place not only contrary to the customary rules of interpretation of international treaties, as codified by the relevant 1969 Vienna Convention[871], but also in a sort of legal vacuum in which panels had to determine by themselves the rules to follows in the following matters: appointment of the experts, decision of the terms of reference, nationality of the experts, etc.

Thus, for instance, the tendency of panels to request competent international bodies (such as the WHO, IOE or the IPPC) assistance in selecting the experts does not find any textual support in the WTO Agreements. Although the panels have limited their requests for assistance in the selection for experts to those international organizations mentioned in the SPS Agreement (in the quality of standard-setting bodies), this does not necessarily mean that the experts should come exclusively from those organizations. In particular, this practice looks controversial to the extent the appointed experts are likely to come from the same organizations which have set the international standards the WTO Members may have tried to depart from. Against this backdrop, it is unavoidable that these experts will tend to defend the existing international standards elaborated by their organization, if not by themselves[872].

The most forceful and most articulate *j'accuse* expressed against the current expert consultation practice has been formulated by Cristoforou who foresees that

> "the developing practice of panels seeking advice only from experts individually, if applied systematically, would render the provisions of the DSU and the SPS and TBT Agreements on expert review groups useless and obsolete"[873].

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[870] It is by relying on this systematic argument that the EU has contested the current expert consultation practice based on individual experts in the Asbestos case, supra note 460.

[871] According to Article 31 of the 1969 Vienna Convention on the Law of Treaties the interpretation must give meaning and effect to all the "terms of a treaty". See Christoforou, supra note 177, at 264 (footnote 115).

[872] As an example of this phenomenon, one may refer to the *Hormones* case where 3 experts out of the 5 appointed by the panel were scientists regularly participating in the Codex Alimentarius committees and one of them was even the rapporteur in the risk assessment on the hormones at issue in the dispute. This example is provided by Christoforou, supra note 177, at 256 (footnote 98).

[873] *Ibid.*, at 264.

It is in the light of the above arguments that scientific advice from an expert review group should be preferred over individual expertise. It is not only more efficient, objective and clear, but is also the sole procedure capable of attaining the main purpose of external expertise: to avoid the judges to face troubling scientific issues by providing a report reflecting the current scientific debate on a specific issue (i.e. mainstream and minority scientific opinions).

### B. The Scope of the Expert Consultation: What a Role for Scientific Experts?

Leaving aside the expertise consultation procedural issues, let's move to the nature and scope of this procedure.

The expert consultation finds its rationale in the assumption that panel Members, by consulting scientists specialized in the concerned areas to the dispute, may be better placed to understand and critically assess the scientific evidence advanced by the parties. In fact, as stated by the panel in the *Salmon* case, the

> "expert opinions are opinions on the evidence submitted by the parties"[874].

Accordingly,

> "a panel is entitled to seek information and advice from experts and from any other relevant source it chooses [...] to help it to understand and evaluate the evidence submitted and the arguments made by the parties, but not to make the case for a complaining party" [875].

[874] See also panel report on *Australia - Salmon*, paras 8.41, 8.126 and 8.172. In full conformity to this approach, in the *Agricultural Products* case, Dr. Ducon simply stated: "The arguments put forward by Japan for requiring varietals trials are not based on scientific data. They are supported by a few experimental data in which varietals difference exists, in terms of LD50, among a lot of other data in which it does not". See Panel Report, *Agricultural Products*, supra note 62, para 8.36.

[875] *Agricultural Products*, AB Report, para 129.

However, panels have shown some confusion about the appropriate role of scientific expertise. Although it might seem that the expert advice should not cover more that the evidence submitted by the parties, panels tend to directly ask experts the very same disputed scientific question that the panel itself has to answer.[876] This clearly happened in the *Agricultural products* case, where it was asked the experts advising the panel whether

> "in their expert opinion, there is an objective or rational relationship between, on the one hand, the varietal testing requirement imposed by Japan and, on the other hand, any evidence submitted by the parties"[877].

This trend toward a 'delegation' of responsibility in deciding the outcome of a dispute has caused uneasiness with an expert appointed in the *Hormones* dispute. In the occasion of the joint meeting with experts, Dr Ritter vocally denounced that to provide an answer to the question of whether residual hormones in beef would produce a biological effect on consumers would "really pre-empt the outcome of the dispute"[878].
Although it might seem clearly abusive, this practice may find some support in the open-textured formulation of Article 13 DSU, which recognizes the panel an almost unfettered right to seek information and technical advice from any individual or body which it deems appropriate and to seek information from any relevant source. Therefore, to avoid the abovementioned risk of 'delegation', it might be necessary to somehow constrain the scope of the expertise consultation. In order to achieve that result, it must be borne in mind the main purpose of the expert consultation, which is to avoid panels to get involved in scientific issues by providing them an assessment of the plausibility of the scientific arguments brought by the parties. In other words, if we want to reduce the role of the panel in addressing and deciding scientific issues without delegating the decision on the final outcome of the dispute there is a need to frame from the outset the scope of the external consultation.

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[876] See J.O. Mc Ginnis and M.L. Movsesian, *The World Trade Constitution*, in 114 Harv L. Rev. (2000) 511, at 594 and T.P. Stewart and A.A. Karpel, *Review of the Dispute Settlement Understanding: Operation of Panels*, in 31 Law & Pol'y Intl Bus (2000) 593.
[877] *Agricultural Products*, Panel Report, para 8.35.
[878] *Hormones*, Panel Report, Annex: Joint Meeting with Experts, para 64.

Ideally, experts' review should therefore be limited to a determination of whether that scientific opinion represents a sufficiently sound application of scientific principles to justify its conclusions.

This analysis will help the judges in determining whether the measure conforms to the risk assessment requirements imposed by the SPS Agreement, thus freeing them from any scientific involvement.

Further confusion would seem to exist concerning the tasks that experts might be entrusted with. Thus, for instance, in the *Hormones* case, the panel asked the appointed experts to address questions that touched upon the cost effectiveness of different regulatory alternatives[879]. But, how laboratory natural scientists may be able to answer to questions dealing with regulatory politics and economics?

