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*Dipartimento di Scienze Giuridiche*

EUROPEAN LEGAL INTEGRATION: THE NEW ITALIAN SCHOLARSHIP

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Alberto Alemanno

**The Shaping of European Risk Regulation by Community Courts**

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## **European Legal Integration: The New Italian Scholarship (ELINIS)**

This Working Paper is part of the ELINIS project: *European Legal Integration: The New Italian Scholarship* – Second Series. The project was launched in 2006 on the following premise. Even the most cursory examination of the major scientific literature in the field of European Integration, whether in English, French, German and even Spanish points to a dearth of references to Italian scholarship. In part the barrier is linguistic. If Italian scholars do not publish in English or French or German, they simply will not be read. In part, it is because of a certain image of Italian scholarship which ascribes to it a rigidity in the articulation of research questions, methodology employed and the presentation of research, a perception of rigidity which acts as an additional barrier even to those for whom Italian as such is not an obstacle. The ELINIS project, like its predecessor – the New German Scholarship (JMWP 3/2003) – is not simply about recent Italian research, though it is that too. It is also new in the substantive sense and helps explode some of the old stereotypes and demonstrates the freshness, creativity and indispensability of Italian legal scholarship in the field of European integration, an indispensability already familiar to those working in, say, Public International law.

The ELINIS project challenged some of the traditional conventions of academic organization. There was a “Call for Papers” and a selection committee which put together the program based on the intrinsic interest of each proposed paper as well as the desire to achieve intellectual synergies across papers and a rich diversity of the overall set of contributions. Likewise, formal hierarchies were overlooked: You will find papers from scholars at very different stages of their academic career. Likewise, the contributions to ELINIS were not limited to scholars in the field of “European Law.” Such a restriction would impose a debilitating limitation. In Italy as elsewhere, the expanding reach of European legal integration has forced scholars from other legal disciplines such as labor law, or administrative law etc. to meet the normative challenge and “reprocess” both precepts of their discipline as well as European law itself. Put differently, the field of “European Law” can no longer be limited to scholars whose primary interest is in the Institutions and legal order of the European Union.

The Second Series followed the same procedures with noticeable success of which this Paper is an illustration.

ELINIS was the result of a particularly felicitous cooperation between the Faculty of Law at the University of Trento – already distinguished for its non-parochial approach to legal scholarship and education and the Jean Monnet Center at NYU. Many contributed to the successful completion of ELINIS. The geniality and patience of Professor Roberto Toniatti and Dr Marco Dani were, however, the leaven which made this intellectual dough rise.

The Jean Monnet Center at NYU is hoping to co-sponsor similar Symposia and would welcome suggestions from institutions or centers in other Member States.

*J.H.H. Weiler*

*Director, Jean Monnet Center for International and Regional Economic Law & Justice*

# The Shaping of European Risk Regulation by Community Courts

By Alberto Alemanno<sup>\*</sup>

## Abstract

Although not originally foreseen in the founding Treaty, today the most important and widespread form of EU regulation in the internal market is concerned with the government of risk. Indeed, similarly to what occurred in the United States in the 1960s and 1970s, the EU has in recent times witnessed the enactment of a vast body of legislation to protect the environment as well as individuals' health and safety. Collectively, this large body of legislation is known as 'risk regulation'. Contrary to conventional wisdom, this phenomenon is not the product of legislative interventions tout court but the result of a rich and informed case-law developed by EU courts in recent years. By systematising this growing case-law, this essay aims at identifying the main distinctive attributes of the emerging European risk regulatory model.

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<sup>\*</sup> Associate Professor of Law, HEC Paris. I am grateful to Professors Joseph H. H. Weiler and Roberto Toniatti for their valuable comments and discussions. Special thanks go to Marco Dani, Barbara Marchetti, Giuseppe Martinico and Oreste Pollicino and to the other participants of the ELINIS Workshop (May 19-20, 2008, NYU School of Law) for comments on previous drafts as well as to Miranda Aldrich de Savorgnani for her excellent revision of the original manuscript. The usual disclaimers apply. Email: [alemanno@post.harvard.edu](mailto:alemanno@post.harvard.edu)

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## I. The genesis of European risk regulation

Although not originally foreseen in the founding Treaty, today the most important and widespread form of EU regulation in the internal market is concerned with the government of risk<sup>1</sup>. Indeed, similarly to what occurred in the United States in the 1960s and 1970s<sup>2</sup>, the EU has in recent times witnessed the enactment of a vast body of legislation to protect the environment as well as individuals' health and safety. Collectively, this large body of legislation is known as 'risk regulation'<sup>3</sup>.

The driving force behind the trend of increasing risk regulation is generally traced, on both sides of the Atlantic, to growing prosperity and consumers' preferences<sup>4</sup>. Indeed, it is the rising standard of living which tends to shift priorities in people's preferences. As Beck puts it,

“in advanced modernity, the social production of wealth is systematically accompanied by the social production of risks”<sup>5</sup>.

At the same time, the prominence of this kind of regulatory policy in recent years should also be seen as a logical consequence of the single European market's completion<sup>6</sup>, which has made all European consumers increasingly dependent on, and inevitably also vulnerable to, the regulatory policies of all other Member States. As a regulatory failure in any Member State may jeopardize

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<sup>1</sup> D. Chalmers, Risk, Anxiety and the European Mediation of the Politics of Life, *European Law Review*, 2005, 30(5), 649-674 and J. Pelkmans, *European Integration – Methods and Economic Analysis*, Prentice Hall, 2 edition, 2002, p. 54.

<sup>2</sup> On the possible influence of the US on European social regulation, D. Majone, *Regulating Europe*, Routledge 1996, p. 52. For an introduction to US risk regulation, see T. McGarity, *Public Participation in Risk Regulation*, 1 *Risk Issues in Health & Safety* 103 (1990) and S. Breyer, *Breaking the Vicious Circle*, Harvard University Press ed., 1993.

<sup>3</sup> It must be noted that Joerges has been discussing this phenomenon in terms of 'social regulation'. C. Joerges, *Scientific Expertise in Social Regulation and the European Court of Justice*, in C. Joerges, K.H. Ladeur, E. Vos, *Integrating Scientific Expertise into regulatory decision-making*, *Nomos*, 1997, p. 296 and, most recently, C. Joerges and E.U. Petersmann, *Constitutionalism, Multilevel Trade Governance and Social Regulation*, Hart, 2006, 491 et seq.

<sup>4</sup> Pelkmans, *supra* note 1, p. 72.

<sup>5</sup> U. Beck, *Risk Society: towards a new modernity*, Sage Publication, London, 1992, p. 19. For an interesting taxonomy of risks, see O. Renn, *Concepts of Risk: An Interdisciplinary Review*, *GAIA* 17/1 (2008), p. 50-66.

<sup>6</sup> C. Joerges, *Scientific Expertise in Social Regulation and the European Court of Justice*, *supra* note 3, p. 296 and 301.

the single market as a whole, the Community legislator had to promulgate (stricter) harmonized rules<sup>7</sup>. As a result, whilst initially legislations were for the most part concerned with “product regulation”, and were justified by the need to prevent obstacles (non-tariff barriers) to the free movement of goods deriving from regulatory diversity, successive legislations have been increasingly focused on “process regulation” (emission quality standards, maximum exposure levels, maximum residue limits of veterinary medicinal products, food safety requirements, etc), and thus aimed overtly at ‘protection’ goals rather than free movement objectives<sup>8</sup>.

This shift in the regulatory focus of the internal market legislation has been accelerated by the crises that have raged through Europe in the last two decades, causing concern, fear, panic and public distrust. In particular, scandals over “mad cow disease”, dioxins, and Perrier water<sup>9</sup>, have demonstrated that environmental protection as well as public health and safety are not only a consumer’s concern, but also a *conditio sine qua non* for a proper functioning of the internal market, and have emphasised the need to develop an appropriate risk regulation model at European level. In particular, the pressure of public opinion during these crises made the European Union aware that to regulate sectors subject-to-risk only through the lens of the internal market would be inadequate to address the challenges brought by the new perceptions of risks. Indeed, Europe, like most parts of the industrialized world today, hosts a ‘risk society’<sup>10</sup>, in which the regulation of ‘manufactured’ risks, as opposed to those being “natural” or “external” to human activity, becomes a defining element of societal conflict and social understanding.

Some relevant institutional changes, since the 1980s onwards, appreciably contributed to make this legislative intervention possible. Indeed, prior to the shift to majority voting in 1987,

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<sup>7</sup> S. Breyer and V. Heyvaert, Institutions for Managing Risk, in R. Revesz, P. Sands, and R. Stewart (eds), *Environmental Law, the Economy and Sustainable Development—the United States, the European Union and the international community* (Cambridge: Cambridge University Press, 2000), 327; T. Christoforou, The Precautionary Principle and democratizing expertise: a European legal perspective, in *30 Science and Public Policy* 3, 2003, p. 210 and D. Vogel, The Politics of Risk Regulation in Europe and in the United States, *The Yearbook of European Environmental Law*, Vol. 3, 2003.

<sup>8</sup> See, on this distinction, Majone, supra note 2, p. 58 and Joerges, in Joerges and Petersmann supra note 3, p. 511 (who argues that, unlike product regulation, process regulation does not need to affect the quality of the output of the production).

<sup>9</sup> In the long list of food safety crises and scandals of that time appear olive oil, contaminated wine, E.coli listeria, salmonella, polluted drinking water, animal feed, pesticides etc.

<sup>10</sup> This is a sociological concept created by Ulrich Beck, which has subsequently been developed by social anthropologists such as Mary Douglas and Aaron Wildavsky, as well as by Anthony Giddens. See, e.g., A. Giddens, *Beyond Left and Right: the Future of Radical Politics*, Stanford University Press, 1994.

Community regulatory capacity was substantively limited by the unanimity requirement imposed on directives replacing national regulations<sup>11</sup>. Moreover, the setting of a “high level of protection” threshold for all Community legislation since the 1997 Amsterdam Treaty has paved the way for a broader reading of the Community legal basis underpinning health, safety and environmental protection and consumer protection policies<sup>12</sup>.

As a result, when called upon to regulate risks, the EU legislator is caught between two competing Treaty-sanctioned goals and must strike a balance between attaining a high level of protection of human health and consumers’ interests and ensuring the effective functioning of the internal market.

Although the EC institutions have not adopted a harmonized and consistent analytical approach to risk, notably to scientific risk assessment, given that is conducted by different bodies following diverging methods, it is possible to discern some common features in the risk analysis techniques applicable to different regulatory areas dealing the potential risks posed to citizens and the environment (such as food safety, chemicals, pharmaceuticals, medical devices, crop protection and GMOs). In other words, a European risk regulation model is taking shape and developing today.

Contrary to conventional wisdom, this model is not the product of legislative interventions *tout court* but, as this essay will illustrate, it is mainly the result of a rich and informed case-law developed by EU courts in recent years. Indeed, risk regulation being one of the most contentious areas of public action, it is not surprising that its implementation has triggered an abundant judicial activity since its first appearance.

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<sup>11</sup> Before the Single European Act, one of the main avenues for Community intervention was Article 100 (current Article 94) of the original Treaty of Rome, which allows the EC institutions to adopt directives aimed at harmonizing national provisions that “directly affect the establishment or functioning of the common market” (note that 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 the Member States as directly affect the establishment or functioning of the common market”).

<sup>12</sup> See Article 152(1) and also (4), 153, 174 (2).



To prove such a claim, this essay will identify the main attributes characteristics of the European risk regulation model by thoroughly discussing the EU courts' case-law. An examination and systematization of this growing body of judgments addressing the legal implications of risk regulation will demonstrate not only the Courts' readiness to promote a given European model of risk regulation but also its capacity to frame it according to a set of well-defined principles aimed at providing guidance to both Member States and Community institutions. It will be shown how, despite their limited capacity to systematically shape Europe's regulatory practice, due to the inevitably random nature of their judicial intervention in the interpretation and application of risk regulation, the EU Courts have paved the way for a significant process of Europeanization of risk regulation.

This is not unusual with the European legal order whose main constitutional principles have been introduced by the ECJ through its activity of *dicere legem*. According to a *déjà-vu* paradigm, although most of the time the exercise of such an activity is triggered by marginal cases, the principles spelled out in these cases can prove relevant for the whole Community.

## **II. Risk Analysis as the *Grundnorm* of the EU risk regulation model**

At the outset of the emerging EU risk regulation model there has been judicial recognition of the structured risk analysis model as developed by the US National Research Commission<sup>13</sup>. This model is based on the three distinct stages of risk assessment, risk management and risk communication<sup>14</sup>. Though partly reinterpreted and adapted to the European context, this analytical methodology has largely inspired both the institutional and normative structures of EU

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<sup>13</sup> In particular, the distinction between risk assessment and risk management has been originally conceived in 1983 with the publication of 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. On the origin of the distinction between RA and RM, see S. Jasanoff, Risk Management and political culture, New York, 1986, p. 26.

<sup>14</sup> One of the earliest and most explicit recognition of such an analytical tool for regulation risk may be found in EFTA Court of 5 April 2001, Case E-3/00 Efta Surveillance Authority v Norway [2001] EFTA Court Report 2000/2001, 73, p. 30. See on this judgment, 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, p. 937 et seq.

risk regulation, which tends to reflect a clear division between a scientific process of risk assessment and a political process of risk management.

The judicial and subsequent legislative acceptance of risk analysis as the privileged methodological tool for regulating risk in Europe does not find any textual basis in the Treaty itself. It is more due to the way in which the arguments have been put to the Courts by the parties on a case-by-case base and also to the existence of some soft law documents elaborated by the Commission services<sup>15</sup>. At the same time, as observed by former Advocate General Mischo, the introduction of such a structured “risk-analysis theory” is fully compatible with the previous approach adopted by Courts when examining the legality of restrictive measures inspired by public health goals<sup>16</sup>.

As a result, risk analysis is the main conceptual framework upon which the EC legislator (and Courts) relies in seeking to achieve, and somehow reconcile, the two Treaty-sanctioned and competing objectives of a high level of protection of human health and life and free movement<sup>17</sup>. As the Court has stated on several occasions, Community risk regulation provisions must ensure, in addition to the protection of human health (or the environment), the free movement of goods, so that their interpretation “cannot result in obstacles to the free movement of goods which are entirely disproportionate to the pursued aim of protection of health”<sup>18</sup>.

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<sup>15</sup> Explicit references to risk analysis can be found, for example, in Communication of 30 April 1997 on consumer health and food safety, COM(97) 183 final, p. 20 (as quoted in Case T-70/99 *Alpharma v Council* [2002] ECR II-3495, paragraph 171) and Commission Communication on the precautionary principle, COM (2000) 1 and in Common Position (EC) No 2/2002 of 17 September 2001 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 (EC) 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. For a reconstruction of the origin of the introduction of the risk analysis main components in the EC legal order, see Opinion of Advocate General Mischo in Case 192/01 *Commission v Denmark* [2003] ECR 9693.

