

# Chapter 2

## EU Risk Regulation and Science: The Role of Experts in Decision-making and Judicial Review

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### Introduction

This Chapter aims at exploring the role that scientific experts and, more particularly, scientific expertise play within European risk governance. While the first part of the Chapter looks at the way in which scientific expertise is integrated into the decision-making process, the second part examines how science and science-based measures are, or may be, judicially reviewed by European courts. This last part also ventures to suggest some ways to help the judge when reviewing science-based measures by looking into expert consultation systems and peer review mechanisms.

In taking this approach, the Chapter will focus primarily on the area of food safety, as it provides a privileged perspective from which to examine the emergence of a European risk regulatory framework. Indeed, although confined to regulating food safety issues, the risk regulatory model laid down by EP and Council Regulation 178/2002 in the aftermath of several food scandals reflects the state of the art in ongoing European reflection about risk governance.<sup>1</sup>

## Scientific Expertise in Decision-Making

### *The Genesis: the Role of Science in EC Law*

Today the use of science as one of the sources of evidence to support decision-making is relevant in a wide range of policy areas, such as food safety, emission limits,<sup>2</sup> chemicals,<sup>3</sup> biocides,<sup>4</sup> GMOs,<sup>5</sup> pesticides,<sup>6</sup> food additives,<sup>7</sup> water protection,<sup>8</sup> consumer protection, worker safety and health.<sup>9</sup> As scientific evidence is crucial at all stages of the drawing up of new legislation and for the execution and management of existing European and national legislation, it is worth illustrating how this process has occurred within the European legal order.

The original 1957 Treaty of Rome did not impose either on the EC institutions or on Member States a duty to justify their health, safety and environmental protection measures according to the latest scientific information. Indeed, its text did not contain any reference to scientific justification or expertise.

However, as Member States began invoking Article 36 (currently Article 30) EC, which allowed them to adopt restrictions on trade justified *inter alia* on grounds of protection of health,<sup>10</sup> they often submitted scientific evidence to the European Court of Justice in order to demonstrate that their measures were covered under this exception. Thus, for instance, in the *Beer Purity case*,<sup>11</sup> Germany, after having banned the marketing of beer containing *any* additive (not just those additives for which there was evidence of risks),<sup>12</sup> tried to justify its measure by arguing not only that Germans drank a lot of beer (*sic*), but also that the long-term effects of additives were unknown. To support its scientific claim, Germany also cited experts' reports referring to the risk inherent in the ingestion of additives in general.<sup>13</sup> Moreover, it was not just the parties to the case that picked up on the scientific element, but also the Court. The ECJ, referring to the previously decided *Sandoz*,<sup>14</sup> *Motte*<sup>15</sup> and *Müller*<sup>16</sup> judgments, held that a Member State's possibility to restrict the

free movement of a foodstuff legally marketed in another Member State 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>17</sup> Having deferentially referred to the scientific findings of these entities, the Court, however, 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>18</sup> and *Debus*,<sup>19</sup> both involving national measures restricting the use of additives.<sup>20</sup>

Thus, without being formally introduced within the Rome Treaty, a *de facto* scientific requirement grew up within the regulatory practice developed around the rules governing the free movement of goods within the EC. However, it was only in 1999 that scientific justification was expressly inserted into Article 95, paragraph 5, as one of the requirements Member States must satisfy in order to *introduce* a measure derogating from European harmonisation legislation.<sup>21</sup> In particular, a Member State that deems it necessary to introduce a national measure aimed at the protection of the environment after the adoption of a Community measure on the matter must provide ‘new scientific evidence’.<sup>22</sup>

As a consequence, an embryonic scientific discipline has evolved over time not with the purpose of protecting human health but rather of resisting national protectionism, and thereby of permitting the establishment of the internal market.

At the same time, the scientific justification discipline that originally developed in relation to Member State measures based on public health had been extended to the acts adopted by the European institutions. In 1992, when the aim of achieving a 'high level' of health was given the status of a general objective in the EC Treaty (Article 3, paragraph 1, (p)), a specific legal basis has been laid down in Article 152 EC for public health measures. Moreover, in the same year, EC environmental policy was redirected to the attainment of a 'high level of protection'<sup>23</sup> and, to this purpose, it was required to 'take account of available scientific and technical data'.<sup>24</sup> Subsequently, in 1997, Article 100a (current 95 EC), which allows the EC institutions to adopt directives aimed at harmonising national provisions that 'directly affect the establishment or functioning of the common market', was amended in order to specify that these objectives should be pursued and based on 'scientific facts'.<sup>25</sup>

Thus, from the moment that the Amsterdam Treaty entered into force in 1999, all Community legislation concerning health, safety and environmental and consumer protection is to aim at achieving a high level of protection by 'taking account in particular of any development based in scientific facts'.<sup>26</sup> This is because the Commission intends 'to use this advice for the benefit of the consumer in order to ensure a high level of protection of health'.<sup>27</sup> As the Commission has pointed out in its 1997 Communication on Consumer Health and Food Safety:

'[...] scientific evidence is of the utmost importance at all stages of the drawing up of new legislation and for the execution and management of existing legislation'.<sup>28</sup>

Recently, scientific justification has been expressly defined as 'an essential requirement for Commission proposals, decisions and policy' relating to consumer safety, public health and the environment.<sup>29</sup> To fulfil its function,

scientific advice on matters relating to consumer health must be based on the principles of excellence, independence and transparency.<sup>30</sup>

These are the only references contained in the Treaty laying down a general duty for the EC and national decision-makers to provide for scientific justification when adopting legislation concerning consumer safety, public health and the environment. However, although it establishes a risk assessment duty, the Treaty does not define who is charged with ensuring such an assessment by leaving open the controversial question of whether risk assessors should be distinguished from those who have to decide if and how to act. In other words, our analysis shows that the Treaty does not set forth a complete risk analysis model aimed at defining the role of the different actors involved in such an analysis. As a result, it is up to the secondary legislation to do so by choosing the risks assessors and establishing their relationship with the risk managers.

### ***EC Sources of Scientific Advice and Expertise***

Contrary to conventional wisdom, there is currently no common system providing scientific advice to EC policy-makers. Scientific support is ensured through a range of different mechanisms, depending on the policy area at issue.

The most common sources of advice used to support EC policies, legislation and regulatory decisions are the following: scientific committees under the control of EFSA and EMEA,<sup>31</sup> three non-food scientific committees that operate under the responsibility of the Directorate General for Public Health and Consumer Products (DG SANCO),<sup>32</sup> reports by advisory agencies, such as the European Environmental Agency (EEA); reports provided by external consultants (individuals, groups or companies, possibly using research contracts); national reports provided by Member States' advisory bodies; reports by ad-hoc expert groups; in-house analysis

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

In an attempt to ensure some consistency in the delivery of advice from so many different sources of expertise, the EC Commission has developed a set of policies and guidelines for the use of scientific advisors. This growing scientific advice policy is contained in three main documents: the Science and Society Action Plan (2002), the Commission Communication on the Collection and Use of Expertise (2002),<sup>33</sup> and the Commission Decision to set up Scientific Committees in the Fields of Consumer Safety, Public Health and the Environment (2004).<sup>34</sup> These documents impose ‘sound and timely science’ as an essential requirement for risk management in the areas of consumer safety, public health and the environment, and they recommend a set of guiding ‘core principles’ for the collection and use of scientific expertise by the Commission departments: quality, openness, effectiveness, independence, pluralism, excellence, impartiality, proportionality and transparency.<sup>35</sup>

Moreover, since 2000, some efforts have been made at setting up a harmonised approach to risk assessment procedures among the Scientific Committees advising the European Commission in the areas of human, animal and plant health and on the environment.<sup>36</sup>

However, these principles and guidelines are not legally binding. Nor do they apply to the formal stages of decision-making as provided by the Treaty and in other EC legislation. Therefore, the formal legislative procedures as well as the formal exercise of the Commission’s implementing powers through the ‘comitology’ committees are excluded from their scope.