After the famous Appellate Body's statement according to which the risk that is to be evaluated in a risk assessment under Article 5.1 is "not only risk ascertainable in a science laboratory, but *also risk in human societies as they actually exist*"[880], one may legitimately wonder whether the relevant expertise within the WTO system should be limited to natural scientists[881]. Should the focus of risk analysis remain on "the real world in which people live and die", it might be reasonable to imagine that panels will consult also experts coming from other fields, capable, for example, of assessing the effectiveness and the consequences stemming from a particular regulatory decision.

Thus, for instance, in the EC Commission collection and use of expertise's practice it is considered "appropriate to mobilize experts beyond the scientific community"[882]. These may include lawyers, ethicists, or those with practical knowledge gained from day-to-day involvement in an activity.

### C. The Legal Status and Authority of the Experts' Opinions

A further drawback of the expert consultation current practice must be found in the panels' tendency of attributing an undue authority to the opinion of any one expert. In the

[879] *Ibid.*, at paras 24, 172, 236, 268, 828, 838-848.
[880] *Hormones*, AB Report, supra note 66, para. 187.
[881] See, on this point, R. Howse and P.C. Mavroidis, *Europe's Evolving Regulatory Strategy for GMOs – The Issue of Consistency with WTO Law: of Kine and Brine*, supra note 674, at 320.
[882] EC Commission, Communication on the Collection and Use of Expertise by the Commission: Principles and Guidelines COM (2002) 713 final, at 16.

*Hormones* case, for instance, the panel dismissed one of the EC arguments by relying solely on the opinion of one of the experts[883]. While the EC argued that there was alternative to carbadox with the same therapeutic action, the panel dismissed this argument by relying on the sole advice of one expert who argued that oxytetracycline was a ready available alternative[884].

This 'pick and choose' approach from individual experts' opinions does seem to bring the panels back to the original problem of having judges playing with science. It shows how panelists may resort to scientific advice for the only reason of dressing a determinate outcome with an apparent "scientific legitimacy" .

Although the expert advice is not legally binding[885], the panel must show deference to it to the extent it comes from a source that has epistemically more authority.

Finally, the readiness of WTO panels to call on experts contrasts with the reluctance of the EC courts to rely on external advice. EC courts prefer to review the contested measures by relying solely on their (by definition, non-scientific) evaluation of the scientific evidence brought to the dispute by the parties. As we will see below, although in principle both EC courts would have this option open through their internal rules, they tend not to use it.

### D. Conclusions on the WTO Expert Consultation System

While recourse to the expert advice undoubtedly increases the ability of WTO panels to understand and assess the scientific evidence brought by the parties, there seems to be some flaws in the current practice of external consultation as developed by WTO panels.

*In primis*, the current practice to appoint solely individual experts may been perceived as ineffective and not entirely conform with the letter of the WTO treaty. Past cases have shown how recourse to individual experts inevitably entrusts panel Members with an extra scientific role. Instead of avoiding the judges to face the troubling scientific issues

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[883] This example is provided by Walker, *Keeping the WTO from Becoming the "World Trans-Science organization": Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute*, supra note 471, 311 (footnote 282).

[884] *Hormones*, Panel Report, para 8.234.

[885] This is expressly established by Appendix 4 of the DSU, paragraph 6, which states that "the final report of the expert review group shall be advisory only".

raised by the dispute, the current (individual) expert consultation practice entrusts them with an even more demanding scientific task: to assess the merits of the experts opinions formulated on the plausibility of the scientific evidence brought by the parties and to verify whether there exist common grounds among the diverging opinions of individual experts, thus legitimizing an even more complex involvement in scientific matters. Furthermore, the panels, while 'picking and choosing' among the various individual experts' opinions, may be induced to recognize an undue authority to the opinion of any one of these experts and this notwithstanding their lack of scientific knowledge.

As to the scope of the requested expertise, there is a growing risk that panels will ultimately delegate the responsibility to decide a dispute to the chosen individual experts it traditionally relies upon. This outcome is quite unfortunate to the extent these experts, not being a WTO institution, do not enjoy the necessary legitimacy to accomplish this task[886]. More sensitively, there is no real control on their scientific activity within the current WTO framework.

Last but not least, following the Appellate Body's famous statement according to which the risk that is to be evaluated in a risk assessment under Article 5.1 is "not only risk ascertainable in a science laboratory, but *also risk in human societies as they actually exist*"[887], one may legitimately wonder whether the relevant expertise within the WTO system should be limited to natural scientists. Should the focus of risk analysis remain on "the real world in which people live and die", it might be reasonable to imagine that panels will consult also experts coming from other fields, capable, for example, of assessing the effectiveness and the consequences stemming from a particular regulatory decision[888]. A multidisciplinary and multi-sectoral expert review groups may not only encourage a cross-fertilization of ideas but also stimulate debate and lead to 'better' opinions.

Despite the abovementioned limits of the current expert consultation practice, the increasing use of expert advice within the WTO is a positive development that must be

[886] However, it may be noted that neither the WTO judicial bodies nor the experts are politically accountable.
[887] *Hormones*, AB Report.
[888] For example, in the *Hormones* case, some risk management issues such as cost effectiveness, relative efficacy of regulatory responses and compliance have been discussed during the meeting with the experts. See Annex to the Panel Report: Joint Meeting with Experts, paras 24, 172, 268, 828, 838-847.

applauded[889]. Expert advice does not only ensure quality, transparency and legitimacy to the WTO decisions but, if adequately fine-tuned, it might potentially reduce the level of scientific involvement currently required by the standard of legal review of science-based measures. In particular, to make the expert consultation a useful tool to somehow lighten the panels' involvement with scientific matters, it is necessary to favor reliance on expert advisory groups (instead of on individual experts) and to determine the exact scope of the consultation expertise.

### 3. Toward an EC Expert Consultation System?

Although in need of some adjustments, the WTO expert consultation system may inspire the development of a similar mechanism within the EC judicial system. As the *Pfizer/Alpharma* have recently clearly shown, also the EC Courts might need to rely on external expertise to assess the scientific plausibility of both Member States' and EC institutions' scientific claims. There are good reasons to believe that reliance on this external help tool might facilitate the role that EC courts are increasingly called to play with science while reviewing science-based measures.