<sup>16</sup> *Ibidem*, paragraph 143. See on this point S. Mahieu, *Le droit de la société de l'alimentation* (Larcier, 2007), p. 141, footnote 317.

<sup>17</sup> See, for a recent judicial recognition of such a principle, Case C-326/05 P, *Industria Quimicas del Valles v Commission*, not yet reported, paragraph 74 and for its legislative endorsement, see Article 6 (1) 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’). This provides that “food law shall be based on risk analysis”.

<sup>18</sup> See, e.g., the very recent judgment in Case C-319/05, *Commission v Germany*, not yet reported, paragraph 71.

It must be noted that, within this “ubiquitous”<sup>19</sup> and generally-accepted analytical methodology for governing risk, what is understood to be ‘risk assessment’ and ‘risk management’, as well as the exact relationship between these two components, vary considerably across and between jurisdictions. As a result, risk assessment tends to be seen as “a construct of administrative constitutionalism instead of being innately scientific”<sup>20</sup>, whereas risk management is a different creature depending on where and by whom it is performed. Moreover, whilst the generally accepted *summa divisio* between the decision-making responsibility of political institutions and the purely advisory role of expertise rests upon the assumption that risk analysis can be divided into a wholly scientific process of analysing the facts and a political process, this distinction has increasingly been doubted through time<sup>21</sup>.

As the contents and nature of this risk analysis framework are blurred by the constant push and pull between facts and values, nature and culture, science and politics, the EU courts have stepped in by defining not only what must be understood as ‘risk assessment’ and ‘risk management’ but also how the relationship between these two components of risk analysis must be conceived when regulating risks in Europe.

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<sup>19</sup> Opinion of Advocate General Mischo in Case 192/01 Commission v Denmark [2003] ECR 9693, paragraph 89.

<sup>20</sup> E. Fischer, *Beyond the Science/Democracy Dichotomy*, in C. Joerges and E.U. Petersmann, *Constitutionalism, Multilevel Trade Governance and Social Regulation*, Hart Publishing, 2006, p. 340.

<sup>21</sup> This distinction has been criticised for being artificial and difficult to maintain in reality. For a US perspective, see D.G. Mayo and R.D. Hollander, *Acceptable Evidence: Science and Values in Risk Assessment*, 1991, p. xi; V.R. Walker, *The Myth of Science as a “Neutral Arbiter” for triggering Precautions*, 26 *Boston College International and Comparative Law Review* 197, at 252; D.A. Wirth, *The Role of Science in the Uruguay Round and NAFTA Trade Disciplines*, *Cornell International Law Journal*, Vol. 27, pp. 817-859, 1994, p. 833-34; R.A. Pollak, *Regulating Risks*, *Journal of Economic Literature*, Vol. XXXIII, March 1995, pp. 179-191, 183 and J.B. Wiener, *Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems*, 13 *Duke Journal of Comparative and International Law* 207 (2003). For a European perspective, see 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, pp. 406-8; 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, p. 937 ; L. Boisson de Chazournes, *Le principe de précaution: nature, contenu et limite*, in *Le principe de précaution – Aspects de droit international et de droit communautaire*, Editions Panthéon Assas, Paris, 2002, pp. 65-94 and, more, recently, K.H. Ladeur, *The Introduction of the Precautionary Principle into EU law: A Pyrrhic 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. The US National Research Council has also questioned the wisdom and the appropriateness of the separation between risk assessment and risk management for excluding other sources of information which are necessary for good decision-making, see P. Stern and H. Fineberg (eds), *Understanding Risk: Informing Decisions in a Democratic Society*, National Academy Press, Washington DC, 1996, pp. 33-35.

These issues are critical because, as will be shown, behind these unqualified empty boxes lie fundamental constitutional questions such as: the role of science in the regulatory process<sup>22</sup>, the interactions between risk assessors (science) and risk managers (policy-making), the role of “non-scientific” factors in risk management, the nature and scope of the precautionary principle within risk analysis, the hierarchy existing among different scientific sources of advice, the intensity of the judicial scrutiny to be exercised over science-based measures, and more generally, different «theories of administrative constitutionalism»<sup>23</sup>.

In the EU Courts’ case-law, recognition of the need to conduct a risk assessment and risk management when regulating risk has occurred at two levels: validity challenges and interpretation questions of Community legislation and actions brought against Member States. Accordingly, both instances will be considered throughout the essay and an attempt will be made to flesh out the different guidelines provided by the Courts depending on whether risk analysis must be conducted in the framework of a Community or a national measure.

It will be shown that every legal challenge to national or Community risk regulation has offered, and continues to offer, the Courts the opportunity to refine their case-law and shape risk regulation even further, in striking a balance between scientific justification and regulatory discretion.

This essay will explore the role that European courts have played (and continue to play)<sup>24</sup> in defining the way in which risk analysis should be conducted and, notably, how scientific expertise is used to inform the EU decision-making process in risk areas.

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<sup>22</sup> As effectively put it by Joerges, “to what degree should, could, or does ‘expertise’ replace legal, political and ethical criteria?”, see 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. Journal of European Law* 1 (2001).

<sup>23</sup> E. Fischer, *supra* note 20, p. 333.

<sup>24</sup> Case C-326/05 P, *Industria Quimicas del Valles v Commission* [2007] ECR 6557 and T-229/04, *Sweden v Commission* [2007] ECR 9273. These recent judgments delivered in two crop protection cases seem to show the courts’ readiness to comment directly on the use of science within both the risk assessment and management processes.

### III. Risk Assessment and European Courts

To fully understand the role played by Community courts in shaping risk assessment, the scientific component of the EU's risk regulation model, it is crucial to examine, first, how a scientific requirement has gradually been introduced in the Community legal order and, second, how courts have contributed to shape this requirement which, once undertaken, may lead to regulatory action.

#### III.1 The origins of risk assessment in the Courts' case-law

##### *(a) Risk assessment and national measures: an anti-protectionist tool*

Originally, the 1957 Treaty of Rome did not impose, either on the EC institutions or on Member States, a duty to substantiate their health, safety and environmental protection measures scientifically. Indeed, its text did not contain any reference to scientific evidence.

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 *inter alia* on grounds of protection of health<sup>25</sup>, the European Court of Justice required Member States to provide some scientific evidence in order to demonstrate that their measures were covered under this exception. As Joerges put it, this was by no means "a trivial requirement"<sup>26</sup>. Thus, in the *Beer Purity case* (also known as *Reinheitsgebot* judgment)<sup>27</sup>, Germany, after having banned the marketing of beer containing *all* additives (not just some additives for which there was evidence of risks)<sup>28</sup>, tried to justify its measure by arguing not only that "more beer is consumed in

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<sup>25</sup> While Article 28 prohibits Member States adopting 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".

<sup>26</sup> Joerges, *supra* note 3, p. 303.

<sup>27</sup> Case 178/84, *Commission v. Germany* [1987] ECR 1227.

<sup>28</sup> According to the *Reinheitsgebot* (the German beer purity law), originally enacted in 1516 by the Bavarian duke Wilhelm IV, only beer containing the following ingredients could be marketed on the German territory: water, hops, barley, and yeast.

Germans than any other food” but also that the long-term effects of additives were unknown. The ECJ, referring to the previously decided *Sandoz*<sup>29</sup>, *Motte*<sup>30</sup> and *Muller*<sup>31</sup> 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, the work of the Community's scientific committee for food, the *Codex alimentarius* committee of the FAO and the World Health Organization"<sup>32</sup>. After having deferentially referred to the scientific findings of these entities, the Court found that not only did the additives not present a risk to public health but also that the German policy was inconsistent insofar as it allowed the use of these same additives in other drinks. References to "the findings of international scientific research, and in particular of the work of the Community's Scientific Committee for Food, the Codex alimentarius Committee of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization" may also be found in subsequent judgments, such as *Bellon*<sup>33</sup> and *Debus*<sup>34</sup>, both involving national measures restricting the use of additives. In *KYDEP*, involving the Community rules governing the maximum levels of radioactive contamination permissible in foodstuffs following the Chernobyl nuclear accident, the ECJ even referred not only to "the opinions of national experts on radioactivity and foodstuffs, the recommendations of the International Commission on Radiological Protection (ICRP)" but even to "the instructions of the US Food and Drug Administration"<sup>35</sup>. In other words, Member States cannot limit themselves to invoking a risk to public health to substantiate a health measure, but “the risk must be measured, not according to the yardstick of general conjecture, but on the basis of relevant scientific research”<sup>36</sup>.

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<sup>29</sup> Case 174/82, *Sandoz BV* [1983], ECR 2445, paragraph 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?*, *Journal of World Trade* (2003) 553, p. 557.

<sup>30</sup> Case 247/84 *Motte* [1985] ECR 3887. This case concerned the import of lumpfish roe prepared with colorants banned in Belgium but allowed in the country of export.

<sup>31</sup> Case 304/84 *Ministère Public v Muller and others* [1986] ECR 1511.

<sup>32</sup> Case 178/84, *Commission v. Germany* [1987] ECR 1227, paragraph 44.

<sup>33</sup> Case C-42/90 *Bellon* [1990] ECR 4863, paragraph 14.

<sup>34</sup> Case C-13/91 and C-113/91, *Debus* [1992] ECR 3617, paragraph 17.

<sup>35</sup> Case C-146/91 *Koinopraxia Enóseón Georgikon Synetairismon Diacheiríséos Enchorion Proïonton Syn. PE (KYDEP) v Council and Commission*, [1994] ECR 4199, paragraph 42.

<sup>36</sup> Case C-17/93 *Van der Veldt* [1994] ECR I-3537, paragraph 17.

Yet, whilst Member States must respect the findings of these international scientific organizations, the Court allows departure from them insofar as there is some scientific uncertainty<sup>37</sup>. Moreover, because of the principle of mutual recognition, under which Member States must open their borders to products lawfully marketed elsewhere in the Community, Member States are requested to support their legislation on sound science as well as scientific studies conducted beyond their territories<sup>38</sup>.

Thus, not formally introduced within the Rome Treaty, a *de facto* risk assessment requirement imposed itself in the regulatory practice surrounding 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"<sup>39</sup>, it regarded Member States' attempts to invoke health reasons as a means of affording a disguised restriction on trade with suspicion.

*(b) Risk assessment and Community measures: a tool for ensuring the scientific rationality of regulation*

In the meanwhile, the scientific justification discipline developed as an anti-protectionist tool in relation to Member State measures based on public health has extended to acts adopted by the European institutions. Indeed, in 1993, in *Angelopharm*, the Court declared invalid a Commission's ban on a hair loss tonic supposedly injurious to public health, because it was not "founded on scientific and technical assessments which must themselves be based on the results of the latest international research"<sup>40</sup>. Moreover, when called upon to define the extent of the obligation for the Commission to consult the competent scientific committee, it held that neither the Commission nor "the Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetic Products Sector", which consists exclusively of representatives of the Member States and of the Commission, are in a position to conduct an assessment, which "in the nature of things and apart from any provision laid down to

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<sup>37</sup> Case 247/84 Motte [1985] ECR 3887; Case 174/82, Sandoz BV [1983] ECR 2445.

<sup>38</sup> Joerges, *supra* note 3, p. 307.

<sup>39</sup> Case C-17/93 Van der Veldt [1994] ECR I-3537, paragraph 15, and Case C-320/93 Ortscheit [1994] ECR 5243, paragraph 16.

<sup>40</sup> Case C-212/91 Angelopharm v. Hambourg, [1994] ECR 17, paragraph 31.

that effect” must “be assisted by experts on scientific and technical issues delegated by the Member States”<sup>41</sup>.

The clear message stemming from this judgment is that EU institutions, and not exclusively Member States, not being “in a position to carry out assessments of this kind”, must consult scientific advice when adopting decisions for which they lack expertise even when they are not formally required to do so<sup>42</sup>. Indeed, “since the purpose of consulting the Scientific Committee is to ensure that the measures adopted at Community level are necessary and adapted to the objective pursued by the Cosmetics Directive of protecting human health, consultation of the Committee must be *mandatory* in *all* cases”. Without going as far as to say that the institutions are bound by the scientists’ advice, the Court made clear that the questions at stake should have been subject to the experts in order to obtain, “from a fully informed position”, which adaptation measures were necessary<sup>43</sup>.

This requirement to conduct a risk assessment when regulating risk has subsequently been confirmed in *Bergaderm* where the Court of First Instance was called upon to review the Commission’s ban on a suntan lotion containing the essence of an herb that had been found to be potentially carcinogenic by the competent scientific committee<sup>44</sup>. Here, the Court, after stressing that the Commission had consulted the appropriate committee and obtained its advice, concluded that

“the Commission cannot be criticised for placing the matter before the Scientific Committee or for complying with that body's opinion, which was drawn up on the basis of a large number of meetings, visits and specialist reports”<sup>45</sup>.

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<sup>41</sup> Ibidem, paragraph 33.

<sup>42</sup> “The Commission cannot successfully argue, as it did during the oral procedure, that consultation of the Scientific Committee is necessary only when authorization of the use of a substance in the manufacture of cosmetic products is envisaged. In the first place, no provision in the Cosmetics Directive makes a distinction according to whether the measure envisaged prohibits or authorizes the use of a substance”. Ibidem, paragraph 37.

<sup>43</sup> Ibidem, paragraph 34.

<sup>44</sup> Case T-199/96, *Bergaderm v Commission* [1998] ECR II-2805.

<sup>45</sup> Ibidem, paragraph 65.



In other words, once the institutions have engaged in a risk assessment and followed it, they benefit from a kind of presumption concerning the legality of their action. This approach to risk assessment as a procedural duty that EC institutions must abide by when regulating risk was subsequently confirmed by the ECJ on appeal<sup>46</sup>.

Finally, the risk assessment duty seems to have been given general application to all science-based measures by the CFI, which 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"<sup>47</sup>.

Although serving different objectives, risk assessment has been imposed as a procedural duty on both national and Community legislators. This is because both entities play important roles in regulating risk policies. Whilst in the former case, resorting to science serves an anti-protectionist goal by preventing the adoption of measures liable to hinder free movement within the internal market, in the latter, its aim is to ensure the scientific rationality of (harmonised) regulation. As stated by Joerges, "[o]n the one hand, Community law, wherever it manages to promote science-based standards of validity, ensures its own authority without the usual entanglements in complex controversies over competencies, conflicting economic interests and highly sensitive issues of political accountability. Member States, on the other hand, when pointing to scientific expertise as providing support for their regulatory concerns, can hardly be accused of promoting one-sidedly some parochial or protectionist interests"<sup>48</sup>. This is perhaps one of the happiest illustrations of the "strategic exploitation" of science in the framework of the internal market.