## ***The Emerging EU Risk Regulatory Framework***

### *The Principle of Risk Analysis*

To understand the role played by experts within the European decision-making process, it is necessary to describe the context within which they are expected to provide their advice. If one looks at the European risk regulatory framework as it emerges from the general food regulation, this framework contains the following three different components: risk assessment, risk management, and risk communication.

As is well known, this structured approach incorporating the three distinct but closely linked stages of risk analysis was firstly developed and popularized by the US National Research Council (NRC)<sup>37</sup> and today finds support in the main guidelines developed by national and international organisations dealing with risk analysis.<sup>38</sup>

In particular, the EC food risk analysis model interprets and promotes the relationship between risk assessment and risk management in terms of clear-cut separation, by giving, for the first time, a normative expression to the 'functional separation' between these two components.<sup>39</sup> The primary reason given for such a distinction or separation between these two components of risk analysis is a desire to ensure the independence and objectivity of the scientific process as conducted during the risk assessment stage. The idea is that only the introduction of a clear-cut separation between risk assessors, who discuss facts, and managers, who discuss values, would effectively insulate scientific activity from political pressure and, accordingly, maintain an analytical distinction between the magnitude of a risk and the cost of coping with it. Following the development of this design, several steps have been undertaken within the Commission to institutionally implement this approach to risk analysis by functionally separating those responsible for production, or the promotion of the market, from those responsible for the assessment of food safety. Thus, for instance, the management of the scientific

committees was transferred to what is now the Directorate General for Health and Consumer Protection (DG SANCO), and subsequently to the EFSA, a supposedly independent scientific body lacking any decision-making power. Thus, a watertight separation between the risk assessment and risk management stages in the field of food safety has been increasingly seen as essential not only to guarantee independence and objectivity to the scientific process,<sup>40</sup> but also as a means of enhancing the democratic legitimacy of the decision-making process by ensuring that decisions are ultimately taken by those who are accountable to the public.<sup>41</sup> According to A.G. Mischo, this distinction meets a dual goal: it ensures a rational technocratic dimension to the decision-making process, while enabling the political process to be independent from the results of scientific assessments.<sup>42</sup>

Finally, the duty to rely on scientific expertise appears to have been given general application to all science-based measures by the Court of First Instance (hereinafter: 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>43</sup>

### *The EU's Approach to Risk Analysis*

Under the emerging EU Risk Regulatory framework, once a risk has been identified, it is the decision-maker's responsibility to decide if it is acceptable, which may imply adopting an attitude of zero tolerance. In particular, risk managers (EC institutions and Member States' authorities) have to take into account:

- a) the results of risk assessment, in particular the 'opinions' of the EFSA;
- b) 'other factors legitimate to the matter under consideration' (the so-called 'social factors' (Echols 1998: 530) or 'non-economic factors'), and

- c) the 'precautionary principle', within the limits laid down in Article 7 of the Regulation 178/2002, in order to achieve the general objectives of food law.

Then, Article 5, paragraph 3, adds to this list:

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

- a) an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law, or
- b) where there is a scientific justification, or
- c) where there would result in a different level of protection from the one determined as appropriate in the Community'.

Therefore, although science plays the major role in the risk management stage, the Regulation reserves the right of risk managers to take other factors into consideration when reaching a final decision<sup>44</sup>. This is because

'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'.<sup>45</sup>

Relevant factors in the area of health protection of consumers may consist, for instance, of societal, economic, traditional, ethical and environmental factors.<sup>46</sup> This approach is in line with the Communication on the precautionary principle, which indicates that in cases of scientific uncertainty

'[...] judging what is an 'acceptable' risk for society is an eminently political responsibility. Decision-makers faced with an unacceptable risk, scientific uncertainty and public concerns have a duty to find answers'.<sup>47</sup>

The perceived need to also consider non science-based factors within the decision-making process characterises the European approach to risk analysis

by differentiating it greatly from the one adopted by US regulatory agencies and by the WTO/SPS legal framework.<sup>48</sup>

The EU approach to risk analysis has been effectively described as a system in which ‘scientific knowledge is authoritative, but not exclusively so’ (Skogstad 2001: 490).

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

The well-known *Hormones* dispute,<sup>49</sup> ‘one of the longest running trade disputes in the modern trading system’ (Sykes 2006: 260), between the EC and the US exemplifies the impact that the EC’s particular risk analysis approach may have, not only on its external trade relations, but also on its internal market dimension.<sup>50</sup> The regulatory regime that was challenged in this dispute was adopted by the EC institutions notwithstanding the advice of the Scientific Working group that the banned growth-hormones were harmless to human health. The ban triggered not only a reaction in the U.S. and Canadian reactions but also encountered internal resistance.<sup>51</sup> Member States were split over the decision: while France, Germany, Italy and the Netherlands supported the total prohibition of these growth hormones, the UK and Ireland opposed it so strongly as to lead to the controversial legislation being brought before the European Court of Justice.<sup>52</sup>

The EC ban turned out to be motivated by a complex mix of political, social, economic and conflicting scientific factors that, as we have seen, may now formally enter into the EC food decision-making process. Today we would probably define such a mix of different interests under the ‘collective preference’ label launched by Pascal Lamy (see Lamy 2004).

Notwithstanding the existence of a scientific consensus concerning a certain substance, the possibility of taking ‘other legitimate factors’ into consideration may lead to divisions across Member States over controversial

food safety measures, while at the same time bringing the EC measures into conflict with the WTO framework.<sup>53</sup>

### *The Flaws of the Emerging EU Risk Regulation Framework*

The distinction between the purely technical assessment of risks by scientists and the management of these risks by decision-makers is being increasingly questioned today.<sup>54</sup>

The critique takes the form of suggesting that the division is not credible insofar as it appears to be totally cut off from the concrete reality of scientific and political work processes (Noiville and De Sadeleer 2001: 408). Risk assessment cannot be conceived as a wholly objective exercise. Not only is it influenced by the extensive use of 'science policies',<sup>55</sup> but also by the values and beliefs of scientists and the judgments of the profession. In other words, when dealing with decisions involving technical and scientific aspects, scientific expertise and political decisions become so intertwined as to become impossible to separate. In fact, the elaboration of these policies and assumptions boil down to a risk management activity (Walker 2003: 263).