Although under the current Statute[890] and their respective Rules of procedures[891], both the CFI and ECJ "may at any time entrust any individual, body, authority, committee or other organizations it chooses with the task of giving expert opinion", they have so far been quite reluctant in relying on external advice. This seems to be especially true for scientific matters. While the Courts, notably the CFI, have been ordered experts' reports to assess quality of a translator's work[892], an official's mental state[893], to examine the rates

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[889] Similarly, also the International Court of Justice's experience with the use of experts may be seen as a positive development (Article 50 of the Statute of the Court states that: "The Court may, at any time, entrust any individual, body, bureau, commission, or other organization that it may select, with the task of carrying out an enquiry or giving an expert opinion." Article 51 of the Statute continues by stating that: "During the hearing any relevant questions are to be put to the witnesses and experts under the conditions laid down by the Court in the Rules of Procedure referred to in article 30."). See, notably, for an excellent survey of expert evidence in the first fifty years of the International Court of Justice, G. White, "The Use of Experts by the International Court", in V. Lowe and M. Fitzmaurice eds., *Fifty years of the International Court of Justice, Essays in Honour of Sir Robert Jennings* (Cambridge University Press, 2005).

[890] EC Statute, Article 25.

[891] ECJ Rules, Article 49 and CFI Rules, Article 70.

[892] Case 10/55, Mirossevich v. High Authority [1954-56] ECR 333.

[893] Case 12/68, X v Audit Board [1969] ECR 109

for and conditions of transport of mineral fuels[894], price rises and the market in dyestuffs[895], the economic consequences of certain gas tariffs[896], to verify the conclusions drawn in the contested act, the evidence relied on and the characteristics of the market[897], they have rarely done so in scientific matters. Occasionally, the parties have themselves submitted an expert's report or, at the hearing, an expert has addressed the Court on behalf of one of the parties[898].

The decision to obtain an expert's report is made by the Court in the form of an order after the parties have been given an opportunity to be heard. The same order appoints the experts, defines the scope of the expertise and sets a time limit for the drafting of the report.

Despite this rather simple framework for the disposal of an expertise, EC courts have traditionally been unwilling of using it.

Therefore, before sketching out a possible expertise system within the EC judicial system, it might be crucial to look at the reasons that have so far discouraged the EC Courts from relying on this possibility. An explanation fort the European courts' reticence in asking external advice may could be found within the EC institutional framework. As EC courts, especially when reviewing a Community measure, may be called upon reviewing scientific studies coming from the EC scientific committees, they might feel that submitting one of these studies to a third party review would amount to put into question both the scientific and institutional legitimacy of these committees, which belong to the same system of governance[899]. However, this argument, which boils down to the idea according to which the CFI/ECJ is an institution among others institutions, does not seem to be entirely persuasive if examined from a US perspective. In fact, the US Federal Courts do not hesitate to review the risk assessments undertaken by federal regulatory agencies. It is therefore controversial whether this legitimacy argument may justify by itself the EC Courts' deferential attitude vis-à-vis the scientific reports prepared by the European scientific committees.

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[894] Case 24 and 34/58 Chambre syndicale de la Sidérurgie de l'Est v. High Authority [1960] ECR 281.
[895] Case 48/69 ICI Ltd v Commission [1972] ECR 619.
[896] Case C-169/84, Société CdF Chimie Azote et Fertilisants SA [1990] ECR 3083.
[897] Cases C-89, 104, 114, 117, 125 to 129/85, Ahlstrom v. Commission [1993] ECR 1307.
[898] Case 204/80 Procureur de la République v. Vedel [1982] ECR 465.
[899] In my view, this argument, according to which the CFI/ECJ is an institution among others institutions, cannot justify a deferential attitude of the Courts vis-à-vis the scientific reports prepared by the EU scientific committee. In fact, the US Federal Courts do not hesitate to review the risk assessments undertaken by federal regulatory agencies. See on this point T. O. McGarity, supra note 681.

A more credible argument aimed at explaining this deferential approach to science marked by a Europe label refers to judicial tradition. Having hardly ever relied on scientific expertise, judges (notably the judge *rapporteur*) might be somehow discouraged in proposing the others' Court members to have an expertise under the Courts' rules of procedures. Finally, if tradition has, and still plays, a crucial role in explaining the Courts' wariness, also fears of delegating the task of solving a dispute may exist.

In attempting to develop a credible and effective expert consultation system for EC courts while dealing with scientific matters, it is important to take in due account the institutional scientific framework the Community relies upon when adopting legislation.
In fact, unlike the WTO judicial bodies, the European courts, when called to judicially review a science-based measure, they are likely to already dispose of a scientific study supporting that measure or, at least, dealing with its scientific foundations. While this is certainly the case when the Courts are called to examine the legality of a EC measure, it might not be when the regulation at stake has been adopted by a Member State. In the latter case, the national measure is supported instead by a national scientific opinion coming from its own authorities.
Against this backdrop, one may wonder who might be consulted by the EC Courts to examine the scientific adequacy of the evidence brought by the parties to the dispute. Should they ask the EC scientific committees' members to review the evidence they have themselves developed? Or should they rely on some third-party scientists? And *quid* in the case of science-based national measures? Should the Court submit the national scientific evidence to the scrutiny of the EC scientific committees?
In the light of the above, it might be imagined an expertise consultation system in which the Courts may rely respectively on national experts to examine the European studies advanced by the EC institutions and on the EC scientific committees to review the national scientific opinions brought by the parties to the dispute. A similar consultation procedure may be more than adequate to assist the EC judges to verify the existence of a minimum scientific level in the studies put forth by the parties. Furthermore, through it cross-based consultation mechanism between Member States' and EC experts, this procedure could avoid a situation where the same scientist who has developed the

scientific opinion supporting the contested measure may be called upon reviewing *ex post* the same study. Last but not least, this system would be in line with the European idea according to which scientific studies could not be ranked depending on their national or European origin. In fact, as shown above, the European Food Safety scientific opinions do not prime over diverging national ones[900].

[900] See Alemanno, "The Evolution of European Food Safety", in C. Ansel and D. Vogel, eds., *Why the Beef? The Contested Governance of European Food Safety*, supra note 102. See also Regulation 178/2002, supra note 32.