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<sup>46</sup> Case C-353/98 P *Laboratoires pharmaceutiques Bergaderm a.o. v. Commission* [2000] ECR 5291.

<sup>47</sup> Case T-13/99 *Pfizer Animal Health v. Council*, 2002 ECR II-3305, paragraph 157.

<sup>48</sup> Joerges, *supra* note 3, p. 297-98.

### **III.2 The codification of the scientific justification requirement: from scientific evidence to risk assessment**

The emerging risk assessment requirement, as developed by the ECJ vis-à-vis both national measures and Community measures, has been gradually codified within the Treaty and gradually integrated into secondary law, where it has been translated into a detailed set of specific assessment procedures and regulatory frameworks<sup>49</sup>. Indeed, as scientific expertise was expected to play a major role in examining information and providing a ‘denationalised’ approach to risk assessment within the internal market, the Community had to devise an adequate environment in order to fully benefit from the integrating functions of scientific expertise<sup>50</sup>.

Whilst risk assessment has been inserted into Article 95, paragraph 5, EC only in 1999 as one of the requirements Member States must satisfy in order to *introduce* a national measure derogating from European harmonization legislation<sup>51</sup>, a risk assessment duty for Community measures was first codified in 1997.

In particular, this occurred when the aim of achieving a "high level" of health and environmental protection was given the status of a general objective in the EC Treaty (Article 3(1) (p)), and Article 100a (current 95 EC) was amended in order to specify that this objective should be pursued and based on "scientific facts"<sup>52</sup>.

Moreover, a further codification of the risk assessment requirement for Community legislation occurred in 1999, when following the entry into force of the Amsterdam Treaty, it was

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<sup>49</sup> For an illustration of this phenomenon, see, Mahieu, *Le droit de la société de l'alimentation* (Larcier, 2007), p. 218 et seq.

<sup>50</sup> Joerges, *supra* note 3, p. 298.

<sup>51</sup> 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". 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. See, on this point, Commission Decision 1999/830/EC on the Danish request for derogation on the use of sulphites, nitrites and nitrates in foodstuffs, OJ 1999 L392/1. The ECJ in Case 3/00, *Denmark c. Commission*, [2003] 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 EC).

<sup>52</sup> Article 100a(3) of EC, current Article 95, paragraph 3.

established that all Community legislation concerning health, safety and environmental protection and consumer protection should aim to achieve a high level of protection by “taking account in particular of any development based on scientific facts”<sup>53</sup>. Notably, EC environmental policy directed towards a high level of protection should “take account of available scientific and technical data”<sup>54</sup>.

Nowadays, risk assessment, having evolved into better defined risk assessment procedures, can be found in all risk-related secondary legislation, such as worker health and safety<sup>55</sup>, chemicals<sup>56</sup>, medicinal products, GMOs<sup>57</sup>, biocides<sup>58</sup>, contaminants, plant protection products (such as pesticides and herbicides)<sup>59</sup>, food additives<sup>60</sup>, water protection<sup>61</sup>, etc.

The next sections will illustrate the Courts’ contribution in establishing the main tenets of risk assessment.

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<sup>53</sup> Article 95, paragraph 3, EC. See also, Articles 152 (1) and (4), 153, 174 (2).

<sup>54</sup> Article 174, paragraph 3, EC.

<sup>55</sup> 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.

<sup>56</sup> Risk assessment of existing chemicals is provided by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, p. 1.

<sup>57</sup> See Articles 4(1) and (2) of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, [2001] OJ L 106/1.

<sup>58</sup> Directive 98/08/EC concerning the placing of biocides on the market.

<sup>59</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1). The 1998 Rotterdam PIC Convention refers to “risk evaluation” as a precondition for regulatory action.

<sup>60</sup> 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.

<sup>61</sup> See Article 16(2) of Directive 2000/60/EC establishing a framework for Community action in the field of water policy.

### III.3 Risk assessment and its main components

The case-law of the Courts has gradually refined the risk assessment duty as applicable to both Member States and EC institutions. The CFI, by drawing on FAO's previous work<sup>62</sup>, has defined risk assessment as a "scientific process consisting in the *identification* and *characterisation* of a hazard, the *assessment of exposure* to the hazard and the *characterisation of the risk*"<sup>63</sup>.

The first step of risk assessment, the so-called hazard identification, focuses on the descriptive elements of the potential risks by identifying 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<sup>64</sup>. Thus, for instance, in *Commission v. Denmark*<sup>65</sup>, the ECJ clearly required from the Danish authorities defending a pre-market system approval for enriched foodstuffs:

"[...] 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"<sup>66</sup>.

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<sup>62</sup> The efforts deployed by WHO, jointly with FAO, have developed guidelines documents for undertaking each of the four components of a risk assessment namely hazard identification, hazard characterization, exposure assessment and risk characterization in harmonization of risk analysis within its area of competence. 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, inter alia, 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.

<sup>63</sup> Case T-13/99 Pfizer Animal Health v. Council, 2002 ECR II-3305, paragraph 156; Case T-70/99 Alpharma v Council [2002] ECR II-3495, paragraph 169. See, e.g., Article 3 of the general food regulation. The identification of these four 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). 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>

<sup>64</sup> Article 3 (14) of the general food regulation.

<sup>65</sup> Case 192/01 Commission v Denmark [2003] ECR 9693.

<sup>66</sup> *Ibidem*, paragraph 51.

The next stage, the heart of RA, provides for a more structured overview of the probabilities of certain phenomena or events. It aims to provide a qualitative and, wherever possible, quantitative description of the inherent properties of an agent or situation having the potential to cause adverse effects. Then, there is an intermediary phase in which the exposure of an organism, system or population to an agent is evaluated<sup>67</sup>. Thus, for instance, in the *Vitamin* line of cases<sup>68</sup>, the Court reminded the national authorities of several Member States that were subjecting the selling of fortified foodstuffs to a pre-market approval system that,

“[t]he object of the risk assessment to be carried out by the Member State is to appraise the degree of probability of harmful effects on human health from the addition of certain nutrients to foodstuffs and the seriousness of those potential effects”<sup>69</sup>.

This assessment of risk exposure leads the way to the final risk assessment stage: risk characterization. This is the stage in which the balance between confidence and uncertainty in the assessment is characterized and in which results are expressed in a form useful to decision-makers and risk managers<sup>70</sup>. 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<sup>71</sup>. The assessment may include a range of characterisations: from a risk that is unlikely to occur, but which is potentially calamitous, to a risk with a very high probability of occurring, but whose impact is minor.

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<sup>67</sup> Thus, for instance, in *Toolex*, it is stated that “[t]he fact that [trichloroethylene] is highly volatile increases the chances of exposure in circumstances that might result in damage to health. Inhaling the substance can cause fatigue, headaches, and difficulties with memory and concentration”. Case C-473/98, *Toolex* [2000] ECR I-5681, paragraph 41. See also T-392/02, *Solvay Pharmaceuticals* [2003] ECR II-4555, paragraph 46.

<sup>68</sup> Case 192/01 *Commission v Denmark* [2003] ECR I-9693; Case C-24/00 *Commission v France* [2004] ECR I-1277; Case C-270/02 *Commission v Italy* [2004] ECR I-1559 and Case C-41/02 *Commission v Netherlands* [2004] ECR I-11375. For a review of these judgments, Alemanno, *Trade in Food – Regulatory and Judicial Approaches in the EC and the WTO*, Cameron May, London, 2007, p. 138 et seq.

<sup>69</sup> Case C-41/02, *Commission v Netherlands*, paragraph 49. In such a context, see also *Commission v Denmark*, paragraph 48; and *Commission v France*, paragraph 55.

<sup>70</sup> Case T-13/99 *Pfizer Animal Health v. Council*, 2002 ECR II-3305, paragraph 156; Case T-70/99 *Alpharma v Council* [2002] ECR II-3495, paragraph 169.

<sup>71</sup> 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 EU courts' case-law has endorsed this four-step analysis as the main analytical framework of risk assessment<sup>72</sup>. But, who is responsible for conducting such an assessment? As stated in *Denkavit*<sup>73</sup>,

“[t]he Court of Justice has already had occasion to note that in matters relating to additives in feedingstuffs the *Community institutions are responsible* for carrying out complex technical and scientific assessments”<sup>74</sup>.

However, while it is true that a scientific risk assessment must be carried out before any preventive measures can be taken, the Courts soon determined that the Commission is not in a position to carry out such an assessment on its own<sup>75</sup>. Thus, for example, the CFI held in *Pfizer* that 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.

As there is currently no common system to provide scientific advice to the EC policy-makers at the European level, the most common sources of advice used to support EC policies, legislation and regulatory decisions are the following: scientific committees within European Food Safety Authority and European Medicinal European Agency; three non-food scientific committees that operate under the responsibility of the Directorate General for Public Health and Consumer Products (DG SANCO)<sup>76</sup>; 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

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<sup>72</sup> See Case T-13/99, *Pfizer*, paragraph 156.

<sup>73</sup> Case 14/78 *Denkavit v Commission* [1978] ECR 2497.

<sup>74</sup> *Ibidem*, paragraph 20.

<sup>75</sup> See, Case C-212/91 *Angelopharm v. Hamburg* [1994] ECR I-173, paragraphs 31 and 32; see also Case C-151/98 *P Pharos v. Commission* [1999] ECR I-8157, paragraph 26.

<sup>76</sup> Commission Decision Decision 2004/210/EC of 3 March 2004, OJ L66, p. 45-50. There are three committees: Scientific Committees on Consumer Products (SCCP); Scientific Committee on Health and Environmental (SCHER) and Risks Scientific Committee on emerging and Newly Identified Health Risks (SCENIHR). To coordinate these committees an Inter-Committee, made up of the Chairs and Vice-Chairs of the three Committees, has been established. Its main task is to assist the Commission on matters relating to the harmonisation of risk assessment. In addition, it deals with questions which are common to more than one Committee, diverging scientific opinions and exchange of information on the activities of the Committees.

and opinions by the Joint Research Centre (JRC) and the Scientific and Technical Options Assessment group in the European Parliament (STOA).

Since 2000, this heterogeneity has given rise to some efforts to set 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 the environment<sup>77</sup>. No substantial results seem to be achieved as of today.

### III.4 Conducting risk assessment

After having defined the task of scientific evaluation and determined that it must be performed solely by experts, EU Courts have shaped the guiding principles that the latter must follow when carrying out a scientific risk assessment. In particular, in order to fulfil its function, scientific advice on matters relating to consumer health must, in the interests of consumers and industry, be based on the principles of *excellence, independence and transparency*<sup>78</sup>.

In order to translate these principles into practical terms, the Courts have over time moulded them into an effective set of procedural duties for risk assessors.

#### *(a) Comprehensive Risk Assessment*

Having defined risk assessment, EU judges introduced the duty of the responsible organ to investigate *all* relevant aspects of the individual case<sup>79</sup>. The rationale of this duty of ‘comprehensive examination’ is to ensure that risk assessment, as undertaken by the experts,

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<sup>77</sup> 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 (!).

<sup>78</sup> Case T-70/99 Alparma v Council [2002] ECR II-3495, paragraph 172 and Case T-13/99 Pfizer Animal Health v. Council, 2002 ECR II-3305, paragraph 159. These findings of the Courts build upon the then recently-published Commission policy documents: 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.

<sup>79</sup> See, Alparma, paragraph 175.

provides reliable and substantiated information so as to enable the responsible public authority to decide with full knowledge of all the implications of the scientific questions posed and determine its policy in the light of the additional facts. In particular, as established in *Alpharma*, where the applicant challenged the risk assessment which had led the Commission to withdraw one of its pharmaceutical products,

“the scientific risk assessment must enable the competent public authority to ascertain, *on the basis of the best available scientific data* and the most recent results of international research, whether matters have gone beyond the level of risk that it deems acceptable for society”<sup>80</sup>.

An interesting expression of such a duty may be found in *Olivieri*<sup>81</sup>, a case concerning the Commission’s authorisation of a new treatment for anaemia. There, Dr. Nancy Olivieri, an internationally recognised scientist who had led the clinical trials into a new treatment for the disease, but who was subsequently removed from the authorisation process in the US by the manufacturer, challenged the Commission’s authorisation of the marketing of the new treatment by putting forth serious doubts regarding the scientific assessment followed<sup>82</sup>. She claimed, in particular, to be “the only person” in a position to guarantee the authenticity of certain trial reports on which the contested decision was based. The main question facing the Court was whether the applicant had an interest in bringing an action against the Commission final decision of granting marketing authorisation for the new treatment. According to Dr Olivieri, her judicial interest was twofold: to protect public health and to defend her professional reputation.

Although the CFI declared the applicant’s action inadmissible, it did so only after having established that:

- not only did “none of the provisions” of the authorisation system prohibit the Commission from following a procedure “during which persons other than the applicant [...] are able to submit their observations so as to enable it to fulfil its duty to check, in

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<sup>80</sup> Ibidem.

<sup>81</sup> T-326/99, Nancy Fern Olivieri [2003] ECR p. II-6053.

<sup>82</sup> Ibidem, paragraph 56.



- the interest of public health, that all the information relating to the scientific evaluation of the product in question [...] had indeed been made available to it”<sup>83</sup> (*in abstracto control*)
- but also that Dr Olivieri’s information had been examined and taken into account, resulting in the initial scientific assessment being called into question and leading to a suspension of the marketing authorisation before the contested decision’s adoption (*in concreto control*)

In so doing, and by enforcing the Commission’s obligation to verify the information relating to the quality, safety or efficacy of the medicinal product, the Court has clearly imposed a supplementary responsibility on the institution consisting of the duty to listen to “observations” submitted by third parties. Although the Court stated that the applicant’s right “ended at the moment when that information was examined and taken into account in the course of that assessment procedure”<sup>84</sup>, this does not mean that the Commission dismissed the applicant’s concerns when authorising the products.

As a result, the Commission not only considered more scientific voices than it was originally supposed to, but also obtained more information than what the manufacturer submitted to it and, in the end, limited the treatment’s authorisation to exceptional cases<sup>85</sup>.

This duty of comprehensive examination has been confirmed on several occasions by Community courts, which have persistently clarified its nature and scope.

Likewise, in *Commission v Netherlands*, the Court, called upon to assess a prohibition on the marketing of foodstuffs to which nutrients have been added, in the light of the free movement rules, held that to satisfy the public health grounds exception the measure must,

“be based on a *detailed* assessment of the risk alleged by the Member State invoking Article 36 of the Treaty”<sup>86</sup>.

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<sup>83</sup> Ibidem, paragraph 73.

<sup>84</sup> Ibidem, paragraph 91.

<sup>85</sup> J. Corkin, Science, Legitimacy and the Law, Regulating Risk Regulation Judiciously in the European Community, *European Law Review*, Vol. 33, issue 3 (2008), pp. 359-384.