This entirely legitimate process inevitably leads to stripping the 'functional separation' between risk assessment and risk management of its original goals: the purity of scientific assessment and accountability of risk managers. These observations suggest that the EC's dichotomous model of risk regulation, which has found both institutional and normative expression in the general food law regulation, fails to normatively recognize the value judgments implicit in the first stage of risk analysis.<sup>56</sup> The risks stemming from this insistence on the need for a clear-cut separation is that the values and uncertainties inherent in risk assessment may go unexamined because they do not formally translate into 'science policies'. Notwithstanding the growing rhetoric over transparency in the EC scientific expertise,<sup>57</sup> the current reductionist Community approach to risk analysis does not seem to ensure

that the reasons underlying the decisions are clearly laid out in the policy choices adopted (judgments, uncertainties and biases in scientific assessment), thus setting them apart from the scientific results on which they rely, so that every citizen (and, eventually, the courts) can identify them. To avoid this and to maintain the original goals pursued by the functional separation between risk assessment and risk management, it is absolutely imperative not only to render science policies explicit by furthering the current efforts aimed at elaborating guidance documents for each EFSA panel,<sup>58</sup> but also to clarify and frame the role played by EC Commission officials attending EFSA scientific panel meetings.<sup>59</sup> In fact, although EFSA is institutionally independent, there are, however, some tensions arising out of the 'grey areas' existing in its relationships with the Commission and from the current emphasis on the EFSA's contacts with stakeholders, including industry.<sup>60</sup> While the need for industry's involvement in EFSA's scientific activities is questionable, improved participation of consumer groups is already an indisputable necessity in order to avoid that consumer interests are overwhelmed by those of industry.

At the same time, it may be advisable to continue the current Commission's efforts aimed at harmonising risk assessment procedures within the Community. In its attempt to develop a harmonised common methodology for the Scientific Committees activities, the Commission should improve consistency in the horizontal application of science policies and risk assessment techniques by developing some robust assessment practices.<sup>61</sup> The Scientific Steering Committee<sup>62</sup> advised the Commission to establish a Working Party on the 'Harmonisation of Risk Assessment Procedures' to specifically address the general principles of risk assessment and their application to broad consumer health issues, with particular reference to measures that would enhance compatibility of approaches within the Scientific Committees. Although it has been recognized that a completely

common methodology for the activities of the Commission Scientific Committees may not be achievable, it is imperative to avoid the same chemical, biological or physical agent being dealt with quite differently by the EFSA panels and the other scientific committees in different contexts, resulting in potential inconsistency in assessment and confusion in application.<sup>63</sup>

### ***The Legal Status and Authority of the Experts' Opinions (EFSA's Scientific Opinions)***

#### *The Lack of a Principle of Supremacy of EU Science over National Scientific Advice*

Historically, scientific opinions delivered from any of the different sources of scientific advice to the Community have not been recognised as legally binding.<sup>64</sup> As a consequence, although the EC institutions are expressly required to take EFSA's opinions into account when drafting a Community measure,<sup>65</sup> the Agency lacks formal authority to reach binding resolutions on potentially contentious scientific issues.<sup>66</sup> Therefore, similar to the old scientific committees and any other European source of scientific advice,<sup>67</sup> it does not have the final word in cases of diverging scientific opinions between its own decisions and those issued by other bodies. This may be inferred from Article 30 Regulation 178/2002 ('the Regulation') which, while establishing a procedure aimed at solving problems arising from 'diverging scientific opinions', attributes neither an authoritative nor a mediating role to EFSA, but simply duties of 'vigilance' and 'cooperation'. This outcome is, at least at first glance, surprising if analysed in light of the EFSA's ambition to become 'the point of reference in risk assessment' for the whole Community.<sup>68</sup> More precisely, under the Regulation, the Authority is to exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the opinions issued by national food agencies or

other bodies carrying out similar tasks.<sup>69</sup> Where there is a conflict between its opinion and those of bodies carrying out similar tasks, the EFSA is ‘obliged to cooperate’<sup>70</sup> with the aim of resolving the differences or of presenting a joint document, which will be made public, identifying the uncertainties and the ‘contentious scientific issues’.<sup>71</sup>

The introduction of a mere duty of co-operation appears to fall short of providing an effective answer to the fundamental question as to the relationships between the European source of expertise and the national scientific responsible authorities.

By not endowing EFSA opinions with scientific supremacy over national scientific studies, the Regulation promotes an alternative method of tackling the issue of diverging scientific opinions between the EFSA and the national scientific bodies. In order to prevent the emergence of scientific controversies, EFSA is required to promote European networking of organisations operating in food safety risk assessment.<sup>72</sup> More specifically, the official aim of such networking is ‘to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices’.<sup>73</sup> In order to facilitate this, the Authority may require national organisations to provide some preparatory work for scientific opinions, scientific and technical assistance, some collection of data and identification of emerging risks.<sup>74</sup> This sort of network activity is not without precedent (Börzel 1998: 253) and it plays a vital role within EFSA’s operation. In fact, the establishment of this network is necessary in order to support EFSA’s scientific activities, in particular in conducting scientific opinions.

*The Indirect Legal Effect*

Notwithstanding their lack of legally binding nature, the Authority's opinions are likely to produce some significant indirect normative effects. In particular, EFSA's opinions have the potential to become a source of constraint not only for the EC institutions, but also for Member States and private parties.

In terms of the EC institutions, the *Pfizer Animal Health* judgment has clearly established a general duty to consult the available scientific reports prepared by experts on behalf of the EC.<sup>75</sup> EC institutions are allowed to depart from this duty only in those exceptional circumstances where equivalent scientific evidence can be found and a justification for relying on it is provided. There are therefore good reasons to believe that these constraints on the possibility of departing from scientific evidence will be maintained by the EC courts with regard to EFSA's opinions by transforming them into *de facto* authoritative measures. In other words, it is likely that within the new food safety regime it will be increasingly difficult for the EC institutions to exercise their discretion beyond the boundaries drawn by a scientific administrative network led by an independent and authoritative authority such as EFSA. This is suggested by Directive 1829/2003 governing the marketing of GMO foods within the EC, where it provides that, should the Commission decision not be in accordance with an EFSA opinion, the Commission must 'provide an explanation for the differences'.<sup>76</sup>

It is submitted that EFSA's opinions are likely to acquire some authoritative value vis-à-vis national decision-makers as well. Although the Regulation introduces the presumption that, in the absence of specific Community provisions, all food is deemed to be safe where it complies with the specific national provisions of the country where it is marketed,<sup>77</sup> the same regulation imposes on Member States the duty to take account of the results of risk assessment, particularly the opinions of the Authority, when regulating the food sector. In sum, while domestic authorities are not

procedurally required to consult the EFSA, they are still required to abide by its scientific opinions in passing new legislation.<sup>78</sup> It would therefore seem impossible for the national authorities to derogate from EFSA's opinions without giving some reasons justifying their rejection.

The Authority's position also has the potential to acquire some legal significance for private parties. As seen above, the Regulation also imposes a general obligation on private business operators engaged in production, processing and distribution to ensure that food placed on the market is safe.<sup>79</sup> Any breach of this duty gives rise, at least in principle, to two separate violations of EC law: a breach of the general obligation to ensure that food is safe, established by Article 14 of the Regulation, on the one hand, and violation of the Product Liability Directive on the other (Chalmers 2003: 534). Although national courts are not required to consult the Authority when investigating such violations, they are likely to rely on its scientific opinions. In other words, if the EFSA has issued an opinion suggesting that a product is unsafe, it would be extremely difficult for a private individual to claim the opposite.