## 4. How to Improve the Role of the Judge in the Review of Food Safety Regulations?

While the scientific process is engaged with scientific research and publication of formulation, corroboration, and advancement of scientific principles and theories, the legal process does not establish nor attempt to develop scientific theories, principles or "truth" for the purpose of science, but only for the purpose of adjudication.

Accordingly, EC courts and WTO judicial bodies are not directly being asked to establish whether a certain risk exists or, more in general, to settle a scientific debate, they are rather increasingly required to evaluate the competing scientific claims made by the parties in order to determine whether the contested measures conform to the scientific discipline in force within their legal system. While this tendency is particularly pregnant with the WTO, also the EC courts would seem increasingly playing a quasi-scientific role, by engaging in scientific controversies in order to adjudicate between diverging scientific claims.

As these courts began referring to "the quality and quantity" of the scientific evidence (WTO) and to require a "detailed assessment" (EC) they have invested themselves with a non-legal task which - as shown above - they cannot realistically carry out. Indeed, on the courts' benches do not sit scientists, but lawyers.

This interpretation of their respective scientific disciplines inevitably opened up the Pandora's box of scientific discussion to these judicial bodies, thus somehow legitimizing their involvement in controversial scientific matters.

The problem raised by this approach is that judges, being non-scientists, are not epistemically capable of discerning between good science and bad science. And this is exactly what EC and WTO courts aim at doing while reviewing science-based measures. They want to make sure that the contested measure is adequately back up not simply by a claim of science, but by a proper and adequate scientific study.

In fact, according to the way in which they have been interpreted, the scientific disciplines by imposing the authorities to base their measure on science do not merely establish a procedural requirement (necessity of scientific evidence or risk assessment),

but they also introduce a substantive test ("detailed risk assessment"; "quality and quantity of scientific evidence") which finally boils down into a *minimum scientific threshold*. Indeed, the Panel in the *Apples* case has clearly stated that the evidence to be considered under Article 2.2 SPS should be "evidence gathered *through scientific methods*, excluding by the same token information not acquired through a scientific method"[901]. Similarly, the ECJ in the *Vitamins* line of cases has held that public authorities must justify their health regulations on "a detailed assessment of the risk" alleged[902].

By borrowing the language used by the Supreme Court in *Daubert*, it would seem that both the WTO and the EC courts have interpreted their scientific disciplines as requiring that the submitted evidence must be "grounded in the methods and procedures of science"[903].

To be "good science" the scientific evidence supporting a measure does not merely have to be a scientifically-dressed study, but it has to meet some minima criteria assuring its scientific character. Therefore, though not adequately equipped to engage into scientific evaluations, these courts tend to adjudicate between diverging scientific claims by "picking and choosing" among different scientific opinions advanced by the parties. That is because judges must, somehow, draw lines between scientific evidence that is "detailed enough" or "sufficient enough" and scientific evidence that is not "detailed enough" or "sufficient enough". The result is that some scientific studies will pass the legal test and will be considered adequate in backing up a certain measure and other won't. Thus, the minimum scientific threshold reveals itself a "pass or fail" test.

Since it is *how* the conclusions have been reached, not *what* the conclusions are that make good science today, both WTO and EC Courts have interpreted their respective scientific discipline as requiring the evidence submitted by the parties to satisfy some *minimum scientific requirements*. This trend seems to challenge the traditional uncritical view that the law has embraced vis-à-vis science's claims of universal truth[904].

While this approach to the review of science-based measures may seem reasonable to the extent it simply allows the judge to verify *how* the scientific study supporting a contested measure has been conducted and *what* its conclusions are, this task cannot be done by the

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[901] *Japan - Apples*, Panel Report, para 8.92.
[902] Case 192/01 Commission v Denmark, supra note 271, para 47.
[903] Daubert v. Merrell Dow Pharmaceuticals, Inc., supra note 857.
[904] J. Atik, *Science and International Regulatory Convergence*, 17 Northwestern J. Int'l L. & B. 736, at 740.

judge alone and it also presupposes the development of some general guidelines establishing which *minima criteria* a scientific study must satisfy to be considered "scientific".

### 4.1. How a Judge May Assess Whether a Scientific Study is 'Scientifically Adequate'?

In answering to this question it is crucial to take in due account the limited role that courts and tribunals may play in reviewing scientific information, notably in assessing the "quality" of the scientific studies quoted by the parties. In fact, judges can neither develop by themselves the criteria determining whether a study is "scientific enough" nor judge whether these criteria are met by a scientific opinion brought by the parties to the dispute. Therefore, since a court may not realistically assess whether the scientific evidence advanced by one party meets the *minimum scientific requirements* required to consider it "good science", reliance on external advice is increasingly needed.

As seen above, the WTO expert consultation system may reveal a useful experience to build upon in order to develop an external scientific support for international courts called to review science-based measures[905]. In fact, this system of external help has been generally successful in facilitating the scientific tasks judges are increasingly called to play while reviewing science-based measures. Although presenting some drawbacks, such for example the constant panels' preference for the appointment of individual experts rather than expert review group, the WTO dispute settlement bodies' practice with external expert consultation has been positive. In the light of the above, it is argued that, though in need of some adjustments, the WTO external consultation system should be extended and become current practice also within the EC judicial architecture.

Thus, it could be envisaged that, not only the WTO judicial bodies but also the EC courts, while reviewing either a Member State or a EC science-based measure, might rely to some external scientific advice in order to assess whether the scientific evidence brought by the parties is 'adequately scientific'. This use of experts would help the judge in

[905] The use of experts by other international organizations is not the object of this paper. However, I intend to tackle this question in the near future. For an excellent survey of expert evidence in the first fifty years of the International Court of Justice, see White, *The Use of Experts by the International Court*, supra note 889.

ascertaining whether a minimum scientific threshold purporting the contested measure has been met, thus preventing the judge from engaging into scientific tasks.

### 4.2. What is a Minimum Scientific Threshold?

As to the issue of determining what is the *minimum scientific threshold* that both WTO and EC courts seem to require while reviewing science-based measures, it is neither for the judge nor for the external experts to develop minimum standards of scientific adequacy to be met by scientific evidence advanced by the parties to a dispute.