A similar lesson may be drawn from a recent judgment of the Court dealing with the marketing of a pesticide called metalaxyl. In *Industrias Químicas del Vallés*<sup>87</sup>, the ECJ had to determine, on appeal, *inter alia* whether the rules governing the assessment procedure for plant protection products allow the rapporteur Member States to use data after the notifier who supplied them has withdrawn from the procedure and one applicant remains interested in the authorisation procedure. Although an opinion of the Commission Legal Service concluded that the assessment of metalaxyl could have been carried out on the basis of *all* the information available (including the studies submitted by the notifier who had withdrawn), the Commission took a different view and, by refusing to rely on the latter information, adopted a negative decision. In doing, the Commission made it particularly difficult for the applicant to submit the missing information before the deadline and, for that reason, the ECJ annulled its decision.

This judgment shows once more the Court's willingness to read the risk assessment procedures in a way as to ensure that *all* information will be taken into consideration. More in general, this judgment also stands for a more general conclusion: compliance with strict-time limits cannot take the priority over public health goals<sup>88</sup>.

This duty has been extended, though partly adapted, to situations in which public authorities are called upon to take decisions characterised by scientific uncertainty. In these circumstances, "notwithstanding the existing scientific uncertainty", they are required to provide

"[...] 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"<sup>89</sup>.

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<sup>86</sup> Case C-41/02 *Commission v Netherlands* [2004] ECR I-11375, paragraph 48.

<sup>87</sup> Case C-326/05 P, *Industrias Químicas del Vallés* not yet reported.

<sup>88</sup> A similar lesson may also be drawn from CEVA. See Cases T-344/00 and T-345/00, *CEVA Santé Animale SA* ECR [2003] II-229, and Case C-198/03 P, *Commission v. Ceva/Pfizer*, [2005] ECR I-6357.

<sup>89</sup> Case 192/01 *Commission v Denmark* [2003] ECR I-9693, paragraph 51.

(b) Updated scientific advice

The scientific authority to which both Member States and Community institutions refer to must be, according to the Courts, the “best scientific information *available*”<sup>90</sup>. The word “available” employed to qualify the kind of science expected to be taken into account at the risk assessment stage has been clarified in *Mirepoix*<sup>91</sup>, a case concerning the harmfulness of pesticide residues for the human organism. Here, the Court held that,

“[t]he authorities of the importing member state are obliged to review the prohibition on the use of a pesticide or a prescribed maximum level if it appears to them that the reasons which led to the adoption of such measures have changed [...] as a result of the discovery of a new use of a particular pesticide or as a result of further information becoming available through scientific research”<sup>92</sup>.

From this judgment one may infer another principle that authorities must abide by when conducting a risk assessment: the existence of a duty to continuously review the scientific underpinning of a risk regulatory measure. This duty has been subsequently confirmed in *Pfizer*<sup>93</sup> and also in *Olivieri*<sup>94</sup>, where the Court derived such a duty directly from the Treaty-enshrined obligation to pursue a high level of human health protection<sup>95</sup>.

As a result, risk assessment must be based on all the available scientific knowledge and undertaken in an independent, objective, transparent, comprehensive and up-to-date manner. All of these requirements have an impact on the composition and functioning of expert committees and on risk assessments procedures, and their compliance is subject to judicial review.

These risk assessment guidelines, having being partly codified by secondary law, illustrate the way in which scientific evaluation is performed today.

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<sup>90</sup> Case 54/85 *Mirepoix* [1986] ECR 1067, paragraph 10.

<sup>91</sup> Case 54/85 *Mirepoix* [1986] ECR 1067.

<sup>92</sup> *Ibidem*, paragraph 16.

<sup>93</sup> Case T-13/99 *Pfizer Animal Health v. Council*, 2002 ECR II-3305, paragraph 158.

<sup>94</sup> T-326/99, *Nancy Fern Olivieri* ECR [2003] p. II-6053.

<sup>95</sup> *Ibidem*, paragraph 68, which reads: “That provision implies that the Community institutions must ensure that their decisions are taken in the light of the *best* scientific information available and that they are based on the *most recent results* of international research”.

Finally, the link between this duty and risk management has been underlined in *Agrarproduktion Staebelow*, where the ECJ held that,

“[w]hen new elements change the perception of a risk or show that that risk can be contained by less restrictive measures than the existing measures, it is for the institutions and in particular the Commission, which has the power of legislative initiative, to bring about an amendment to the rules in the light of the new information”<sup>96</sup>.

### **III.5 Proceduralising risk assessment: RA as a “procedural guarantee”**

The Courts are showing their readiness to ensure adherence to these highly detailed procedural rules concerning the modalities in which risk assessment should be conducted within the different sectoral areas. This is because, according to Community courts, the integration of scientific advice into the regulatory decision-making process gives rise, at both national and Community levels, to a delegation of legal responsibilities which needs to be compensated by appropriate procedural guarantees.

At least this seems to be the message sent by the Court in *Technische Universität München*<sup>97</sup>, a case concerning the grant of a customs exemption for a scientific instrument imported into the Community under an existing preferential regime for the importation of educational, scientific and cultural materials. Called upon to review the validity of a Commission’s decision denying the duty exemption to a scanning electron microscope, the ECJ recognised that “since an administrative procedure entailing complex technical evaluations is involved, the Commission must have a power of appraisal in order to be able to fulfil its tasks”. Yet, it immediately added that,

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<sup>96</sup> Case C-504/04 *Agrarproduktion Staebelow* [2006] ECR I-679, paragraph 40. To know more on this judgment, see S. Mahieu, *Consommation et alimentation* (1er janvier 2006 – 30 septembre 2007), *Journal de droit européen* (2008), 20, 26.

<sup>97</sup> Case C-269/90 *Technische Universität München* [1991] ECR I-5469.

“[h]owever, where the Community institutions have such a power of appraisal, respect for the rights guaranteed by the Community legal order in administrative procedures is of even more fundamental importance. Those guarantees include, in particular, the duty of the competent institution *to examine carefully and impartially all the relevant aspects* of the individual case, the right of the person concerned to make his views known and to have an adequately reasoned decision. Only in this way can the Court verify whether the factual and legal elements upon which the exercise of the power of appraisal depends were present”<sup>98</sup>.

In other words, if the Community institutions have been granted the power to carry out, by relying on their experts' advice, and technical evaluations, respect for the right of individuals is to be ensured by the duty of the competent authorities to examine carefully and impartially *all the relevant aspects* of the individual case.

The Court, in *Pfizer*, extended this case-law to risk regulation, by holding that,

“[...] a *scientific risk assessment* carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an *important procedural guarantee* whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures”.

It is in the light of the above principles that EU courts examine whether the risk assessments carried out by Community institutions are vitiated by errors alleged by the applicant.

An remarkable illustration of this case-law may be found in the recent *Paraquat*<sup>99</sup> case, concerning the assessment of one of the most commonly used herbicides in the world within the framework of the authorisation procedure for plant-protection products, as laid down by the relevant regulations<sup>100</sup>. This case was triggered by a challenge brought by Sweden against the

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<sup>98</sup> Ibidem, paragraph 14.

<sup>99</sup> Case T-229/04, Sweden v Commission [2007] ECR II-2437.

<sup>100</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1) and Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8 (2) of Council Directive 91/414/EEC (OJ 1992 L 366, p. 10).

Commission's decision to authorise paraquat as an active substance to be used as a herbicide. Sweden alleged *inter alia* procedural irregularities in the assessment of this substance particularly in regard to the Commission's conclusion according to which "there is no indication that paraquat is neurotoxic"<sup>101</sup>.

The CFI, showing its willingness to ensure procedural adherence by Community institutions to the highly detailed assessment of plant-protection products as laid down by the relevant regulations, found the Commission's assessment procedure which led to that statement in breach of the procedural requirements laid down by the relevant regulation<sup>102</sup>.

Indeed, although there were indications of a possible link between exposure to paraquat and Parkinson's disease, the rapporteur Member State's examination of the dossier submitted by the notifier (Syngenta) did

"contain no assessment of the literature concerning possible links between paraquat and Parkinson's disease"<sup>103</sup>.

On this basis, it concluded that the claim made in the Commission's report that there is no indication that paraquat is neurotoxic stemmed from a consideration of the dossier which does not satisfy the required procedural requirements<sup>104</sup>.

### **III.6 Diverging Scientific opinions: the lack of a supremacy doctrine of EU scientific evidence**

Once the risk assessment duty was established as a procedural requirement applicable to both Member States and EC institutions, EU courts were soon faced with situations where the outcome of scientific studies conducted at EU level conflicted with, or merely diverged from, the results of national scientific opinions. Although the Courts have consistently held that EU

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<sup>101</sup> Case T-229/04, Sweden v Commission, paragraph 103.

<sup>102</sup> Ibidem, paragraph 110.

<sup>103</sup> Case T-229/04, Sweden v Commission [2007] ECR 2437, paragraph 108.

<sup>104</sup> Ibidem, paragraph 110.

scientific opinions “do not have binding force”<sup>105</sup>, they had not determined whether, in case of conflict with national sources of scientific advice, they might prevail over the latter by virtue of a supremacy doctrine of EU scientific advice. Lacking clear rules of (scientific) conflict in Community risk regulation, the solution elaborated by the courts, by playing the role of a polar star for the EU legislator, was subsequently codified when the legislator eventually stepped in<sup>106</sup>. The ECJ was first confronted with the controversial issue of diverging scientific opinions, when France<sup>107</sup>, in the aftermath to the BSE crisis<sup>108</sup>, refused to accept British beef even after the Community had re-authorised exports in July 1999<sup>109</sup>. By relying on the scientific opinion of the newly-established *Agence française de sécurité sanitaire des aliments* (French Food Safety Agency, hereinafter the AFSSA), France did not lift the embargo on British beef in contravention of EU scientific data, and the Commission brought France before the ECJ, claiming a violation of EC law<sup>110</sup>. The Commission maintained that

“[a] Member State cannot, by relying on the scientific opinion of a national body, substitute its own assessment of the risks for that carried out by the Commission in accordance with its powers”<sup>111</sup>.

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<sup>105</sup> Case 247/84 Motte [1985] ECR 3887, paragraph 20, where the Court said that Member States must “take into account the results of international scientific research”, but it also stated that “it must be emphasised that the Opinions of the Committee do not have binding force”.

<sup>106</sup> See, e.g., Article 30 of the general food regulation.

<sup>107</sup> Case C-1/00, *Commission v France* [2001] ECR I-9989. For a review of this judgement, see A. Alemanno, Contentieux, Arrêt “Commission /France”, *Revue du droit de l’Union Européenne*, 1/2002, pp. 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, *European & International Law* (2004).

<sup>108</sup> For background information and a detailed description of the situation leading to the case, see see A. Alemanno, *Food Safety and the Single European Market*, in D. Vogel and C. Ansell (eds.), *What’s the Beef? The Contested Governance of European Food Safety*, MIT Press, 2006, at 237-258; E. Vos, *EU Food Safety Regulation in the Aftermath of the BSE Crisis*, 23 *Journal of Consumer Policy* 233 (2000), p. 227-255 (2000); 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.

<sup>109</sup> Commission decision 98/256/EC O.J. L 113, pp. 32-43.

<sup>110</sup> *Ibidem*.

<sup>111</sup> Case C-1/00, *Commission v France* [2001] ECR I-9989, paragraph 88.

The Court, by rejecting the French defence on procedural grounds (it could not challenge the legality of Commission's re-authorisation in an infringement proceeding), showed itself reluctant to endorse the hierarchical approach – as suggested by the Commission – vis-à-vis the different sources of scientific advice available in Europe. Instead of proclaiming “some kind of supremacy doctrine in the field of ‘science’”<sup>112</sup>, the ECJ condemned France for not having lifted the embargo, as requested by EC law.

Additionally however, the Court partly justified France's behaviour by recognizing that traceability of UK Beef, essential up to the point of sale in order to enable a consignment not fulfilling EC law requirements to be recalled, was not guaranteed at the time of the contested decision to lift 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 local risk assessors, EU courts are called upon to perform the difficult task of reconciling the conflicting visions by examining the value of domestic measures to the local population as against the damage to the Community (free movement) interest. In so doing, they rely on the authority of scientific expertise as yardstick for the assessment of the reasonableness of the national measures. As has been said, this approach “condenses” local differences without providing a single, objective standard for ‘safety enabling economies of scale and trade liberalization across the Union’<sup>113</sup>.

An early expression of such an approach may be found as early as in *Commission v Germany*<sup>114</sup>, involving a French eye lotion which Germany classified as a medicine. Here, former AG Van Gerven suggested in his opinion that,

“[i]f the Commission wishes to contest the data furnished by the Member States, it must do so on the basis of equally reliable data”<sup>115</sup>.

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<sup>112</sup> As claimed by 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. Journal of European Law* 1 (2001), p. 8.

<sup>113</sup> Chalmers, *supra* note 1.

<sup>114</sup> Case C-290/90, *Commission v Germany* [1992] ECR I-3317.



In other words, EC institutions cannot rely on the supposedly inherent superiority of their science advice over that of national origin.

Another interesting rejection of a hierarchical order between national, transnational and infranational scientific sources may be found in the framework of the first controversy that was fought under Article 95(4) EC<sup>116</sup>. Under this provision, Member States are allowed to derogate from a harmonisation measure, adopted in accordance with the procedure laid down in paragraph 1 of the same Article, in specific circumstances<sup>117</sup>. In *France v Commission*<sup>118</sup>, France sought the annulment of a Commission decision authorising the adoption by Germany of rules concerning the prohibition of pentachlorophenol (“PCP”) which were stricter than the corresponding Community harmonisation measures<sup>119</sup>. Called upon to review the legality of the Commission decision, the ECJ first recalled that to be valid this derogating measure had to fulfil the conditions provided for by Article 95(4) and that it was competent to review their compliance<sup>120</sup>. In scrutinising the respect of the procedure leading up to the decision at issue, the Court found that the contested decision was in breach of the requirements of Article 190 (current Article 253) which imposes on EU institutions the obligation to “state the reasons on which” their acts are based<sup>121</sup>. It reached this conclusion after holding that: “the Commission confined itself to describing in general terms the content and aim of the German rules and to stating that those

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<sup>115</sup> Ibidem, paragraph 5.

<sup>116</sup> For an overview on the safeguard clauses of Article 95 EC and the related interpretative problems, see, e.g., 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 intérêts nationaux dignes de protection, *Revue trimestrielle de droit européen*, 38, 2002, 63; P. Oliver, Free Movement of Goods in the European Community, 2003, p. 466; R. Verheyen, The Environmental Guarantee in European Law and the New Article 95 EC in practice – A Critique, *RECIEL*, 1/2000, pp. 180-187; H. G. Sevenster, The Environmental Guarantee after Amsterdam: Does the Emperor have New Clothes?, *Yearbook of European Environmental Law*, 2000, vol. I, pp. 236 ss. 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 judgment, see A. Alemanno, Case C-3/00, [2003] *Denmark v. Commission*, in *Revue du Droit de l'Union Européenne*, 02/03.