Finally, EFSA's opinions may also produce legal effects vis-à-vis national courts. In *HLH Warenvertriebs*, where the ECJ had expressly been asked to determine whether the scientific opinions of that Authority may have binding force on the national courts, it held that

'[a]n opinion delivered by that Authority, possibly in a matter forming the subject-matter of a dispute pending before a national court, may constitute evidence that that court should take into consideration in the context of that dispute'.<sup>80</sup>

Notably, the Court has stated that national courts should ascribe to such an opinion the same value as that accorded to an 'expert report'.<sup>81</sup> Thus, EFSA's scientific opinions appear susceptible to acquiring a legal status similar to that of scientific expertise requested by the same national courts of third parties.

Although not binding *per se*, the scientific report ‘should be taken into consideration in the context of the dispute’.<sup>82</sup>

In conclusion, while EFSA’s opinions have not been expressly granted a direct regulatory authority, they are likely to acquire a *de facto* legally binding value for both the EC and the Member States authorities when passing legislation and amount to a strong probative authority against private business operators placing unsafe food on the market. More generally, it can reasonably be expected that EFSA’s opinions will structure the terms of debate on these issues by influencing enforcement within the Member States as well as directing public opinion.

## **Scientific Expertise before Courts**

Having illustrated the role played by scientific expertise within decision-making, the second part of this chapter focuses on how science and science-based measures are, or may be, judicially reviewed by European courts. In so doing, it refers primarily to the scientific advice provided within the food safety area by EFSA.

### ***European Courts and Scientific Opinions***

Although the issue as to whether Community courts may review the legality of the opinions delivered by EC sources of scientific advice is an open question to the extent that it has not definitively been resolved, it is possible to make some reasoned suggestions for how it is likely to unfold.

A comparative analysis of the ‘judicial accountability’ of the different European agencies does not offer any help in developing an answer to the question of the reviewability of EFSA opinions insofar as their constituent regulations provide for very different solutions. Thus, for instance, while some of these regulations explicitly provide that the acts adopted by the

agency are challengeable under Article 230 EC,<sup>83</sup> others entrust a specific chamber of the agency<sup>84</sup> or the same Commission<sup>85</sup> with the task of reviewing the legality of the agency's decisions. In the case of the EFSA, the general food regulation that establishes that agency does not contemplate the possibility of submitting its acts to legal review. Rather, a role for EC courts is envisaged exclusively in the area of contractual and non-contractual liability of the Authority.<sup>86</sup>

As a result, the question as to whether EFSA opinions or any other EC source of scientific advice may be challenged before the European courts is governed by Article 230 EC.

The application of this provision to scientific opinions raises several problems. Firstly, Article 230 EC does not contain any reference, either explicit or implicit, to acts of European agencies or any other scientific committee or source of expertise.<sup>87</sup> It merely refers to the 'acts adopted jointly by the European Parliament and the Council, [...] acts of the Council, [...] the Commission and [...] the ECB, other than recommendations and opinions, and [...] acts of the European Parliament intended to produce legal effects vis-à-vis third parties'.<sup>88</sup> Moreover, it is difficult to envisage EFSA or any other source of scientific advice being considered as one of the institutions or bodies listed therein. Put differently, EFSA decisions or those coming from external sources do not, strictly speaking, stem from one of those EC institutions listed in Article 230, paragraph 1, EC.<sup>89</sup> Secondly, being 'preliminary or purely preparatory acts', scientific opinions would not seem to fall within the category of acts which can be subject to an action for annulment, i.e. which covers solely those acts 'intended to produce legal effects vis-à-vis third parties'.<sup>90</sup> Last but not least, not being addressed to any individual, scientific opinions could not be assimilated to Community decisions, but fall within the scope of the fourth paragraph of Article 230, which provide for very demanding standing requirements.<sup>91</sup>

Notwithstanding their non-binding legal nature, it has been established, with reference to the scientific opinions given by the EMEA's Committee for Proprietary Medicinal Products (CPMB), that the opinions are

'[n]onetheless extremely important so that any unlawfulness of that opinion must be regarded as a breach of essential procedural requirement rendering the Commission's decision unlawful'.<sup>92</sup>

In other words, although these scientific opinions do not bind the Commission, they provide it with the scientific evidence that is necessary to determine, 'in full knowledge of fact', the appropriate measure to ensure a high level of health protection. Therefore, whenever the scientific opinions are procedurally vitiated, their unlawfulness will reflect on the subsequent decision which might be subject to judicial review.

In light of the above, in the *Artegodan* judgments,<sup>93</sup> subsequently confirmed by the ECJ, the CFI held that EC courts may be called upon to review the formal legality of an agency scientific committee's opinion as well as the Commission's exercise of its discretion. Although the CFI has stated that it cannot 'substitute its own assessment for that of the scientific committee', it has held that it may nonetheless review the proper functioning of the committee, the internal consistency of the opinion and the statement of reasons contained therein.

Should the Courts extend this approach to EFSA's scientific opinions, EC courts might rely on the growing number of guidance documents which are prepared by the EFSA's scientific panels in order to define their own method for conducting risk assessment.<sup>94</sup> In fact, these are the only documents which may potentially provide a useful legality benchmark in reviewing the proper conduct of the panel when carrying out the risk assessment.

A series of very recent opinions delivered by the CFI seem, however, to rule out the possibility that EFSA scientific opinions may be judicially

reviewed as such.<sup>95</sup> In these decisions, having examined all the arguments adduced by the applicants concerning the nature of the contested acts, it held that

‘[...] the applicant has not prima facie put forward evidence to establish that the Court has jurisdiction to hear and determine actions for annulment challenging EFSA’s acts as such, on the one hand, or to support the conclusion that whether or not EFSA’s acts may form the subject of an action for annulment is not to be assessed in relation to the requirements of Article 230 EC’.<sup>96</sup>

### ***European Courts and Science-based Measures***

While the review of scientific opinions by Community Courts has not become reality yet, the judicial review of Community science-based measures already occurs. As scientific evidence is becoming crucial at all stages of the drawing up of new legislation, EC Courts are increasingly called upon to review measures that are grounded in scientific data.

#### *The Standard of Judicial Review of Science-based Measures*

As seen above, the European scientific discipline has emerged gradually and quite recently, having first been spontaneously introduced by the Member States in order to support measures that derogated from EC law. This introduction of science was then subsequently codified and extended to EC action in the field of health and environmental protection, notably in the food safety area. As a result, there is a growing body of science-based case-law by the European courts dealing with measures adopted by EC Member States and by EC institutions to address risks to health and the environment.

In the absence of an express indication of the standard of review to be applied to those measures, it is necessary to look at this body of case-law in order to determine the level of intensity of the scrutiny exercised by the EC courts.