There is currently a strong trend, internationally, to formalize procedures for dealing with risk analysis issues and to promote commonalities of approaches throughout the different sectors where risk assessment may be developed[906]. Thus, for instance, at EC level, some efforts have been deployed to develop a harmonized approach to risk assessment procedures among the Scientific Committees advising the European Commission in the area of human, animal and plant health and on the environment[907]. At international level, this trend towards formalizing procedures for risk assessment is even more significant and is traditionally led by some of the international standardization bodies mentioned within the SPS Agreement. In recent years, these standards organizations have contributed more to the trade system by setting out scientific approached to regulation than by promulgating standards that are identical across countries[908]. Thus, as illustrated above, the *Codex Alimentarius Commission* is engaged since 1995 in developing Working Principles for Risk Analysis aimed at determining the main steps and procedures that scientific assessors must follow when engaging in risk analysis applied to food safety issues[909]. Similarly, the UN Food and Agricultural Organization (FAO) has developed new guidelines that will help countries assessing the risks of living modified

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[906] This trend is also visible at national level. See, for example, U.S. Envtl. Protection Agency, Proposed Guidelines for Carcinogenic Risk Assessment, 61 Fed. Reg.

[907] To this end, it has been established a Working Party on "Harmonization of Risk Assessment Procedures" to address specifically the general principles of risk assessment and its application to broad consumer health issues, with a particular reference to measures that would enhance compatibility of approaches between the Scientific Advisory Committees. See the Updated Opinion of the Scientific Steering Committee on Harmonization of Risk Assessment Procedures, adopted on 10-11 April 2003. A full Second Report on the Harmonization of Risk Assessment Procedures is expected by the end of the year.

[908] Josling, supra note 5, at 46.

[909] The Codex Alimentarius Commission has been discussing policies for risk analysis since its 20th Session (1995), when it adopted an Action Plan for Codex-wide Development and Application of Risk Analysis Principles and Guidelines. The Joint FAO/WHO Committee on General Principles, meeting in Paris in April 2005, is elaborating further guidance specific to the food safety field, see Proposed Draft Working Principles on Risk Analysis for Food Safety, supra note 838.

organisms (LMOs) and determine whether some should be considered as weeds or other organisms that damage plants[910].

The objective of these international efforts is to provide guidance to their respective Member States so that food safety and health related aspects of their decisions and recommendations are based on risk analysis.

From a conceptual point of view, it might be useful to underscore that the harmonization activity brought forward by these bodies does not aim at setting up technical standards, but merely at developing a common approach to the risk analysis in a specific field[911]. Somebody has designed these common approaches to risk analysis as "meta-standard"[912]. It is argued that this task, which may be called 'light harmonization' or 'soft convergence' in risk analysis, carries the potential of not only guiding scientists in conducting risk assessment but also facilitating the task of the experts called to determine the scientific adequacy of the opinions and studies brought by the parties. In other words, these guidelines may help the experts in evaluating not the scientific studies' validity but instead their methodologies. Should these scientific studies satisfy the general guidelines on risk analysis developed on that particular scientific area, experts and, accordingly, panels should show deference to them.

### 4.3. Conclusions

Given the increasingly strict scrutiny applied by EC and WTO courts on science-based measures leading their judges to engage into scientific debates, this chapter, by adopting a critical stance of the current trend, made an attempt to reorient the role of the judge while reviewing science-based regulations. After having illustrated the struggle of both EC and WTO judicial bodies while strictly reviewing science-based measures, it has

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[910] These guidelines are available at http://www.fao.org/newsroom/en/news/2004/43684/. Similarly, FAO has established Guidelines for Pest Risk Analysis. These guidelines have been discussed in the *Japan-Agricultural Products* case. See, e.g., Panel Report, paras 2.25-2.33.

[911] See also the efforts deployed by WHO in harmonization of risk analysis within its area of competence. WHO, jointly with FAO, are developing guidelines documents for undertaking each of the four components of a risk assessment namely hazard identification, hazard characterization, exposure assessment and risk characterization. To date guidelines for hazard characterization of pathogens in food and water have been finalized, and the draft guidelines for exposure assessment of pathogen in food have been prepared and are currently under review. FAO and WHO are now planning the development of practical guidelines for risk characterization of microbiological hazards in foods. See http://www.who.int/foodsafety/micro/en/

[912] Josling, supra note 5, at 46.

found that their growing scientific involvement has to be reconducted to the effort to assess whether the scientific evidence advanced by the parties to the dispute constitutes 'good science'. This effort seems more justified within the WTO context than in the EC, since WTO judicial bodies do not dispose, unlike the latter, of any risk management guidance to rely upon while reviewing a food safety measure.

Since it is *how* the conclusions have been reached, not *what* the conclusions are that make 'good science' today, both WTO and EC Courts have interpreted their respective scientific discipline as requiring the evidence submitted by the parties to satisfy some *minimum scientific requirements*. This interpretation of their respective scientific disciplines inevitably opened up the Pandora's box of scientific discussion to these judicial bodies, thus somehow legitimizing their involvement in controversial scientific matters. However, judges, being non-scientists, are not epistemically capable of discerning between 'good science' and 'bad science'.

Against this backdrop, it has been argued that this task cannot be done by the judge alone and that it presupposes the development of some general guidelines establishing which *minima criteria* a scientific study must satisfy to be considered "scientific".

To solve the first problem it has been suggested to improve (within the WTO) and to develop (within the EC) the external experts' consultation practice as it might facilitate the current judicial bodies' attempt to verify whether the scientific evidence advanced by the parties to the dispute is "scientifically adequate". As to the second related problem, to facilitate the task of the expert in accomplishing its task it might be advisable to rely on those guidelines, currently elaborated by several international standardization organizations and by the same EC scientific committees, aimed at promoting commonalities of approaches in risk analysis for different sectors.

It is believed that this approach, by reducing the level of scientific involvement of courts and by giving an operational meaning to what 'minimum science' is, might prove successful in assigning a more appropriate role for the international judge in risk analysis.