<sup>117</sup> The insertion of this derogation must be seen as a "counterweight" to offset the relinquishment of the principle of unanimity with regard to the adoption of measures necessary for the creation and operation of the internal market, in the cases provided for in Article 100A (current Article 95). See opinion of AG Tesouro delivered on 26 January 1994, *French Republic v Commission*, [1994] ECR I-1829.

<sup>118</sup> Case C-41/93, *French Republic v Commission*, ECR [1994] I-1829.

<sup>119</sup> Directive 91/173/EEC amending for the ninth time Directive 76/769/EEC concerning PCP. Germany, together with other three Member States, had voted against the adoption of this directive, as it intended to continue to apply the national provisions relating to PCP.

<sup>120</sup> *French Republic v Commission*, supra note 117, paragraphs 23-24.

<sup>121</sup> Ibidem, paragraph 37.

rules were compatible with Article 100a(4), without explaining the reasons of fact and law on account of which the Commission considered that all the conditions contained in Article 100a(4) were to be regarded as fulfilled in the case in point”<sup>122</sup>. The annulment of this decision led the Commission to consult a scientist from a then non-Member State, Sweden, in order to scientifically substantiate the previously authorised German safeguard measure. By relying on this scientific report, the Commission finally showed itself able to defend the stricter German approach to PCP and, surprisingly, declared its intention to reassess the adequacy of the Commission directive on the basis of the further research.

Once more the Court has shown (and the outcome of this case proves that it was actually successful) that Community risk regulation must be based on a comprehensive risk assessment and this regardless of the origin of the scientific source (even if of non-EU origin!).

As it has been stated, the outcome of this controversy “only underlines what it is already obvious: the validity of scientific findings cannot depend on the boundary of the legal system which integrates these findings into law”<sup>123</sup>. Thus, European courts did not only reject the introduction of a supremacy doctrine of European science over national scientific sources, but they also claimed that European science does not necessarily need to be European-made to be able to inform risk regulatory decisions.

#### **IV. Risk Management and European Courts**

The judicial acceptance of the universally known risk analysis model has led the European courts not only to introduce and define a duty of risk assessment, on both national and EC legislators, but it has also obliged them to address the challenge of transforming the outcome of scientific advice into clearly defined risk management policies.

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<sup>122</sup> Ibidem, paragraph 36.

<sup>123</sup> Joerges, supra note 3, p. 308.

Although some critiques have been raised, *in tempore non suspecto*, to call into question the ability of the courts in coherently building up “the kind of infrastructures transnational risk management practices require”<sup>124</sup>, this analysis will illustrate that there exists today a set of judicially-made principles guiding risk managers when they interpret the results of scientific expertise and translate them into risk management decisions.

#### **IV.1 Framing risk management: degree of risk and decision-making**

Risk management may be defined as the process of weighing policy alternatives in the light of the results of risk assessment and, if necessary, selecting and implementing appropriate control options, including regulatory measures<sup>125</sup>.

Having verified the existence and the nature of the risk at stake, the competent authorities are supposed to decide whether and how to act. Before doing that though, both national and EC Member States are called upon to manage the health risk by establishing the risk threshold acceptable for the whole of society.

##### *(a) Degree of Risk deemed acceptable for society*

Since the 1980s, EU Courts have consistently held that it is for the Community organs<sup>126</sup>, or for the national legislators (provided the EC legislator has not yet stepped in)<sup>127</sup>, to lay down the level of protection which they consider appropriate for society.

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<sup>124</sup> Joerges, *supra* note 3, p. 320.

<sup>125</sup> 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>.

<sup>126</sup> See, *inter alia*, Case 174/82, Sandoz BV [1983] ECR 2445, paragraph 16; Case C-13/91 and C-113/91, Debus [1992] ECR 3617, paragraph 13; Case C-293/94 Brandsma [1996] ECR I-3159, paragraph 11, and Case C-400/96 Harpegnies [1998] ECR I-5121, paragraph 33; Case T-13/99 Pfizer Animal Health v. Council, 2002 ECR II-3305, paragraph 150 and Case C-24/00 Commission v France [2004] ECR I-1277, paragraphs 49 and 68.

<sup>127</sup> According to established case law, it is for the Member States, in the absence of harmonization at Community level, to decide on the level of protection which they wish to accord to the protection of human health, whilst taking account of the requirements of the free movement of goods within the Community. See in particular the judgments

It is by reference to that level of protection that they must then determine the level of risk, “i.e. the critical probability threshold for adverse effects on human health and for the seriousness of those possible effects”, which in their judgment is no longer acceptable for society and above which it is necessary, in the interests of protecting human health, to take preventive measures<sup>128</sup>. Thus, the Court held in *Bellio*, that

“a risk-management decision rests with each Contracting Party, which has a discretion as to the level of risk it considers appropriate”<sup>129</sup>.

The level of risk deemed unacceptable will depend on the assessment made by the competent public authority of the particular circumstances of each individual case. In that regard, the Courts have recognized that the authorities may take account, *inter alia*, of:

- the severity of the impact on human health were the risk to occur, including the extent of possible adverse effects;
- the persistency or reversibility of those effects;
- the possibility of delayed effects of this damage; and
- the more or less concrete perception of the risk based on available scientific knowledge<sup>130</sup>.

Moreover, in so doing, EC institutions, unlike Member States, are under the Treaty obligation, as enshrined in Article 152(1) EC, to pursue a “high level of protection”<sup>131</sup>. However, as decided in *Safety High Tech*, in order to conform to this duty, the chosen level must not necessarily be the

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in Case 178/84 *Commission v Germany* [1987] ECR 1227; 266/87, paragraph 22; Case 205/89 *Commission v Greece* [1991] ECR 1361, paragraph 8 and *Toolex*, paragraph 45. Once agreed on common rules, Member States are still free to choose for a stricter level of protection but only within the limits set in Article 95 (4) and (5).

<sup>128</sup> Case T-13/99 *Pfizer Animal Health v. Council*, [2002] ECR II-3305, paragraph 153.

<sup>129</sup> Case C-286/02 *Bellio F.lli Srl v Prefettura di Treviso*, [2004] ECR, paragraph 58.

<sup>130</sup> Case T-70/99 *Alpharma v Council* [2002] ECR II-3495, paragraph 166.

<sup>131</sup> Article 95, paragraph 3, EC. In fact, as illustrated above, in the absence of Community harmonisation with regard to a certain product, Member States are free, at least in principle, to choose the level of protection of public health they deem appropriate to ensure within their own territory. This freedom is, however, restricted by Article 28 EC governing the free movement of goods within the EC.

highest possible level from a technical point of view<sup>132</sup>. In any event, in determining the degree of risk, decision-makers are banned from relying on a purely hypothetical consideration of the risk focusing their decisions on a zero risk<sup>133</sup>.

Therefore, according to courts, the determination of the degree held to be unacceptable depends on the assessment by the responsible authorities of the particular circumstances of the individual case. An interesting illustration of this case-by-case analysis may be found in a string of cases dealing with nutrients. In these cases the ECJ was called upon to examine four infringement proceedings brought against Denmark<sup>134</sup>, France<sup>135</sup>, Italy<sup>136</sup> and the Netherlands<sup>137</sup>. In particular, the Commission contested, on the one hand, the Danish and Dutch practices entailing the systematic prohibition on marketing of foodstuffs fortified with certain nutrients which did not meet a nutritional need of the Danish and Dutch populations. On the other hand, the Commission challenged the French and Italian systems of prior approval for fortified foods lawfully produced and marketed in other Member States<sup>138</sup>. 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<sup>139</sup>.

In these cases, according to the ECJ, the object of the risk assessment to be carried out by the Member State was to appraise

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<sup>132</sup> Case C-284/95, *Safety High-Tech* [1998] ECR I-4301, paragraph 49, then confirmed in Case T-70/99 *Alpharma v Council* [2002] ECR II-3495, paragraph 166.

<sup>133</sup> Judgments in *Pfizer Animal Health v Council*, paragraphs 145 and 146, and *Alpharma v Council*, paragraphs 157-159, 165.

<sup>134</sup> Case 192/01 *Commission v Denmark* [2003] ECR I-9693.

<sup>135</sup> Case C-24/00 *Commission v France* [2004] ECR I-1277.

<sup>136</sup> Case C-270/02 *Commission v Italy* [2004] ECR I-1559.

<sup>137</sup> Case C-41/02 *Commission v Netherlands* [2004] ECR I-11375.

<sup>138</sup> 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, p. 118.

<sup>139</sup> This legislative vacuum has been subsequently filled up by Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods OJ L 404.

“the degree of probability of harmful effects on human health from the addition of certain nutrients to foodstuffs and the seriousness of those potential effects”<sup>140</sup>.

Competent authorities’ discretion is not limited to the evaluation of the significance of a risk, which leads to a determination of the acceptable level of protection, but it also extends to the choice of the action to be taken to achieve the desired threshold of protection.

*(b) The duty to take into account scientific advice*

As stated by the CFI, “scientific risk assessment must also enable the competent authority to decide, in relation to risk management, *which measures* appear to it to be *appropriate* and *necessary* to prevent the risk from materialising”<sup>141</sup>.

Offering the principal basis upon which to rely for the adoption of the political decision on the government of risk, the results of risk assessment must be taken into account by the risk managers. The *Danish food additive* case illustrates this<sup>142</sup>. After the Danish authorities notified to the Commission national provisions on the use of sulphites, nitrites and nitrates with a view to maintaining them by way of derogation from the provisions of Council Directive 95/2 on food additives, the Commission found them, though “aimed at protecting public health”, “excessive in relation to this aim” in a decision based on Article 95(6) of the EC Treaty<sup>143</sup>. The Danish Government obtained the annulment of this decision before the Court of Justice in so far as the Commission rejected the national provisions relating to the use of nitrites and nitrates in foodstuffs. The Commission had indeed failed to take into account a critical opinion of the Scientific Committee for Food relating to the use of those additives<sup>144</sup>. In particular, the

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<sup>140</sup> Case 192/01 *Commission v Denmark* [2003] ECR I-9693, paragraph 48; and *Commission v France*, paragraph 55.

<sup>141</sup> Case T-13/99 *Pfizer Animal Health v. Council*, [2002] ECR II-3305, paragraph 163.

<sup>142</sup> Case C-3/00 *Denmark v. Commission* [2003] ECR 2643.

<sup>143</sup> Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners (OJ 1995 L 61, p. 1).

<sup>144</sup> This does not mean that the Community institution is automatically bound by an opinion delivered by an expert committee. Since the members of such committees have neither democratic legitimacy nor political responsibilities, their scientific legitimacy cannot be a sufficient basis for the exercise of public authority. But the Community courts will verify whether the expert opinion has been duly taken into account by the Community institution (Case T-13/99 *Pfizer v. Council* [2002] ECR II-3305, paragraphs 199-201).

Commission did not take into account the fact that the opinion called into question the maximum amounts of nitrites set out in the Community directive, in assessing the Danish justification concerning the use of nitrites and nitrates.

A similar conclusion was reached in *Lilly*<sup>145</sup>, where the refusal by the Commission to include a certain substance in one of the annexes despite the favourable opinion issued by the Committee on Veterinary Medicinal Products was found illegal. However, it is appropriate to point out that, under the provisions which applied in that case, consultation with the competent scientific committee within a period prescribed by those provisions was a pre-requisite for adoption of a Commission proposal.

Thus, the courts have imposed on risk managers not only the duty to consult scientific experts before regulating risk, but also to “duly” take into account their advice.

This duty has recently been confirmed by the CFI, in an interim order delivered in the currently pending case *France v. Commission*<sup>146</sup>. Following an application for interim measure introduced by France, the President of the CFI decided to suspend the relevant provision of a Commission regulation introducing less restrictive measures of surveillance and eradication in relation to certain spongiform encephalopathies, as compared with those laid down in Regulation (EC) No 999/2002<sup>147</sup>. According to the plaintiff the new scientific elements relied upon by the Commission to justify the introduction of these less restrictive measures ignore the scientific uncertainties which continue to surround the risk of transmission to human beings of transmissible spongiform encephalopathies (TSE) other than bovine spongiform encephalopathy (BSE). As the existence of such uncertainties clearly stem from the available scientific opinions, such as that carried out by EFSA, France claims a breach, at the risk assessment stage, of the precautionary principle by the Commission. The Court, after reminding that “in the context of

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<sup>145</sup> T-120/96 *Lilly Industries v Commission* [1998] ECR II-2571, paragraph 83.

<sup>146</sup> Case T-257/07 R, *France/Commission* [2007] II-4153.

<sup>147</sup> Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, OJ L 147, p. 1.

the application of the precautionary principle, a risk assessment was a prerequisite for the adoption of the contested provisions”<sup>148</sup>, stated that

“ [...] the weight of the applicant’s claim regarding the error committed by the Commission in the risk assessment must be evaluated principally in the light of the opinion of EFSA and its Scientific Panel”<sup>149</sup>.

Against this backdrop, it went on by indicating that

“[...] recital 9 in the preamble to [the contested Regulation] expressly refers to the conclusions of the [EFSA] opinion, but conceals a part of it which seems to call in question the Commission’s dual premise on which the contested provisions are based, namely, that TSEs other than BSE cannot be transmitted to humans and that the discriminatory tests are reliable. [...] It should be pointed out that the Commission, in [the contested Regulation], not only expurgated without justification part of EFSA’s conclusions but also reproduced incorrectly that part of the conclusions which it retained.”<sup>150</sup>

It is by relying on this factual element that the Court concluded that

“[I]n those circumstances, the claim that the Commission infringed the precautionary principle by committing an error in the risk management requires an in-depth examination which may be carried out only by the court adjudicating on the merits”<sup>151</sup>.

It is on this basis that it awarded the interim measures seek by France.

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<sup>148</sup> Case T-257/07 R, France/Commission [2007] II-4153, paragraph 70.

<sup>149</sup> Ibidem, paragraph 71.

<sup>150</sup> Ibidem, paragraphs 72 and 75.

<sup>151</sup> Ibidem, paragraph 86.



*(c) Departing from the scientific outcome*

Once established a duty to conduct a risk assessment and to take its outcome into account, the question left to the courts was: to what extent may risk managers depart from that advice? May, for instance, public authorities prohibit the marketing of a product notwithstanding a scientific study declaring its safety?