At a general level, the EC Treaty, unlike the ECSC Treaty,<sup>97</sup> does not provide any indication as to the standard of review that courts should apply when scrutinising EC acts. Finding themselves in a normative vacuum, the European courts filled it by drawing inspiration from the ECSC treaty, which set forth a rather deferential standard. Thus, in solving a specific legal dispute, EC courts tend, traditionally, to limit their review to questions of whether the authorities have or have not used their regulatory discretion in an arbitrary or unjustifiable manner.<sup>98</sup>

While the review of EC action is limited in principle to examining ‘whether the exercise of its discretion is vitiated by a manifest error or a misuse of power’, this standard of review has, through time, been specifically adapted and shaped so as to apply science-based measures, notably in the food safety area.

Thus, for instance, when the ECJ was called upon to determine whether the Commission lacked the competence to adopt Decision 96/239 providing for a total ban on exports of bovine animals, bovine meat and derived products from the territory of the United Kingdom to the other Member States and to third countries in the aftermath of the BSE crisis,<sup>99</sup> it declared that

‘[...] since the Commission enjoys a wide measure of discretion, particularly as to the nature and extent of the measures which it adopts, the EC judicature must, when reviewing such measures, restrict itself to examining whether the exercise of such discretion is *vitiated by a manifest error or a misuse of powers or whether the Commission did not clearly exceed the bounds of its discretion*’.<sup>100</sup>

Furthermore, it is settled case-law that

‘[...] where a Community authority is required to make complex assessments in the performance of its duties, its discretion also applies, to some extent, to the establishment of the factual basis of its action’.<sup>101</sup>

This deferential approach to the judicial review of Community measures has been further elaborated in the *Upjohn* judgment, which dealt with medicinal products. Here, the ECJ declared

‘[...] where a Community authority is called upon, in the performance of its duties, to make complex assessments, it enjoys a wide measure of discretion, the exercise of which is subject to a limited judicial review in the course of which *the EC judicature may not substitute its assessment of the facts for the assessment made by the authority concerned*. Thus, in such cases, the EC judicature must restrict itself *to examining the accuracy of the findings of fact and law* made by the authority concerned and to verifying, in particular, that the action taken by that authority is not vitiated by a manifest error or a misuse of powers and that it did not clearly exceed the bounds of its discretion’.<sup>102</sup>

This deferential standard of review has recently been specifically extended by the CFI to those situations where Community institutions are

‘[...] required to undertake a scientific risk assessment and to evaluate highly complex scientific and technical facts’.<sup>103</sup>

Accordingly, in the *Bellio* case,<sup>104</sup> the ECJ upheld the right of the EC to pursue a policy of ‘zero tolerance’ in regard to the contamination of animal feed by material that possibly contained the BSE-causing agent, even in circumstances where the contamination was probably accidental and there was scientific uncertainty as to the minimum amount of infected material needed to cause the disease in humans (see Alemanno 2004: 319–323). The Court came to this conclusion on the basis that that policy had been adopted ‘on the recommendation of experts having at their disposal the relevant scientific data’ and that it formed ‘part of a coherent body of legislation the purpose of which is to combat TSEs’.<sup>105</sup> By relying on the same deferential standard of review, the Court has recently overturned, in *CEVA*, a CFI finding that the Commission had failed to act to establish a maximum residue level for progesterone under Regulation 2377/90.<sup>106</sup> While the CFI found

that the political and scientific complexity of the progesterone scientific file ‘does not excuse the Commission’s inaction’, the ECJ confirmed that

‘in delicate and controversial cases, the Commission must have a sufficiently broad discretion and enough time to submit for re-examination the scientific questions which determine its decision’.<sup>107</sup>

Although EC courts have developed different standards of review depending on whether the health claim stems from the EC or a Member State,<sup>108</sup> they have generally tended, under both standards, not to get involved in the scientific issues underlying the contested measure and have refrained from examining the merits and the methodologies of the scientific findings advanced by the parties.

However, the *Pfizer* judgment casts some doubts not only on the EC courts’ traditional deferential approach in reviewing EC science-based measures,<sup>109</sup> but also on its traditional reticence in addressing the scientific basis of the contested regulations. This judgment has recently been followed by a line of cases in which the ECJ has shown some willingness to involve itself more in the technicalities of scientific matters when judicially reviewing science-based regulations.

### ***The Pfizer Judgment***

In this judgment,<sup>110</sup> the CFI showed a readiness to become more involved in the examination of the scientific evidence adduced by the parties to the dispute, even though the contested measure was of Community origin.<sup>111</sup> Immediately following the adoption of an EC Regulation banning the use of four antibiotics as additives in animal feedstuffs,<sup>112</sup> Pfizer, the producer of one of these antibiotics (virginiamycin), challenged the measure by alleging manifest errors in the process of risk assessment and a misapplication of the precautionary principle.

Although the CFI clearly stated from the outset that it was not for it ‘to assess the merits of either of the scientific points of view argued before it and to substitute its assessment for that of the Community institutions’, it could not prevent itself from discussing the scientific validity and merits of the scientific evidence advanced by the parties. This inevitably led the Court to engage in a quasi-scientific debate on the main scientific controversy underlying the legal dispute, i.e. whether there is a link between the use of virgiamycin as an additive in feedstuffs and the development of streptogramin resistance in humans. In particular, the Court expressly decided to consider whether, as maintained by Pfizer, the contested regulation was unlawful ‘because of the inadequate nature of the scientific data’ provided by the parties. In other words, the Court went so far in its judicial-scientific involvement as to directly ask itself whether the scientific evidence available to the EC institutions was ‘sufficiently reliable and cogent for them to conclude that there was a risk associated with the use of virgiamycin as a growth promoter’.<sup>113</sup>

For the first time, an EC Court felt the need to make an express reference to the quality of the scientific evidence that the EC institutions had relied upon. Such evidence, so the CFI found, must be ‘sufficiently reliable and cogent’.<sup>114</sup>

Before beginning its analysis, the CFI recalled that, due to the complex assessments of scientific and technical nature behind the challenged regulation

‘[...] judicial review is restricted and does not imply that the Community judicature can substitute its assessment for that of the Community institutions’.<sup>115</sup>

Notwithstanding this declared limitation, the CFI carried out a detailed review of the scientific findings brought by the parties so as to determine whether the EC institutions erred when they concluded, ‘on the basis of the scientific knowledge available at the time of the adoption of the contested

regulation', that the use of virginiamycin as an additive in feeding stuffs entailed a risk to human health. By engaging in a quasi-scientific analysis of the scientific studies advanced by the parties to the dispute, the Court found that

'[...] the Community institutions could *reasonably* take the view that they had a *proper scientific basis* for a possible link between the use of virginiamycin as an additive in feeding-stuffs and the development of streptogramin resistance in humans'.<sup>116</sup>

In other words, the Community was right to take the view that

'[...] the various experiments and observations [...] were *not mere conjecture* but amounted to *sufficiently reliable and cogent scientific evidence*'.

### ***The Vitamins Line of Cases***

A trend towards greater involvement in scientific debate by the EC courts, inaugurated in the *Pfizer* case, appears to have been followed up by a recent line of cases decided by the ECJ. In this series of cases involving fortified foods, the Court was called upon to examine four infringement proceedings brought against Denmark,<sup>117</sup> France,<sup>118</sup> Italy<sup>119</sup> and the Netherlands.<sup>120</sup> In particular, the Commission contested, firstly, the Danish and Dutch practices of requiring enriched foodstuffs lawfully produced and marketed in other Member States only to be marketed in their territories if it could be shown that such enrichment with nutrients meets a need in the Danish and Dutch populations and, secondly, the French and Italian systems of prior approval for fortified foods lawfully produced and marketed in other Member States.