# *Conclusion*

The recent food safety crises that have outraged Europe through the last years probably constituted the most serious challenge to the European integration process during its first fifty years of existence[913]. These food scandals dramatically showed the inadequacy of the way in which food laws are created and implemented by the EC institutions and the Member States highlighting the complexity of the European system of governance and the limits of its functionalist approach to integration. Relying for too long on "improvisational compromises"[914], the European governance of food safety became "contested"[915]. Unlike the legislation existing in most of the Member States, the EC Food policy has developed in a piecemeal fashion, being based on a variety of different legal basis provided in the European Community Treaty in order to serve different policy objectives. The Community began regulating the food sector, as many other sectors, in conjunction with its effort to eliminate trade barriers arising from different domestic legislations in order to establish an internal market. However, various peculiarities of foodstuffs, such as their long-rooted tradition at national level and their risk component, have increasingly involved the Community by requiring more and more supranational legislative intervention. In particular, the EC institutions have assumed new tasks that are largely related to what is generally referred to as "risk regulation"[916]. Thus, under the public opinion pressure induced by the recent food scandals, the Community became aware that to regulate the food sector only through the economic lens of the internal

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[913] See Azoulay, supra note 13, comparing BSE to the other political crisis of the EU and J. Bowis, Rapporteur of the EU Parliament Committee on the Environment, Public Health and Consumer Policy on the Draft Report on the Commission White Paper on Food Safety, supra note 133, who effectively summarized the dimension of the food safety crises: "Poor practice and scandals have exercised the media, the public and their elected representatives in recent years. The list is long, ongoing and potentially endless given that absolute safety is not an attainable goal. Olive oil, contaminated wine, Perrier water, *E. coli*, *Listeria*, salmonella, polluted drinking water, *BSE*, dioxin sludge and slurry entering the human food chain, pesticides, animal feed, GMOs—all in their time and in their way have caused concern, fear, panic and public inquiry".

[914] Lister, supra note 100.

[915] By "contested governance", Ansell and Vogel mean a "pervasive conflict in policy arenas that goes beyond politics-as-usual to challenge who should make decisions and where, how and on what basis they should be made". In other words, "Contested governance entails a significant challenge to the legitimacy of existing institutional arrangements". See C. Ansell and D. Vogel, *Why the Beef? The Contested Governance of European Food Safety*, in European Food Safety Regulation: The challenge of Multi-level Governance, (MIT Press, forthcoming 2006).

[916] See, e.g., Breyer, *Breaking the Vicious Circle*, supra note 192; J.D. Graham & J.B. Wiener, *Risk vs. Risk: Tradeoffs in Protecting Health and the Environment* (Harvard University Press ed., 1995).

market could have been inadequate to address the new challenges brought by the generally new perception of risks. In other words, its traditional functionalist approach to integration was proving unsuccessful in handling reality[917].

While undermining the credibility of the EC's food safety regulatory system and balkanizing the functioning of the internal market, the food crises of the 1990s brought their own impetus for reforming the EC food regime leading to calls for an agency solution. Under the pressure of mounting political and public opinion, the Community had to rapidly design a new approach to consumer health and food safety moving away from its economic-oriented system toward an approach enlightened by consumer protection and food safety concerns[918]. Through the publication of several policy documents, such as the Green Paper on the general principles of food law[919] and the White Paper on food safety[920], the Community launched an effective and exemplary policy-making process leading to the creation of a European Food Safety Authority, originally promoted as a "European FDA". For its effectiveness and speediness, this process may be seen as a model for the conception and development of new EC policies. In less than five years, the Community managed to develop not only an institutional reform of its food policy, symbolized by the establishment of the EFSA, but also to combine this innovation with a profound regulatory reform of its food law: the 'Global Approach' to food Safety. In doing so, the Community involved virtually all interested parties: Member States, producers, manufacturers and consumers[921].

The challenge facing Europe was to develop a food risk regulation model which would ensure the ultimate political decision-making responsibility and, at the same time, appropriately scientific and independent technical advice. To do this, the general food law regulation introduces an innovative institutional separation between the decision-making responsibility of risk managers (EC institutions) and the merely advisory role of experts (EFSA). This institutional separation finds a normative expression in the 'structured' risk analysis framework sketched out by the same regulation. This model of

[917] For an overview of the functionalist theory, see, e.g., B. Rosamond, *Theories of European Integration*, New York, 2000.
[918] Communication from the Commission on consumer health and food safety, supra note 117.
[919] The General Principles of Food Law in the European Union - Commission Green Paper, supra note 107.
[920] White Paper on Food Safety, supra note 133.
[921] The 1997 Green Paper invited "a public debate on our food legislation with a particular emphasis on how legislation was meeting the 'needs and expectations' of consumers, producers, manufacturers and traders". See supra note 102.

risk analysis, addressed not only to the EC institutions but also to the Member States, comprises the three distinct stages of risk assessment, risk management and risk communication. This approach to food risk has been subsequently endorsed by following legislation[922] and case law[923].

However, risk assessment cannot be a wholly objective exercise. Not only it is influenced by the extensive use of 'science policies', but also by the values and beliefs of scientists and the judgments of the profession. This entirely legitimate process inevitably leads to strip the "functional separation" between risk assessment and risk management of its original goals: purity of scientific assessment and accountability of risk managers. These observations suggest that the EC's dichotomial model of risk regulation, which has found both an institutional and a normative expressions in the general food law regulation, is not adequate because it fails to recognize the value judgments implicit in the first stage of risk analysis. The risks stemming from this insistence on the need for a clear-cut separation is that the values and uncertainties inherent in risk assessment may go unexamined because they do not formally translate into "science policies". Notwithstanding the growing rhetoric over transparency in the EC scientific expertise[924], the current EC food safety regime does not seem to ensure that the reasons underlying the decisions clearly indicate the policy choices adopted (judgments, uncertainties and biases in scientific assessment), thus setting them apart from the scientific results on which they rely, so that every citizen (and the courts) can identify them. To avoid this and to maintain the original goals pursued by the functional separation between risk assessment and risk management it is absolutely imperative not only to render science policies explicit by furthering the current efforts aimed at harmonizing risk assessment procedures but also to clarify the role played by EC Commission officials attending EFSA scientific committees' meetings.