This scenario was the central issue in *Pfizer*. The Community institutions concluded that the use of an antibiotic, called virginiamycin, as an additive in feedingstuffs, constituted a risk to human health despite the fact that the opinion of the Scientific Committee for Animal Nutrition (SCAN) concluded that virginiamycin did not entail an immediate risk to human health in Denmark<sup>152</sup>. There was a fear that such additives could foster the development of antibiotics resistance in the microbioflora of animals, and that such a resistance could be transferred to humans. Pfizer, the only producer in the world of virginiamycin, brought an action seeking the annulment of Regulation 2821/98, by which the authorisation for use of Virginiamycin as growth promoter in animal feedstuff was withdrawn<sup>153</sup>. Against this backdrop, the CFI had first to determine whether, under the relevant legislation, the Commission was bound to accept the conclusions reached in a SCAN opinion requested by it. On this point, the Court held that “the role played by a committee of experts, such as SCAN, in a procedure designed to culminate in a decision or a legislative measure, is restricted, as regards the answer to the questions which the competent institution has asked it, to providing a reasoned analysis of the relevant facts of the case in the light of current knowledge about the subject, in order to provide the institution with

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<sup>152</sup> In its opinion, the Scientific Committee for Animal Nutrition concluded that “the use of virginiamycin as a growth promoter did not constitute a real immediate risk to public health in Denmark since Denmark had provided no new evidence to substantiate the transfer of streptogramin resistance from organisms of animal origin to those resident in the human digestive tract, which would compromise the future use of human medicinal products”. See Case T-13/99 *Pfizer Animal Health v. Council*, 2002 ECR II-3305, paragraph 193.

<sup>153</sup> The use of additives in feedstuffs has been regulated at the Community level since 1970 (Council directive 70/524/ECC concerning additives in feedstuffs, 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 feedstuffs, OJ L235/9). This regulatory regime allows Member States to temporarily 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 the 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.

the factual knowledge which will enable it to make an informed decision”<sup>154</sup>. However, it concluded that “[T]o the extent to which the Community institution opts to disregard the opinion, it must provide *specific reasons for its findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding the latter*”<sup>155</sup>. Having established the possibility of departing from scientific evidence, the Court outlined the modalities to be followed when exercising it:

- “the statement of reasons must be of a *scientific level at least commensurate with that of the opinion* in question:
  - o [i]n such a case, the institution may take as its basis either a *supplementary opinion* from the same committee of experts or
  - o *other evidence, whose probative value is at least commensurate with that of the opinion* concerned.
- [i]n the event that the Community institution disregards only part of the opinion, it may also avail itself of those parts of the scientific reasoning which it does not dispute”<sup>156</sup>.

Although Courts have recognised the possibility to depart from the scientific opinion obtained by the competent expert authorities, they have significantly limited such a departure, by requiring risk managers to justify their derogating measures with evidence having a probative value commensurate with that of the opinion in question.

This approach has been subsequently codified in several sectoral risk regulations<sup>157</sup>. For instance, directive 1829/2003 governing the marketing of GMO foods within the EC, provides that, should the Commission decision not be in accordance with an EFSA opinion, it must “provide an

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<sup>154</sup> Case T-13/99 Pfizer Animal Health v. Council, 2002 ECR II-3305, paragraph 197.

<sup>155</sup> Ibidem.

<sup>156</sup> Pfizer, paragraph 199.

<sup>157</sup> See, for instance, Art. 17, par. 1, of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods OJ L 404, p. 9; Art. 10, par. 1, and Art. 35, par. 1, of Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, p. 1 as well as Article 11, par.2., Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ, L 338, p. 4.

explanation for the differences”<sup>158</sup>. Similarly, the third subparagraph of Article 10(1) of Regulation 2309/93, on the authorisation of medicinal products, enables the Commission draft decision on the marketing authorisation to depart from the terms of the scientific opinion “provided that the Commission gives a detailed explanation of the reasons for the differences”<sup>159</sup>.

This reflects the efforts undertaken by the Courts to use science as the main frame of reference to ensure that risk management principles adhere to non-national standards. As a result, EC institutions are allowed to depart from the results of risk assessment only in those exceptional circumstances where equivalent scientific evidence can be found and a justification for relying on it is provided<sup>160</sup>.

*(d) The role of other (non-scientific) factors*

The *Pfizer* judgment has also been the occasion for the CFI to lay down another important principle guiding risk managers when regulating risk.

While it is true that scientific advice must be obtained and duly taken into account by the decision-makers, it is equally true that:

“scientific legitimacy is not a sufficient basis for the exercise of public authority”<sup>161</sup>.

According to the CFI, this is because “[w]hilst the Commission's exercise of public authority is rendered legitimate, pursuant to Article 155 of the EC Treaty (now Article 211 EC), by the

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<sup>158</sup> See Article 7 of Regulation 1829/2003.

<sup>159</sup> 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 (OJ 1993 L 214, p. 1).

<sup>160</sup> To know more on the “indirect legal effects” of EFSA’s scientific opinions and their judicial review, see Alemanno, EFSA at Five, *European Food and Feed Law Review*, 1/2008 and also Alemanno, *The European Food Safety Authority before the European Courts, Some reflections on the judicial review of EFSA scientific opinions and administrative acts*, *European Food and Feed Law Review*, 5/2008.

<sup>161</sup> Case T-13/99 *Pfizer Animal Health v. Council*, 2002 ECR II-3305, paragraph 201. This has been echoed in the general food regulation where it may be read “it is recognized that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based”. See Recital (19) of this Regulation.

European Parliament's political control, the members of SCAN, although they have scientific legitimacy, have neither democratic legitimacy nor political responsibilities”<sup>162</sup>.

Thus, by relying on grounds of principle relating to the political responsibilities and democratic legitimacy of Community institutions, the Court opens up the risk management phase to other (non-scientific) factors.

This Community approach to risk management has been effectively described as a system in which “scientific knowledge is authoritative, but not exclusively so”<sup>163</sup>.

One of the best illustrations of this approach can be found in *CEVA*<sup>164</sup>. Here, after disregarding two consecutive opinions issued by the Committee for Veterinary Medicinal Products (CVMP), which advised the qualification of a veterinary progesterone product as one for which no maximum residue limit should be established, the Commission failed to adopt the necessary measures for enabling that progesterone to be marketed. CEVA, a pharmaceutical company marketing a veterinary medicinal product containing the progesterone hormone at stake, brought an action for failure to act and damages against the Commission.

In its defence, the Commission argued that: “a high level of human health protection may be achieved only if assessments made by committees such as the CVMP are balanced by the competent institutions against all the scientific information available, taking into account scientific uncertainty, consumers' concerns, ethical or moral considerations or other legitimate factors and the precautionary principle”<sup>165</sup>.

Though the CFI, in its ruling, condemned the Commission for failure to act and vindicated CEVA's claim for damages, the Court set aside this judgment. It came to this conclusion after having judged that “[r]egard being had to the extent of the discretion available to the

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<sup>162</sup> Case T-13/99 Pfizer Animal Health v. Council, 2002 ECR II-3305, paragraph 201.

<sup>163</sup> G. Skogstad, *The WTO and Food Safety Regulatory Policy Innovation in the European Union*, in 39 *Journal of Common Market Studies* 485, 490 (2001).

<sup>164</sup> Cases T-344/00 and T-345/00, *CEVA Santé Animale SA* [2003] ECR II-229, and Case C-198/03 P, *Commission v. Ceva/Pfizer*, [2005] ECR I-6357.

<sup>165</sup> Cases T-344/00 and T-345/00, *CEVA*, paragraph 66.

Commission and to all of the factual circumstances, it does not appear that, in taking that decision on the basis of public-health considerations, the Commission disregarded in a clear and serious manner the limits on its discretion”<sup>166</sup>.

In so doing, the Court has explicitly upheld the competent authorities’ right to balance different factors when taking a risk management decision<sup>167</sup>. These relevant factors for the health protection of consumers may consist, for instance, of societal, economic, traditional, ethical and environmental factors<sup>168</sup>.

The perceived need to consider non science-based factors within the decision-making process characterizes the European approach to risk analysis and differentiates it greatly from the one adopted by the U.S. regulatory agencies and by the WTO/SPS legal frameworks<sup>169</sup>. Unless differently provided<sup>170</sup>, EU risk managers are able to rely also on non-scientific considerations when taking a decision governing risk.

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<sup>166</sup> Case C-198/03 P, *Commission v. Ceva/Pfizer*, [2005] ECR 6357, paragraph 89. In particular, the Court observed that the Commission’s adoption of draft measures establishing a provisional MRL on the basis of Article 4 of Regulation 2377/90 claimed by the parties would have been possible only “provided that there are no grounds for supposing that residues of the substance concerned at the level proposed present a hazard for the health of the consumer”. According to the Court, this condition was “not satisfied in a situation of scientific uncertainty and disquiet of public health”. See *Ibidem*, paragraph 91.

<sup>167</sup> For an embryonic recognition of the multidimensional approach to risk management, see order in Case C-180/96 R *United Kingdom v Commission* [1996] ECR I-3903, paragraph 89 (“the Court would still have to balance the applicant’s interest in a suspension of the ban on exports of bovine animals, meat and derivatives against the interest of the other parties in having that ban maintained”) and also the judgment in that case (Case C-180/96 [1998] ECR I-2265) and Case T-199/96 *Bergaderm and Goupil v Commission* [1998] ECR II-2805.

<sup>168</sup> An example of “other factors” that may be taken into account in risk management is provided for in the list contained in the Preamble of the general food regulation. Although this list seems slightly narrower than the one contained within the White Paper on Food Safety (COM (99) 719, paragraph 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”, it represents a good example of relevant “other factors”.

<sup>169</sup> To know more on this point, see Alemanno, *Trade in Food – Regulatory and Judicial Approaches in the EC and the WTO*, Cameron May, London, 2007, p. 395 et seq.

<sup>170</sup> The pharmaceutical sector represents an exception as its main regulation (Regulation 2309/93) rules out the possibility that the Commission’s decision to grant a marketing authorisation be based on economic or other non scientific criteria. This decision “must be taken in the interest of public health, based on the objective scientific criteria of the quality, the safety and the efficacy of the medicinal product concerned”. See the third recital of the regulation.

The most direct consequences stemming from the adoption of such a European non-exclusively science-based approach to risk analysis can be found in the health scare related to the use of hormones to fatten cattle.

Indeed, the well-know *Hormones* dispute<sup>171</sup>, "one of the longest running trade disputes in the modern trading system"<sup>172</sup>, between the EC and the US exemplifies the impact which the EC analysis of risk may have, not only on its external trade relations, but also on its internal market dimension<sup>173</sup>. This dispute involved a complaint by the United States and Canada against an EC regulatory regime prohibiting the administration of growth hormones (such as estrogen, progesterone and testosterone) to cattle<sup>174</sup>. This prohibition not only addressed the use of these hormones domestically, but also banned the production and importation of meat derived from animals treated with non-therapeutic growth hormones. The concern was the potential for cancer in humans resulting from the consumption of hormone-treated beef. This regulatory regime 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

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<sup>171</sup> 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).

<sup>172</sup> A.O. Sykes, Domestic Regulation, Sovereignty and Scientific Evidence Requirements: A Pessimistic View, G. Bermann and P.C. Mavroidis (eds.), *Trade and Human Health and Safety*, Cambridge University Press, 2006, p. 260.

<sup>173</sup> On this dispute, notably on its genesis, see, e.g., 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, (2000) 8 *N.Y.U. Environmental Law Journal*, pp. 622 ss.; 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* p. 147 (1999) and R. Howse, Democracy, science and Free Trade: Risk Regulation on Trial at the WTO (2000) 98 *Mich.L.R.* 2329.

<sup>174</sup> See Council Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action (OJ L222 32-33); Council Directive 88/146/EEC prohibiting the use in livestock farming of certain substances having a hormonal action (OJ L70 16-18) and Council Directive 88/299/EEC on trade in animals treated with certain substances having a hormonal action and their meat, as referred to in Article 7 of Directive 88/146/EEC (JO L128 36-38). Other measures relevant to the dispute are contained in Directives 72/462/EEC, 81/602/EEC, 81/851/EEC, 81/852/EEC, 85/358/EEC, referenced in Directive 88/146/EEC; the decisions, control programme and derogations referred to in Article 6(2), Article 6(7) and Article 7, respectively, of Directive 88/146/EEC; and any amendments or modifications, including Directives 96/22/EC and 96/23/EC.

not only the US and Canadian reactions but also some internal resistance<sup>175</sup>. Member States were split over the decision: while France, Germany, Italy and the Netherlands supported the total prohibition, the UK and EIRE opposed it so strongly as to lead to the controversial legislation being brought before the European Court of Justice<sup>176</sup>.

The EC ban was motivated by a complex mix of political, social, economic and conflicting scientific factors that, as we have seen, may now formally enter into the risk management stage of regulation risk. Today we would probably define such a mix of different interests under the “collective preference” label launched by Pascal Lamy<sup>177</sup>.

## **IV.2 The general principles of risk management**

Having recognised the multidimensional nature of risk management, EU Courts have contributed to further guiding such activity by flashing out and framing a set of defined risk management principles that risk managers must follow when regulating risk. In particular, under the emerging EU risk regulation model, competent authorities, when called upon regulating risk, must also take into account:

- a) the precautionary principle;
- b) the principle of proportionality;
- c) the consistency precept;

Once a level of risk is determined which, by relying on the result of risk assessment as well as on “other factors”, in their judgment, is no longer acceptable for society, risk managers must, when

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<sup>175</sup> 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.

<sup>176</sup> Case C-180/96, United Kingdom v. Commission, [1998] ECR 3903, paragraph 93. 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.

<sup>177</sup> See Pascal Lamy, The Emergence of Collective Preferences in International Trade: Implications for Regulating Globalisation, 15 September 2004, available at [http://trade.ec.europa.eu/doclib/docs/2004/september/tradoc\\_118925.pdf](http://trade.ec.europa.eu/doclib/docs/2004/september/tradoc_118925.pdf)

necessary, decide “which measures appear to it to be appropriate and necessary” to govern the risk or prevent it from materialising<sup>178</sup>.

It is by reference to this choice (the choice whether and how to act), that this set of principles has been designed.

*(a) The precautionary principle: from scientific uncertainty to legal certainty*

Although expressed in a mere *obiter dictum*, the 1983 *Sandoz* judgment probably represents the first (judicial) recognition, at EC level, of the precautionary principle’s *raison d’être*: a decision-making tool allowing for public action even in the absence of conclusive scientific evidence<sup>179</sup>. Facing uncertainty relating to the daily intake of vitamins by citizens<sup>180</sup>, which had led the Netherlands to subject the marketing of enriched foodstuffs to prior authorisation, the Court has 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”<sup>181</sup>.

The follow-up of the emergence of such a risk management approach may be found in the *Heijn*<sup>182</sup> and *Mirepoix*<sup>183</sup> cases, where although there was no doubt as to the harmfulness of

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<sup>178</sup> Case T-13/99 Pfizer Animal Health v. Council, 2002 ECR II-3305, paragraph 163.