In these judgments, the Court established that in order to show that the national measures are necessary to give effective protection to public health the competent authorities must base their decisions

'[...] on a *detailed assessment* of the risk alleged by the Member State invoking Article 30 EC'.

This detailed scientific requirement had originally been sketched out by the EFTA Court in the *Kellog's* case, where it was established, although within the EEA context, that Member States must, when invoking the precautionary principle, conduct a 'comprehensive evaluation of the risk to health'.<sup>121</sup>

In reference to the Italian situation the Court found directly that the Italian government had failed to show 'any alleged risk to public health' and could not 'explain on what scientific data or medical reports' it had relied.<sup>122</sup> In the case brought against France, the Court found that the scientific opinions cited by the government were not specific enough to prove the alleged risk since they refer

'vaguely to the possibility of a general risk of excessive intake, without specifying the vitamins concerned, the extent to which those limits would be exceeded or the risk incurred'.<sup>123</sup>

Moreover, in the same French case, the Court found that, contrary to the studies focusing on L-tarrate and L-carnitine, the studies it relied upon concerning drinks such as *Redbull* fulfilled the requested scientific requirement ('detailed assessment') and proved that excessive caffeine content and the presence of taurine was harmful to human health. On this basis, it concluded that the Commission had failed to explain or to adduce evidence to rebut those studies. However, the Court's opinion simply raises the question of who is to decide whether the scientific opinion a State relies upon in the adoption of public health measures is a 'detailed assessment' within the meaning of the ECJ's case law.

This line of cases shows clearly that the Court, by imposing a stricter scientific assessment process, (a 'detailed assessment') seems to be willing to get involved in scientific matters. Both the CFI (in *Pfizer/Alpharma*) and the ECJ (in the *Vitamins* line of cases) were eager to play with science by weighing the merits and assessing the validity of scientific opinions set forth by the parties to the dispute. Both courts have thus inaugurated a new

approach to scientific issues that allows them to ‘pick and choose’ those scientific opinions they believe better fulfil the minimum scientific requirements for a measure to be considered as ‘based on a detailed risk assessment’.

### *The Role of Scientific Experts before the Courts*

Following the *Pfizer* and *Vitamins* line of judgments, one may legitimately wonder whether the EC courts need a source of external expertise in order to assess the scientific plausibility of the scientific claims being put forward both by Member States and EC institutions. There are good reasons to believe that reliance on such external help might facilitate the role that EC courts are increasingly called upon to play when reviewing science-based measures.

Although under the current Statute<sup>124</sup> and their respective Rules of procedure,<sup>125</sup> both the CFI and ECJ ‘may at any time entrust any individual, body, authority, committee or other organizations it chooses with the task of giving expert opinion’, they have so far been quite reluctant to rely on external advice. This seems to be especially true for scientific matters. While the courts, notably the CFI, have ordered expert reports *inter alia* to assess the quality of a translator’s work,<sup>126</sup> an official’s mental state,<sup>127</sup> to examine the rates for and conditions of transport of mineral fuels,<sup>128</sup> price rises and the market in dyestuffs<sup>129</sup> and the economic consequences of certain gas tariffs,<sup>130</sup> they have rarely done so in scientific matters. Occasionally, the parties have themselves submitted an expert’s report or, at the hearing, an expert has addressed the Court on behalf of one of the parties.<sup>131</sup>

The decision to obtain an expert’s report is made by the Court in the form of an order after the parties have been given an opportunity to be heard. The same order appoints the experts, defines the scope of the expertise and sets a time limit for the drafting of the report.

Despite this rather simple framework for having expertise at its disposal, EC courts have traditionally been unwilling to use it.

Therefore, before sketching out a possible expertise system within the EC judicial system, it might be crucial to look at the reasons that have so far discouraged the EC courts from relying on this possibility. An explanation for the European courts' reticence in asking for external advice may be found within the EC institutional framework itself. One can easily imagine that where the courts are called upon to review scientific assessments from EC scientific committees (especially where reviewing a Community measure, for example), they might feel that submitting one of these studies to a third party review would amount to questioning both the scientific and institutional legitimacy of these committees, which ultimately belong to the same system of governance. However, this argument, which boils down to the idea that the CFI/ECJ belong to the same institutional family than the Community legislator, does not seem to be entirely persuasive if examined from a US perspective. In fact, US Federal Courts do not hesitate to review the risk assessments undertaken by federal regulatory agencies.<sup>132</sup> One can therefore wonder therefore whether this 'legitimacy' argument alone can explain the EC courts' deferential attitude vis-à-vis the scientific reports prepared by the European scientific committees.

A more credible argument for understanding this deferential approach to science marked by a Europe label refers to judicial tradition. Having traditionally not relied on scientific expertise, judges (notably the judge *rapporteur* in the EC judiciary jargon) might be somehow discouraged from proposing recourse to expertise under the courts' rules of procedure to other Court members. Finally, if tradition plays a crucial part in explaining the courts' wariness to rely on scientific experts, fears of ultimately delegating the task of solving a dispute may also exist.

In attempting to develop a credible and effective expert consultation system for EC courts when dealing with scientific matters, it is important to take due account of the institutional scientific framework upon which the Community relies when adopting legislation.

Unlike the WTO's judicial bodies, the European courts, when called upon to review a science-based measure, are likely to already have a scientific study supporting that measure or, at least, dealing with its scientific foundations. While this is certainly the case when the courts are called upon to examine the legality of an EC measure, it might not be the case when the contested regulation has been adopted by a Member State. In the latter case, the national measure is supported instead by a national scientific opinion produced by its own authorities.

Against this backdrop, one may wonder what body might be available for consultation by the EC courts to examine the scientific adequacy of the evidence brought by the parties to the dispute. Should they ask the EC scientific committee members, perhaps those sitting within EFSA, to review the evidence they have themselves developed? Or should they rely on some third-party scientists? And *quid* in cases of science-based national measures? Should the Court submit the national scientific evidence to the scrutiny of the EC scientific committees?

It is extremely difficult to answer this very last question as there is no hierarchy between research bodies and their scientific advice. It is therefore problematic to see how, in the event of conflicting scientific studies, it could be justified to follow one set of scientific opinions rather than another.

#### *Peer Review as an Alternative Method to External Expertise*

A valid alternative method to external expertise might be represented by reliance on peer review.<sup>133</sup> This is a formal science-based process that is traditionally used when a scientific work is nearly complete, and utilises

independent experts who were not involved in the development of the scientific study.

Although it is used primarily by publishers to select and screen submitted manuscripts,<sup>134</sup> and by funding bodies, to decide the awarding of research funding, the peer review process is also utilised for risk assessment procedures. In these circumstances, it involves an in-depth assessment of the assumptions, calculations, alternate interpretations, methodology and conclusions. In particular, by taking the form of a deliberation, it involves an exchange of judgments about the appropriateness of methods and the strength of the author's inferences.<sup>135</sup>

The practice of peer review of risk assessment products is not entirely unknown in the Community or in the WTO. Thus, for instance, within the framework of the European directive on the placing of plant protection products on the market, EFSA has launched a peer review of the assessments made by Member States with the aim of creating a 'positive list' of pesticides.<sup>136</sup>

It is thus suggested that, like decision-makers, courts can also rely on peer review, by either asking experts to peer review the scientific evidence advanced by the parties or by simply showing deference to that evidence whenever it has been subject to peer review.