Although the EFSA is institutionally independent, however, there are some tensions arising out from the 'grey areas' existing in its relationships with the Commission and

[922] See, for instance, Regulation 1829/2003 on Genetically Modified Food and Feed [2003] OJ L 268/1, which entrusts EFSA with the task to provide the initial assessment on the application.
[923] See, for instance, Alpharma, paras 162-9 and Pfizer, supra note 161, paras 149-56.
[924] EC Commission, White Paper on European Governance, COM(2001) 428 final; EC Commission, Communication on the Collection and Use of Expertise by the Commission: Principles and Guidelines COM (2002) 713 final; EC Commission, The Operating Framework for the European Regulatory Agencies COM (2002) 718 final.

from the current emphasis on the EFSA's contacts with stakeholders, including the industry. While the need of a industry's involvement in EFSA's scientific activities is questionable, an increasing consumer groups' participation is already an indisputable necessity in order to avoid that consumer interests be overwhelmed by those represented by the industry.

Despite these limits, the EC food safety assessment policy, by denying any supremacy to EFSA's scientific opinions upon national ones, preserves Member States' rights to carry out their scientific studies. It is argued that this deliberate choice not to turn EFSA into an Oracle of Delphi spelling out the "truth" in all scientific matters, while it is likely to bring about conflicts among Member States, may be seen as an attempt to defend the European culinary patrimony and cultural richness against the mounting trend toward the obliteration of local traditions led by the multinationals of processed food. Accordingly, in case of diverging opinions between the EFSA and national food authorities, it is up to the EC courts, and not to EFSA, to solve these conflicts by striking a balance between the European (universal) and a national (local) vision of both safety and of the socio-cultural perception of a particular food. Moreover, the EC risk management policy, allowing risk managers to take into account, apart from the scientific opinions, also "other factors legitimate to the matter under consideration" and the precautionary principle[925], must be applauded to the extent it embraces the political nature of risk regulation. Against this backdrop, it is argued that the EC regulation of food carries the potential to emerge as an effective model to reconcile science, traditions, consumer concerns and free movement.

Since the EC food safety regime does not live in a normative vacuum, but it is rather subject to the respect of a set of legally binding obligations, such as those of the WTO, it has been felt the need to explore the scope of the WTO/SPS rules addressing food safety issues. Although the WTO food safety regime responds to an exclusively trade-oriented logic, by aiming at minimizing the negative effects that Members' food safety regulations may have on international trade, rather than at prescribing a minimum level of safety that these regulations should reach, it produces the effect of circumscribing the exercise of Members' sovereign right to regulate food. Being the EC a full Member of the WTO, together with its Members States, it is crucial to verify whether the EC food safety regime

[925] Article 6 (3) of the Regulation.

as illustrated above may be accommodated within the WTO/SPS legal system. There seemed to exist several points of tension between these two food safety regimes, mainly arising out from their respective risk analysis schemes.

In particular, while the EC has hold a line on risk regulation by asserting a dichotomy between the technical and the political, the WTO has refused to endorse any particular model of risk analysis by leaving its Members free, at least in principle, to adopt the protective measures they consider the most appropriate to achieve their chosen level of protection, provided they comply with the prescribed risk assessment requirements. Lacking a clear risk management policy, the WTO model totally denies to recognize the political nature of risk regulation as a whole and inevitably it prioritizes the scientific element over any other legitimate concerns. Accordingly, WTO courts have began to narrowly interpret the scientific basis for SPS measures (i.e. Article 5.1), thus limiting Member States' ability to consider non-scientific factors within their management procedures and to take precautionary measures. To what extent a food safety measure inspired by "other legitimate factors" or by a "precautionary approach" may still be validly be considered "based on risk assessment" within the meaning of Article 5.1?

Although Members' reliance on 'other factors' would not seem directly reviewable under Article 5.1 SPS, which deals merely with the scientific basis of the adopted measure, panels could eventually consider the legitimacy of these factors while determining whether there is a rational relationship between the adopted food safety measure and the risk assessment. Thus, on the one hand, should the panel share the consumer fears related to the consumption of a certain product, it is likely that it will be particularly willing to endorse the adoption of a conservative regulation. On the other hand, if a panel were not so favorably disposed toward a certain 'other factor', it would be keener on looking at the relevant measure as no longer enjoying that logical relationship.

While the Appellate Body has not made clear its attitude to whether social and other non economic factors may have a legitimate role in risk management, by rejecting the distinction between risk assessment and risk management, the most recent case law developed on the role of the precautionary principle seems to have diluted the scope of Article 5.7, by restricting its invocation to not well defined situations of 'scientific insufficiency'. The invocation of this provision would seem therefore, in conformity with a theleological interpretation, to be limited to situations of emergency. It remains to be

seen whether, as pointed out by the Appellate Body in an *obiter dictum* of its Report in the *Hormones* case, a precautionary approach may find support in some other provisions of the SPS Agreement[926].

The lack of any risk management guidance to WTO Members stems directly from the SPS negotiators' choice to "delegate" to Codex Alimentarius its positive integration activities through the SPS harmonization requirements. Hence, Codex has become not only a "quasi-legislator" in charge of elaborating international standards but, gradually, also a unique forum for the elaboration of guidelines for regulatory action in the food safety sector, including both the risk assessment and risk management stages of risk analysis.

Against this backdrop, it is likely that, in settling present and future trade disputes centered on the compatibility of the EC, or other Member States', food regime with WTO law, WTO judicial bodies will look at the emerging body of guidelines promoting commonalities of approaches in risk analysis which have developed within Codex, notably at the Draft Working Principles for Risk Analysis for Food Safety which are currently under consideration. In the light of the above, it is believed that agreement on this additional Codex meta-standard, which is intended for the first time for government use, it is crucial for the future development of a worldwide harmonized food safety risk analysis model being capable of filling up the current gap existing within the WTO risk analysis, notably regarding its risk management policy. Possibly, both points of tensions existing between the EC and the WTO food regimes would thus be attenuated.