<sup>179</sup> Case 174/82, *Sandoz BV* [1983] ECR 2445. See also Opinion in Case C-192/01, *Commission v Denmark*, [2003] ECR I-9693, para 50 («this judgment seems to me to constitute an application of the precautionary principle before the fact») quoting Alemanno, *Le principe de precaution en droit communautaire: stratégie de gestion des risques ou risque d’atteinte au marché intérieur?*, *Revue du droit de l’Union européenne*, 4/2001 (“[f]or the first time, the Court would seem to have recognised, although in an obiter dictum which does not explicitly mention the precautionary principle, the possibility of Member States adopting measures in a situation of scientific uncertainty”).

<sup>180</sup> 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 regular diet over a longer period of time.

<sup>181</sup> Case 174/82, *Sandoz BV* [1983] ECR 2445, paragraph 16.

<sup>182</sup> Case 94/83 *Heijn* [1984] ECR 3263.

<sup>183</sup> Case 54/85 *Mirepoix* [1986] ECR 1067.



pesticide residues for the human organism, there was uncertainty with respect to the non-calculable intake quantity of such residues.

Yet, although the genesis of a precautionary approach in the health field dates back to the 1980s, it is only since 1992 that this principle, though limited to the environmental protection field, has been codified by Article 130r(2) of the Treaty<sup>184</sup>. Its scope has been subsequently widened by the interpretative activity of the ECJ so as to also apply to other domains of EC law, such as public health<sup>185</sup>.

While it was in the *BSE* line of cases that, even though not expressly mentioned as such<sup>186</sup>, the precautionary principle was first accepted by the EU courts, it was the EFTA Court that delivered a major judgment which has significantly contributed to the shaping of the precautionary principle, particularly when it is invoked by a Member State<sup>187</sup>.

At the origin of this judgment lies a Norwegian ban on the import and marketing of fortified corn flakes, which had been lawfully manufactured and marketed in other EEA States, motivated by an alleged (uncertain) risk of these products for the Norwegian population. The EFTA Surveillance Authority argued that the ban on imports of fortified products cannot be justified

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<sup>184</sup> For a reconstruction of the genesis and developments of the principle, see, e.g., J.L. da Cruz Vilaça, *The Precautionary Principle in EC Law*, 10 *European Public Law* 2, p. 402; A. Alemanno, *The Shaping of the Precautionary Principle by European Courts: From Scientific Uncertainty to Legal Certainty*, L. Cuocolo, L. Luparia (eds.), *Valori costituzionali e nuove politiche del diritto*, Halley, 2007 and P. Craig, *EU Administrative Law*, Oxford, p. 717-748.

<sup>185</sup> One of the latest references to the horizontal nature of the precautionary principle may be found in Case C-41/02, *Commission v Netherlands* [2004] ECR I-11375, paragraph 45, where it is said that: "It is clear from Article 130r of the EC Treaty (now, after amendment, Article 174 EC) that the protection of human health is one of the objectives of the Community policy on the environment, that that policy aims at a high level of protection and is to be based *inter alia* on the precautionary principle, and that the requirements of that policy must be integrated into the definition and implementation of other Community policies. In addition, it follows from the case-law of the Court that the precautionary principle may also apply in policy on the protection of human health which, according to Article 129 of the EC Treaty (now, after amendment, Article 152 EC) likewise aims at a high level of protection".

<sup>186</sup> The first explicit reference to the principle in a court ruling was made by the CFI in 2000 in *Bergaderm*, where the Court affirmed that "[...] the appellants dispute the references to the precautionary principle in paragraph 66 of the contested judgment". Case C-353/98 P *Laboratoires pharmaceutiques Bergaderm a.o. v. Commission* [2000] ECR I-5291, paragraph 52. For a previous reference to the principle, see the Opinion of Advocate General Gulmann in case C-405/92 *Mondiet* [1993] ECR I-6133, paragraph 28.

<sup>187</sup> EFTA Court of 5 April 2001, Case E-3/00 *Efta Surveillance Authority v Norway* [2001] EFTA Court Report 2000/2001, 73, at 30. For a comment of this case, see Alemanno, *Le principe de precaution ...*, supra note 14, pp. 947-50. Among the judgments of the EFTA Court dealing with the precautionary principle, see also the more recent E-4/04 *Pedichel AS v Directorate for Health and Social Affairs* [2006], not yet reported.

under Article 13 EEC (corresponding to Article 30 EC)<sup>188</sup>, because Norway has not substantiated its claim that the fortification in question constitutes a danger to public health.

After recognising that “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”, the Court developed the bare definition of the principle, finding its origin in the ECJ’s *Sandoz* case<sup>189</sup>, by holding that:

“This means that a *risk management* decision rests 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”<sup>190</sup>.

In making operational the original judicial endorsement of the idea behind the precautionary principle, the Court demonstrated its familiarity with the traditional structured risk analysis model despite the fact that such a framework had not yet been codified within the EC/EEA context<sup>191</sup>.

After qualifying the principle as a tool to rely upon in the risk management stage of regulating risk, the EFTA Court laid down the basis for invoking the precautionary principle within the EEE:

“[...] measures taken [...] must be based on scientific evidence; they must be proportionate; non-discriminatory, transparent and consistent with similar measures already taken”<sup>192</sup>.

This set of conditions governing the invocation of the precautionary principle has subsequently been confirmed and further developed by the case-law of the EU Courts<sup>193</sup> before being

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<sup>188</sup> Article 13 EEA, similarly to Article 30 EC, 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.

<sup>189</sup> Case 174/82, *Sandoz BV* [1983] ECR 2445, at 16-18.

<sup>190</sup> Case E-3/00 *Efta Surveillance Authority v Norway* [2001] EFTA Court Report 2000/2001, 73, p. 25.

<sup>191</sup> This has occurred following the adoption of the general food regulation.

<sup>192</sup> Case E-3/00 *Efta Surveillance Authority v Norway* [2001] EFTA Court Report 2000/2001, 73, p. 26.

eventually codified, for the first time, in the Community legal order in Article 7 of the general food regulation<sup>194</sup>.

In particular, in relation to the scientific prerequisite triggering the application of the precautionary principle, the EFTA Court added that while “[a] purely hypothetical or academic consideration will not suffice”<sup>195</sup>, there is a requirement for “a comprehensive evaluation of the risk to health based on the most recent scientific information”<sup>196</sup>.

However, as indicated in *Alpharma*,

“unless the precautionary principle is to be rendered nugatory, the fact that it is impossible to carry out a full scientific risk assessment does not prevent the competent public authority from taking preventive measures, at very short notice if necessary, when such measures appear essential given the level of risk to human health which the authority has deemed unacceptable for society”<sup>197</sup>.

As a result, “in such a situation”, the competent public authority must therefore “weigh up its obligations and decide either to wait until the results of more detailed scientific research become available or to act on the basis of the scientific information available. Where measures for the protection of human health are concerned, the outcome of that balancing exercise will depend, account being taken of the particular circumstances of each individual case, on the level of risk which the authority deems unacceptable for society”<sup>198</sup>.

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<sup>193</sup> Case C-192/01 *Commission v Denmark* [2003] ECR 9693; Case C-24/00 *Commission v France* [2004] ECR I-1277, paragraph 52 and C-41/02 *Commission v Denmark* [2004] ECR I-11375, paragraph 46.

<sup>194</sup> It is interesting to observe that the language employed by the EU Courts, and today codified within the general food law regulation, to frame the invocation of the precautionary principle is largely resonant of that of the Appellate Body in the *Hormones* case. As has been noted, 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 margin of manoeuvre may be easily bypassed by way of judicial interpretation. 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

<sup>195</sup> Case E-3/00 *Efta Surveillance Authority v Norway* [2001] EFTA Court Report 2000/2001, 73, p. 29. See also and Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, paragraph 106.

<sup>196</sup> *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, paragraph 199; Case E-3/00 *Efta Surveillance Authority v Norway* [2001] EFTA Court Report 2000/2001, 73, p. 30.

<sup>197</sup> Case T-70/99 *Alpharma v Council* [2002] ECR II-3495, paragraph 173.

<sup>198</sup> *Ibidem*, paragraph 174.

In other words, at the risk management stage, decision-makers, by considering the outcome of scientific assessment in the light of the level of risk deemed unacceptable for society, have to decide whether and how to act.

After *Pfizer*, indications have been provided as to what kind of risk assessment must be conducted by the invoking authorities. The required risk assessment no longer has to satisfy a mere negative condition (not to rely on hypothetical considerations to establish scientific uncertainty)<sup>199</sup>, but it has to consist in “sufficiently reliable and cogent information” allowing the authority to ascertain whether the feared situation has exceeded the level of risk deemed acceptable for society<sup>200</sup>. In particular,

“[n]otwithstanding the existing scientific uncertainty, the scientific risk assessment *must enable the competent public authority to ascertain, on the basis of the best available scientific data and the most recent results of international research, whether matters have gone beyond the level of risk that it deems acceptable for society [...]*”<sup>201</sup>.

That is “the basis on which the authority must decide whether preventive measures are called for”<sup>202</sup>.

It must be observed how the CFI has made this determination in qualitative rather than in quantitative terms, by stating that if a complete risk assessment may be impossible in cases of uncertainty, it must allow the competent authorities to determine whether the situation has exceeded the level of risk deemed acceptable for society. This is the required risk assessment justifying the adoption of a precautionary measure.

At the same time, the risk assessment must also

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<sup>199</sup> See on this point, the Opinion by AG M. Poiares Maduro in Case C-41/02 [2004] I-11375, para 28.

<sup>200</sup> Case T-13/99 *Pfizer Animal Health v. Council*, 2002 ECR II-3305, paragraph 162.

<sup>201</sup> *Ibidem*.

<sup>202</sup> *Ibidem*.

"enable the competent authority to decide, in relation to risk management, which measures appear to it to be appropriate and necessary to prevent the risk from materialising"<sup>203</sup>.

This is the risk assessment required to prove the proportionality of the precautionary action.

This means that in order to judicially review a precautionary measure, in particular the adequacy of its scientific basis, courts do need to know what level of protection is sought to be achieved by the competent authorities<sup>204</sup>. Without a determination of this element, it will prove impossible for them to verify whether a contested precautionary regulation is “adequately backed up by the scientific data available at the time when the measure was taken”<sup>205</sup>.

In a risk analysis model where risk management decisions cannot depend solely on the outcome of scientific expertise but must also take into account "other legitimate factors", such as "societal, economic, traditional, ethical and environmental factors as well as the feasibility of controls"<sup>206</sup>, the precautionary principle finds fertile ground in which to lay roots. Conversely, the precautionary principle would struggle in a risk analysis model where only the scientific element dictates the permitted regulatory action.

The shaping of the precautionary principle by Community courts does not come as a surprise insofar as the same Commission Communication on the principle anticipated that

“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”<sup>207</sup>.

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<sup>203</sup> Ibidem, paragraph 163.

<sup>204</sup> For a US perspective on judicial review of risk assessment, see T.O. McGarity, On the Prospect of "Daubertizing" Judicial Review of Risk Assessment, 66 Law & Contemp. Probs. 155, p. 163

<sup>205</sup> Case T-13/99 Pfizer Animal Health v. Council, 2002 ECR II-3305, paragraph 144.

<sup>206</sup> See recital (19) of the Preamble of the general food regulation as well as Article 3(12) and Article 6, paragraph 3. See also Article 6(6) of Regulation 1829/2003 on GM food and feed which provides that as risk assessment cannot provide all the information on which a risk management decision should be based "other legitimate factors" relevant to the matter under consideration may be taken into account.

<sup>207</sup> See Commission Communication on the precautionary principle, supra note 15, p. 10.

It is in these circumstances that the difficult tasks of evaluating the scientific uncertainty triggering the invocation of the principle and the assessment of the proportionality of the precautionary measure adopted is entrusted to the judicial bodies. Indeed, the Courts are called upon to resolve the ambiguities which remain in relation to the application of the precautionary principle by reaching a definitive answer any time a precautionary measure is contested before them.

*(b) The proportionality principle*

Unlike the precautionary principle, proportionality has not been conceived *ab initio* as a risk management tool, but rather as a control mechanism over the legality of Member State<sup>208</sup> and Community action in various areas of Community law. Yet, similarly to the former principle, it was established and fully developed by Community Courts before partly being codified in Article 5 EC as part of subsidiarity<sup>209</sup>.

The proportionality assessment implies a judgment on whether an adopted measure, be it of national or Community origin, exceeds the limits of what is appropriate and necessary to achieve the declared objective<sup>210</sup>. Therefore, whenever it is invoked against a national or a Community measure, it serves as a ground against which to verify the legality of a given act.

However, in the risk regulation field, where it is used to challenge a discretionary policy made by a national or Community legislator, it has acquired its own specificity. In the paradigm case in which proportionality is invoked to contest a risk regulatory act, the applicant tends to argue that the policy choice made by the legislator was disproportionate because the measure was not suitable or necessary to achieve the pursued goal, or even because its costs were excessive in relation to the benefits.

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<sup>208</sup> As long as Community action falls within the sphere of application of Community law. See Craig, *supra* note 184, p. 655.

<sup>209</sup> See also Protocol No 30 on the application of the Principle of Subsidiarity and Proportionality.

<sup>210</sup> Case C-331/88 Fedesa and Others [1990] ECR I-4023, paragraph 13; Joined Cases C-133/93, C-300/93 and C-362/93 Crispolti and Others [1994] ECR I-4863, paragraph 41; Case C-157/96 National Farmers' Union and Others [1998] ECR I-2211, paragraph 60; and Case C-189/01 Jippes and Others [2001] ECR I-5689, paragraph 81; Case C-3/00 Denmark v Commission [2003] ECR I-2643, paragraph 49.

Although Community Courts have repeatedly stated that they should not substitute their judgment for that of the legislator<sup>211</sup>, they have over time laid down a set of useful guidelines for the risk managers, thereby converting proportionality into a useful risk management tool.

One of the best illustrations of the role played by proportionality in EU risk regulation may be found, once again, in *Pfizer*. Here, following the withdrawal of the authorisation for an additive to animal feeding stuffs, Pfizer also challenged the measure on grounds of proportionality “inasmuch as it is a manifestly inappropriate means of achieving the objective pursued and the institutions, which had a choice between a number of measures, failed to choose the least onerous one”<sup>212</sup>.