One of the main advantages stemming from judges' reliance on peer review is that, via this tool, they might determine the exact scope of experts' review, by, for instance, asking them to distinguish scientific facts from professional (science policies) judgments.

This might turn out to be especially useful in the current EC risk analysis framework, which does not recognise that uncertainty is inherent in science and that in many cases scientific studies do not produce conclusive evidence.

In particular, it is suggested that proof of a prior peer review must give rise to a presumption of conformity of that evidence with the relevant scientific evidence. However, prior peer review is not by itself sufficient ground for triggering such a presumption. There is clearly a need for some evidence proving the adequacy of prior peer review. Thus, for instance, publication in an important scientific journal may mean that adequate peer review has been performed.

An example of such a deferential approach to peer reviewed scientific evidence may be seen in *Methanex*,<sup>137</sup> a recent case decided by the North American Free Trade Agreement's NAFTA Tribunal under the provisions in the NAFTA Chapter 11 on investment and the UNCITRAL arbitration rules.<sup>138</sup> At the heart of this case was an investment dispute between the Canadian-based Methanex Corporation and the United States. Methanex is a major producer of methanol,<sup>139</sup> a gasoline additive that was banned by California in 2002 on environmental and human health grounds. Methanex, having submitted a claim to NAFTA, argued, *inter alia*, that the ban was not a genuine environmental measure but a disguised restriction of trade.<sup>140</sup> In replying to this argument, the NAFTA Tribunal, 'having considered all the expert evidence adduced', accepted the scientific evidence underpinning the contested measure 'as reflecting a serious, objective and scientific approach to a complex problem in California'. In particular, the Tribunal came to this conclusion by taking account of the fact that this scientific evidence 'was subject at the time to public hearings, testimony and peer-review'. In light of the above, it concluded that

'its emergence as a serious scientific work from such an *open and informed debate* is the best evidence that it was not the product of a political sham engineered by California'.<sup>141</sup>

I believe that there is a great deal to be learned from this use of peer-review within the EC judicial review of science-based measures and that, if well-

tuned, it might even represent a valuable alternative to expert consultation mechanisms.

## Conclusion

Despite the flaws and limitations that we have highlighted, the emerging risk regulatory framework, by denying any supremacy to the EC sources of scientific opinions over national advice, preserves Member States' rights to carry out their own scientific studies and even strengthens their roles through the establishment of the European networking of scientific authorities. In particular, it is argued that the deliberate choice not to turn EFSA into an Oracle of Delphi, spelling out the 'truth' in all scientific matters, while likely to bring about conflicts among Member States, may be seen as an attempt to reconcile science, traditions, consumer concerns and free movement. Accordingly, in cases of diverging opinions between the EFSA and national food authorities, it is up to the EC courts, and not to EFSA, to solve these conflicts by striking a balance between the European (universal) and a national (local) vision of both safety and of the socio-cultural perception of a particular food (Chalmers 2003: 534). Furthermore, the EC risk management policy, which allows risk managers to take into account 'other factors legitimate to the matter under consideration' and the precautionary principle in addition to hard scientific opinions<sup>142</sup> must be applauded to the extent that it embraces the political nature of risk regulation. However, to maintain the original goals pursued by the functional separation between risk assessment and risk management, it is absolutely imperative to render science policies explicit by furthering the current efforts aimed at elaborating guidance documents for each EFSA panels.<sup>143</sup>

As to the role played by scientific expertise before courts within the emerging European regulatory framework, it has been illustrated that

scientific opinions, as non-legally binding acts but rather mere preparatory acts, do not seem susceptible of judicial review as such. However, as scientific evidence is becoming crucial at all stages of the creation of new legislation, EC Courts are increasingly called upon to review science-based measures. In so doing, Courts have generally avoided becoming enmeshed with scientific evidence by showing great deference to the technical and complex assessments underpinning the contested measures. However, some recent cases show a readiness of the Courts to become more involved in the examination of the scientific evidence presented, even where the contested measure has a Community origin. To mitigate partly the difficulties faces by the Courts in performing this difficult task it has been suggested that they should rely primarily on peer-review mechanisms rather than on external consultation procedures.

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## Notes

<sup>1</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council 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, *OJ* 2002 L 31 (hereinafter: the Regulation).

<sup>2</sup> See, e.g., Council Directive 1999/30/EC of 22 April 1999 relating to limit values for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter and lead in ambient air (*OJ* L 163) and Directive 2001/80/EC of the European Parliament and of the Council of 23 October 2001 on the limitation of emissions of certain pollutants into the air from large combustion plants (*OJ* L 309).

<sup>3</sup> Risk assessment of existing chemicals is provided by Council Regulation (EEC) 793/93 (*OJ* L 84) and Commission Regulation (EC) 1488/94 (*OJ* L 161). As for new chemicals, risk

assessment procedures are imposed by Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Directive 67/548/EEC, *OJ L 227*. See also CEC, Commission of the European Communities, *Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (Reach), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) (on Persistent Organic Pollutants)* COM(2003) 644 final, 29 October 2003, Brussels.

<sup>4</sup> Directive 98/08/EC concerning the placing of biocides on the market, *OJ L 150*, p. 71.

<sup>5</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, *OJ L 106*. Moreover, under Article 8 of the Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (*OJ L 43*), a novel food or food ingredient is considered to be “equivalent” to its conventional counterpart unless established risk assessment techniques can prove that this is not the case.

<sup>6</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, *OJ L 230*, p. 1-32. See also the 1998 Rotterdam PIC Convention which requires a “risk evaluation” as a precondition for regulatory action.

<sup>7</sup> Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (*OJ L 40*) according to which the food additive must be subjected to appropriate testing and evaluation.

<sup>8</sup> See Article 16(2) of Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, *OJ L 327*.

<sup>9</sup> Council Directive 80/1107/EEC of 27 November 1980 on the protection of workers from the risks related to exposure to chemicals, physical and biological agents, *OJ L 327/8*; Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage the improvements in the safety and health of workers at work, *OJ L 183*; Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work, *OJ L 196*.

<sup>10</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>11</sup> Case 178/84, *Commission v. Germany* [1987] ECR 1227.

<sup>12</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.

<sup>13</sup> Case 178/84, *Commission v. Germany* [1987] ECR 1227, para 48.

<sup>14</sup> Case 174/82, *Sandoz BV* [1983] ECR 2445, para 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 on this case, see Slotboom 2003: 557.

<sup>15</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>16</sup> Case 304/84 *Ministère Public v. Muller and others* [1986] ECR 1511.

<sup>17</sup> Case 178/84 *Commission v. Germany* [1987] ECR 1227, para 44.

<sup>18</sup> Case C-42/90 *Bellon* [1990] ECR 4863, at 14.

<sup>19</sup> Case C-13/91 and C-113/91 *Debus* [1992] ECR 3617, at 17.