However, the problem is that, at present, no Codex risk analysis guidance does seem to provide more useful answers than the SPS Agreement does. Hence, Codex's present inability to solve at the regulatory level the long-standing issues of the role of the precautionary principle and that of "other factors" in risk management makes the relationship between the EC food safety regime and WTO law increasingly difficult today, by maintaining the EC regime at odds with WTO law.

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[926] *EC – Hormones*, AB Report, at para 124, where the AB precised "that there is no need to assume that Article 5.7 exhausts the relevance of the precautionary principle. It is reflected also in the sixth paragraph of the preamble and in Article 3.3. These explicitly recognize the right of Members to establish their own appropriate level of sanitary protection, which level may be higher (i.e. more cautious) than that implied in existing international standards, guidelines and recommendations".

Until this debate is resolved, what if countries invoke the precautionary principle or rely on "other factors" while developing their food safety policies?

As only part of these questions is expected to be clarified by the *Biotech* case pending before the WTO and opposing the US, Canada and Argentina to the EC[927], these issues are expected to give rise to further disputes in the near future.

This shows how the original decision not to agree on a well-defined management policy within the SPS Agreement is producing the effect of transferring the responsibility to shape a WTO risk analysis model from the diplomatic level to the dispute-settlement dimension; in other words, from the 'executive-legislative' powers to the 'judiciary'. By borrowing the words of the Appellate Body, one may say that it is up to the WTO judicial bodies to find an appropriate "balance in the SPS Agreement between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings"[928].

One may legitimately wonder whether should be the judges to fulfill this function, by determining which risk management policies are compatible with risk analysis model developed within SPS. In fact, notwithstanding their well-know commitment to textual fidelity, the WTO judicial bodies will be inevitably obliged to develop answers that rather than stemming from the texts of the WTO Agreements will flow from their understanding of the risk management policies developed in national and international contexts, such as Codex. This excess of discretion impliedly recognized to the WTO courts, if not appropriately offset, is likely to harm the WTO system by diminishing the level of legitimacy and social acceptability of its decisions.

A comparison between the standards of review developed by the EC courts and the WTO judicial bodies has revealed that, as a consequence of this lack of normative reference points within the WTO, the WTO judicial approach of food safety measure is much more intrusive than that adopted by the EC courts, notably regarding the scientific foundation of the contested measure. This is because, by exalting the rational, science-based stage of risk assessment, the WTO ambiguous (non) model of risk analysis inevitably leads WTO

[927] In its first written submission, the EC has maintained that Member States "product-specific moratoriums" (safeguards measures authorized by Article 16(1) of Directive 90/220/EC and Article 12(1) of Regulation No 258/97) are provisional measures pending a full assessment at EC level and therefore fall to be assessed under Article 5.7.

[928] *EC – Hormones*, AB Report, para 177.

courts, while reviewing the legality of a contested food safety measure, to prioritizing the scientific and technical evidence over other legitimate interests. Though incomplete, this model of risk analysis presents an undeniable advantage: by allowing placing science in a privileged position, it permits the panels to avoid the problem of weighing policy concerns that, by definition, are neither neutral-value as the scientific elements nor common among Member States.

However, besides the fact that science is not neutral, by focusing exclusively on the scientific element, the courts face the challenge to 'judge science' while called upon scrutinizing the legality of food safety measures. Even if they are not directly being asked to establish whether a certain risk exists, or more in general, to settle a scientific debate, WTO judicial bodies tend to evaluate the competing scientific claims made by the parties in order to make sure that the contested measure is adequately backed up not simply by a claim of science, but by a proper scientific study. Hence, the lack of a complete risk management policy and the consequent development of a scientifically intrusive standard of review have inevitably opened the Pandora's box of scientific discussion to these judicial bodies, by somehow legitimizing their involvement in controversial scientific matters.

Yet, one would not expect any panel or AB's member called to decide a science-based case to have any specific scientific knowledge in the field. In fact, being poorly equipped to evaluate scientific evidence, they struggle in investigating the 'quality and quantity' of the scientific data advanced by the parties to the dispute. To somehow mitigate such difficulties the WTO panels, unlike the EC judiciary, tend to rely on external advisors. Notwithstanding some flaws, such for example the constant panels' preference for the appointment of individual experts rather than expert review groups, the recurrent use of expert advice is a positive development that must be applauded and, possibly, promoted within the EC courts' judicial practice. Expert advice does not only ensure quality, transparency and legitimacy to the WTO decisions but, if adequately fine-tuned, it might also potentially reduce the level of scientific involvement currently inherent to the level of scrutiny exercised upon science-based measures.

In particular, instead of delegating the experts with the task of solving the very same disputed question that the panel itself has to work out, panels should merely ask the expert to verify whether a particular scientific opinion represents a sufficiently sound



application of scientific principle to justify its conclusions, i.e. to establish whether a *minimum scientific threshold* has been reached. It is suggested that, in determining whether the studies advanced by the parties satisfy such a *minimum scientific threshold*, experts could easily find some guidance in the Codex Working Principles for Risk Analysis and other more specific risk assessment principles developed by its bodies, which would show them how a risk assessment must be conducted[929]. These documents, which may be called 'light harmonization' in risk analysis, carry the potential of not only guiding scientists while conducting risk assessment but also facilitating the task of experts called to assess the scientific adequacy of the opinions brought by the parties.

This expert-based approach, by diluting the scientific involvement of courts and by providing a guidance to external expertise, might prove successful in striking the right balance between judicial intrusiveness and judicial effectiveness when reviewing food safety measures, thus paving the way for the elaboration of a more appropriate, and particularly more deferential, standard of review.

Finally, although it would be more constructive to resolve several of the most contentious issues relating to food regulation in negotiations rather than in controversial and highly technical disputes, such negotiations do not seem part of the Doha Round.

This is regrettable to the extent, as our study has proved, there is a clear case for injecting additional clarity about the existing legal obligations contained in the WTO/SPS framework. While it is arguable whether this interpretative work would be better conducted by the WTO Members delegations during a Negotiation Round or by the more specialized SPS Committee, a clarification of the current WTO/SPS risk management policy it is inescapable priority for the future of the world increasingly integrated food system.

[929] Depending on the specific scientific field at issue, experts may rely, for instance, on the Principles and Guidelines for the Conduct of Microbiological Risk Assessment or on the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology.

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