The CFI, by reiterating its established case-law on the scope of the principle<sup>213</sup>, stated that proportionality requires:

- that measures adopted by Community institutions should not exceed the limits of what is suitable or appropriate in order to attain the legitimate objective pursued by the legislation in question (suitability limb) ;
- where there is a choice between several appropriate measures recourse must be had to the least onerous method (necessity limb), and
- that the disadvantages caused must not be disproportionate to the aims pursued (*stricto sensu* proportionality)<sup>214</sup>.
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The Court then indicated that a “cost/benefit analysis is a particular expression of the principle of proportionality in risk management”<sup>215</sup>. Although it is controversial whether this third element is

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<sup>211</sup> See Case C-120/97, *Upjohn Ltd* [1999] ECR 223, para 34. (“[...] 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). See, also, Case C-405/92 *Mondiet* [1993] ECR 6133. See, for a similar statement, in the competition law field, *Joined Cases 56/64 and 58/64 Consten and Grundig v Commission* [1966] ECR 299, p. 347.

<sup>212</sup> Case T-13/99 *Pfizer Animal Health v. Council*, 2002 ECR II-3305, paragraph 407.

<sup>213</sup> Case C-331/88 *Fedesa and Others* [1990] ECR I-4023, paragraph 13.

<sup>214</sup> *Pfizer*, paragraph 411.

<sup>215</sup> *Ibidem*, paragraph 410.

also part of the Community test, EU courts generally make reference to this aspect of proportionality when the applicant presents arguments directed specifically to it<sup>216</sup>.

After considering the contested measure as appropriate<sup>217</sup> and necessary (the least-onerous)<sup>218</sup> for attaining the desired end, the CFI focuses on the third part of the proportionality test in order to verify whether the measure entailed disadvantages that were disproportionate to the objectives pursued<sup>219</sup>.

Before tackling the *stricto sensu* proportionality test, the CFI first observed that the importance of the objective pursued by the contested regulation, i.e. the protection of human health, may justify adverse consequences, and “even substantial adverse consequences”, for certain traders insofar as,

“The protection of public health, which the contested regulation is intended to guarantee, must take precedence over economic considerations”<sup>220</sup>.

On these premises, the balancing activity, imposed by application of the third limb of the principle, between the financial losses suffered as a result of the measure (economic considerations) and the objective sought by the Community (public health) could not but lead the Court to uphold the contested measure. Indeed, after emphasising that the use of antibiotics is not “strictly necessary in animal husbandry”, that “there are alternative methods of husbandry even if they can lead to higher costs for farmers and consumers”, and that “withdrawal of the authorisation of virginamycin [...] is a provisional measure which is subject to the Community institutions’ duty of re-examination”, the CFI concluded that, although “the measures taken in

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<sup>216</sup> Craig, *supra* note 184, p. 657.

<sup>217</sup> Pfizer, paragraph 440.

<sup>218</sup> *Ibidem*, paragraph 451.

<sup>219</sup> Pfizer claimed that, referring to the BSE judgment, withdrawal of authorisation could only be proportionate where there was a serious and identifiable risk causing great uncertainty and where there was evidence that the source against which action is to be taken is most likely explanation of the risk faced. See paragraph 452.

<sup>220</sup> *Ibidem*, paragraph 456. For a previous recognition of such a preference, see C-183/95, *Affish* [1997] ECR 4315, paragraph 43 and Case 160/88 *Fedesa v. Council* [1988] ECR 6399.



the contested regulation entail serious economic consequences for Pfizer”, this “does not mean that it can be described as disproportionate for the purpose of challenging its unlawfulness”<sup>221</sup>. Another string of interesting examples of the use of the proportionality principle as a risk management tool may be found in national risk regulation, in particular in the context of free movement. When a Member State seeks to defend a national measure restricting the free movement by relying on one of the recognised exceptions, such as public health, it is not enough to assert that that measure is warranted on grounds of public health, but, under this principle, it will also need to produce evidence or data proving that the measure “is restricted to what is actually necessary to secure the protection of public health”<sup>222</sup>. An early illustration of the principle as applied to national measures may be found in *Sandoz*<sup>223</sup>. Here, the Court, after recognizing that the Netherlands could in principle refuse the marketing of muesli bars that contained added vitamins, subjected the Dutch prohibition to proportionality, thereby requiring that limits on imports should be restricted to what was necessary to attain public health<sup>224</sup>. A similar approach has been followed in *Kaasfabriek Eyssen*<sup>225</sup>, *Heijn*<sup>226</sup>, *Beer Purity case*<sup>227</sup> and *Muller*<sup>228</sup>. In other judgments, the Court went even further by suggesting to national authorities an alternative, less-restrictive method, for attaining the pursued public health goal. Thus, for instance, in *Van der Veldt*<sup>229</sup>, after finding the Belgian prohibition of marketing bread whose salt content exceeds 2% illegal, the Court added that “instead of prohibiting and penalizing the marketing of bread and other bakery products whose salt content is higher than 2%, the Belgian legislature could have prescribed suitable labelling to give consumers the desired information regarding the composition of the product”<sup>230</sup>.

Proportionality as applied to national risk regulations serves a twofold objective. On the one hand, it is designed as to ensure that the adopted measure effectively pursues its declared

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<sup>221</sup> *Ibidem*, 459-460.

<sup>222</sup> Case 178/84, *Commission v. Germany* [1987] ECR 1227, paragraph 44. As is well known, the Court inferred this principle from the last sentence of Article 30 EC which enables trade restrictive measures but insofar as they do not “constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States”.

<sup>223</sup> Case 174/82, *Sandoz BV* [1983], ECR 2445.

<sup>224</sup> *Sandoz*, paragraph 18.

<sup>225</sup> Case C-83/80, *Officier van Justitie/Kaasfabriek Eyssen* [1981] ECR 409.

<sup>226</sup> Case 94/83 *Heijn* [1984] ECR 3263.

<sup>227</sup> Case 178/84, *Commission v. Germany* [1987] ECR 1227.

<sup>228</sup> Case 304/84 *Ministère Public v Muller and others* [1986] ECR 1511.

<sup>229</sup> Case C-17/93 *Van der Veldt* [1994] ECR I-3537.

<sup>230</sup> *Ibidem*, paragraph 19.

objective, by testing whether the objective could be attained in a less restrictive manner. On the other, it is intended to ensure that the measure does not operate as arbitrary discrimination or a disguised restriction on trade between Member States.

Finally, whilst it is true that “the protection of public health [...] must take precedence over economic considerations”<sup>231</sup>, risk managers – be they national or European – must ensure that the chosen measure to attain the public health objective is proportionate to that goal, i.e. necessary, appropriate while its disadvantages cannot be disproportionate to the aim pursued.

Proportionality thus becomes a main tenet of the risk management phase by providing a detailed and useful set of guidelines that risk managers must abide by when regulating risk. In particular, risk regulators must know that “under the requirement of proportionality, the need to safeguard public health must be balanced against the principle of free movement of goods”<sup>232</sup>.

*(c) The consistency precept*

Another relevant risk management tool which has been shyly introduced by Community Courts is the consistency precept<sup>233</sup>.

One of the most famous *ante litteram* illustrations of this precept, as applied to national measures, may be found in the legendary *Cassis de Dijon* case<sup>234</sup>. After concluding that a German rule prescribing minimum alcohol content for fruit liqueurs was an obstacle to the free movement of goods, the Court considered whether the rule was necessary in order to protect consumers’ public health, as alleged by Germany. In particular, the German government claimed that the rationale for the rule was “to avoid the proliferation of alcoholic beverages on the national market”, in particular those “with a low alcohol content”, since, in its view, “such products may more easily induce a tolerance towards alcohol than more highly alcoholic beverages”<sup>235</sup>. The Court rejected this argument “since consumers can obtain on the market an

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<sup>231</sup> Ibidem, paragraph 456.

<sup>232</sup> Case E-3/00 EFTA Surveillance Authority v Norway, paragraphs 27 and 28.

<sup>233</sup> This has also been defined as “coherence precept” by A. Hagen Meyer, Risk Analysis in accordance with Article 6, Regulation (EC) 178/2002, European Food and Feed Law Review, 3/2006, p. 150.

<sup>234</sup> Case 120/78, Rewe-Zentrale AG v. Bundesmonopolverwaltung für Brantwein, [1979] ECR 649.

<sup>235</sup> Ibidem, paragraph 10.

extremely wide range of weakly or moderately alcoholic products and furthermore a large proportion of alcoholic beverages with a high alcohol content freely sold on the German market is generally consumed in a diluted form”<sup>236</sup>.

In other words, it is by playing on the inconsistency of the German defence that the Court concluded for the illegality of the national measure.

A more evolved application of the consistency precept can be found in another famous judgment, the *Beer Purity* case<sup>237</sup>. Here, Germany, after having banned the marketing of beer containing any additives (not just some additives for which there was evidence of risks), tried to justify its measure on public health grounds by arguing not only that “it is important, for reasons of general preventive health protection, to minimize the quantitative of additives ingested”, but that it is “particularly advisable to prohibit altogether their use in the manufacture of beer, a foodstuff consumed in considerable quantities by the German population”<sup>238</sup>. To reject this argument, the Court merely emphasised that “some of the additives authorised in other Member States for use in the production of beer are also allowed under the German rules, in particular the regulation of additives, for use in the manufacture of all, or virtually all, beverages”<sup>239</sup>. After highlighting such an inherently inconsistent approach to the regulation of additives in beverages, the Court easily concluded that the German prohibition was contrary to the principle of proportionality and therefore not covered by the public health exception provided for in Article 30 EC.

Another interesting application of the consistency test has occurred in the *Kellogg's* case<sup>240</sup>, where, after establishing that the Norwegian prohibition of import of fortified corn flakes could constitute an impediment to the free movement of goods, the EFTA Court examined whether such a prohibition was justified, as alleged by Norway, “insofar as there is no nutritional need in the Norwegian population for the fortification”. In dismissing this argument the EFTA Court observed that:

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<sup>236</sup> Ibidem, paragraph 11.

<sup>237</sup> Case 178/84, Commission v. Germany [1987] ECR 1227.

<sup>238</sup> Ibidem, paragraph 48.

<sup>239</sup> Ibidem, paragraph 49.

<sup>240</sup> Case E-3/00 Efta Surveillance Authority v Norway [2001] EFTA Court Report 2000/2001.

“[that measure] was inconsistent in that, on the one hand, authorisation 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 with up to 10 mg of iron per 100 of cheese to be freely sold in the country”<sup>241</sup>.

On this basis, it concluded that Norway failed to comply with its free movement obligation.

The idea behind this precept is that risk measures should be tailored to other measures which were taken in the past under similar circumstances or based on similar approaches. There must be some consistency between the regulatory responses to comparable risks (additive in beer and additive in other beverages; vitamin fortification of cereals and vitamin fortification of other foodstuffs) and this in particular when the chosen level of protection is similar.

Although this precept has not been codified (like in Article 5.5 of the SPS Agreement), appearing solely in the case-law of the Courts, it provides a useful guidance for the EU risk managers when assessing the different policy options.

As aptly stated in the WTO context, the presence of an arbitrary or unjustifiable character of differences in the level of protection chosen by a Member as "appropriate" in differing situations,

"may [...] operate as a "warning" signal that the implementing measure in its application might be a discriminatory measure or might be a restriction on international trade disguised as a [...] measure for the protection of human life or health"<sup>242</sup>.

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<sup>241</sup> Ibidem, paragraph 41.

<sup>242</sup> EC-Hormones, AB Report, para 215.

## V. Conclusion

As clearly emerges from this essay, Advocate General van Gerven's call, in *Technische Universität München*, according to which the Court "cannot shy away from technical questions" has not been left unanswered<sup>243</sup>. In the space of three decades, the EU Courts have elaborated, in parallel with the unforeseen development of such types of policies, a sophisticated approach to risk regulation. By using the cases randomly brought to them by private and institutional actors, the EU courts have gradually shaped the way in which risk is governed in Europe. Although their first move boiled down to a legal borrowing, consisting in the judicial import of the risk analysis framework as developed on the other side of the Atlantic, the EU courts have promptly stepped up to the bat in order to adapt that model to the European context.

After adopting the structured risk analysis model, by transforming it into the privileged methodological tool for regulating risk in Europe, the Courts have defined not only what must be understood as risk assessment and risk management but also how these sub-components must interact between each other. By showing great concern for the legitimacy of its own rulings, the Court has developed an original risk analysis model in which scientific expertise, regardless of its national or Community origin, must be integrated in risk decision-making but which is not self-sufficient to legitimise regulatory action. Indeed, as clearly expressed by the European Court of First Instance, "[s]cientific legitimacy is not a sufficient basis for the exercise of public authority"<sup>244</sup>.

This is because, when deciding "which measures appear to be appropriate and necessary to prevent the risk from materialising"<sup>245</sup>, the advice obtained from scientific advisors come from sources which, although "scientifically legitimate", "have neither democratic legitimacy nor political responsibilities"<sup>246</sup>.

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<sup>243</sup> Case C-269/90 Technische Universität München [1991] ECR I-5469.

<sup>244</sup> Case T-13/99 Pfizer Animal Health v. Council, 2002 ECR II-3305, paragraph 201.

<sup>245</sup> Ibidem, paragraph 163.

<sup>246</sup> Ibidem, paragraph 201.

This departure from science as a universal and neutral criterion to rely upon in regulating risk, by enabling risk managers to consider also “other legitimate factors”, symbolises at best the European approach. In a risk analysis model where risk management decisions cannot depend solely on the outcome of scientific expertise but must also take into account “other legitimate factors”, such as “societal, economic, traditional, ethical and environmental factors as well as the feasibility of controls”<sup>247</sup>, the precautionary principle finds fertile ground in which to lay roots and offers a useful risk management tool<sup>248</sup>.

In designing such a risk analysis model, the courts have apportioned authority to both the scientists, who are charged with the scientific resolution of the dispute, and the policy-makers, who are expected to decide whether to act.

Under this model, the courts are not called upon to determine which risks to accept or how to live with them, but are rather expected to ensure procedural conformity with the set of principles which reflect the balance they have struck between the scientific and the political components of risk. It might be predicted that, under the pressure of private parties, Courts will increasingly be called upon engaging into such a scrutiny. In so doing, Courts will be expected not only to better define procedural parties’ rights but also to shed some light on the extremely heterogeneous institutional settings of European agencies.

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<sup>247</sup> See recital (19) of the Preamble of the general food regulation as well as Article 3(12) and Article 6, paragraph 3. See also Article 6(6) of Regulation 1829/2003 on GM food and feed which provides that as risk assessment cannot provide all the information on which a risk management decision should be based "other legitimate factors" relevant to the matter under consideration may be taken into account.

<sup>248</sup> It is well known though that such an opening to non-scientific factors is susceptible to bring the EC model in conflict with the WTO/SPS regime, which, by lacking a clear defined risk management policy, requires only scientific soundness. For a comparison of the regulatory risk analysis schemes under the EU and the WTO, see Alemanno, *Trade in Food – Regulatory and Judicial Approaches in the EC and the WTO*, Cameron May, London, 2007, pp. 387-407.