<sup>20</sup> In *KYDEP*, involving the Community rules governing the maximum levels of radioactive contamination permissible in foodstuffs following the Chernobyl nuclear accident, the ECJ has 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”. See Case C-146/91 *Koinopraxia Enóseon Georgikon Synetairismou Diacheiríséos Enchorion Proïonton Syn. PE (KYDEP) v. Council and Commission* [1994] ECR 4199, at 42.

<sup>21</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”.

<sup>22</sup> Although a similar scientific requirement is not expressly provided for with reference to the situation in which a Member State does *maintain* a measure derogating from a harmonized measure (Article 95, paragraph 4), it may reasonably be argued that a scientific requirement is also *de facto* imposed within the context of the application of paragraph 4 of Article 95. See Alemanno 2007a: 300.

<sup>23</sup> Article 174, paragraph 3, EC.

<sup>24</sup> See Article 174, paragraph 2, EC.

<sup>25</sup> Article 100a(3) of EC, current Article 95, paragraph 3.

<sup>26</sup> Article 95, paragraph 3, EC. See also, Articles 152 (1) and (4), 153, 174 (2).

<sup>27</sup> CEC, Commission of the European Communities, *Communication from the Commission on consumer health and food safety*, COM(97) 183 final, 30 April 1997, Brussels.

<sup>28</sup> *Ibid.*

<sup>29</sup> See Commission Decision 2004/210/EC of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment, *OJ L* 66, recital 6 of the Preamble.

<sup>30</sup> Communication from the Commission on Consumer Health and Food Safety, *supra* note 27, and CEC, Commission of the European Communities, *Communication on the precautionary principle*, COM(2000) 1, 2 February 2000, Brussels.

<sup>31</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 L* 214.

<sup>32</sup> Commission Decision 2004/210/EC, *supra* note 29, pp. 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.

<sup>33</sup> CEC, Commission of the European Communities, COM(2002) 713 final, 11 December 2002, Brussels.

<sup>34</sup> Commission Decision 2004/210/EC, *supra* note 29, p. 45.

<sup>35</sup> Whenever the Commission departments collect and use the advice of experts from outside the responsible department they should ensure quality, by seeking advice from an appropriately high quality source (i.e. based on the principles of excellence, independence and pluralism), by showing flexibility when looking for advice, and effectiveness, by making sure that its methods for collecting and use of expert advice are effective.

<sup>36</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 being editing and will be published shortly (*sic!*).

<sup>37</sup> For decades the National Research Council (NRC) has been called on to consider how to improve decisions about risks to public health, safety and environmental quality. The NRC has conducted a series of studies on how society can understand and cope with those risks. In particular, the distinction between risk assessment and risk management was 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. However, as we will see further, later publications of the NRC recognized the difficulties of maintaining a sharp dividing line between the two processes and emphasized the importance of ensuring interaction and communication between risk assessors and risk managers. See Stern and Fineberg 1996 and for a brief account of this development see also Suezener, Tamplin, Buchanan, Dennis, Tollefson and Hart 2003.

<sup>38</sup> See, within the U.S., National Academy Press 1994: 4 (prepared by a Committee of the National Research Council/National Academy of Science in response to a U.S. Environmental Protection Agency request mandated by the Clean Air Act Amendments of 1990); see, within the OECD 2003; see within FAO/WHO 1995:6; Joint FAO/WHO (1997); Joint FAO/WHO (1998).

<sup>39</sup> This separation was originally introduced by the 1997 Communication on Consumer Health and Safety, *supra* note 27, and subsequently confirmed by the CEC, Commission of the European Communities, *Green Paper on Food Law*, COM(97) 176 final, 30 April 1997, and the *White Paper on Food Safety*, COM(99) 719, 12 January 2000, para 32.

<sup>40</sup> Among the major drivers for this separation was a clear desire to remove value judgments from risk assessment and to prevent risk assessors from being unduly influenced by risk managers.

<sup>41</sup> According to the Commission's White Paper, the EFSA should not be entrusted with risk management tasks because this would reduce democratic accountability within the Union, *supra* note 39, at 32.

<sup>42</sup> Opinion in Case 192/01 Commission v. Denmark [2003] ECR 9693.

<sup>43</sup> Case T-13/99 Pfizer Animal Health v. Council [2002] ECR II-3305, at 157. See already Case 212/91, Angelopharm v. Freie Hansestadt Hamburg [1993] ECR I-171, paras 31-33.

<sup>44</sup> Several provisions of the Regulation provide that risk management decisions may consider not only risk assessment but also “other legitimate factors”. See preamble (19), Article 3 (12) and Article 6 (3). See also, e.g., Article 7(1) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, *OJL* 287.

<sup>45</sup> The Regulation, *supra* note 1, Recital (19).

<sup>46</sup> The list of examples provided by the Preamble of the Regulation seems slightly narrower than that contained within the White Paper (see *supra* note 39, para 4), which mentions “environmental considerations, animal welfare, sustainable agriculture, consumers’ expectation regarding product quality, fair information and definition of the essential characteristics of products and their process and production methods”. However, as both lists contain only mere examples, their differences do not carry any particular value and should not be overemphasised.

<sup>47</sup> Commission Communication on the precautionary principle, *supra* note 30, at 5 of the summary.

<sup>48</sup> For a comparison between the EC and WTO risk analysis schemes, see Alemanno 2007a: 387 ss.

<sup>49</sup> See Appellate Body Report, European Communities – Measures Concerning Meat and Meat Products, WT/DS26/AB/R, WT/DS48/AB/R (January 16, 1998) (adopted February 13, 1998; Panel Report, European Communities – Measures Concerning Meat and Meat Products, WT/DS26/R/USA (August 18, 1997) (hereinafter: *EC-Hormones*). For a detailed reconstruction and insightful analysis of the dispute, see Christoforou 2003: 239 and Wüger 2002: 777.

<sup>50</sup> On this dispute, notably on its genesis, see, e.g., Christoforou 2000: 622 ss.; Scott 2000; Pardo Quintillán 1999: 147; Howse 2000: 2329.

<sup>51</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>52</sup> Case C-180/96, United Kingdom v. Commission [1998] ECR 3903, at 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>53</sup> This Agreement subjects all sanitary and phytosanitary measures to scientific evidence and risk assessment procedures by imposing on Member States the duty to demonstrate that their measures are necessary to protect human health. Under the existing SPS Agreement, scientific

evidence is, at least textually, the only legitimate criterion upon which to base SPS measures. For more on the WTO/SPS framework, see Alemanno 2007a: 227-290.

<sup>54</sup> This distinction has been criticised for being artificial and difficult to maintain in reality. For a European perspective, see Noiville and De Sadeleer 2001: 406-408; and, more, recently, Ladeur 2003: 1465. For a U.S. perspective, see Walker 2003: 252 and Wirth 1994: 833-834.

<sup>55</sup> These may be defined as “decision rules about the way in which risk assessment scientists should proceed when they encounter specified types of uncertainties”, which are established at political level. See Walker 2003: 214. One of the most common science policies is the presumption that a certain agent that can cause disease in laboratory animals can equally cause disease in humans. Other examples include the use of a linear dose-response model, the assumption that absorption in animals and humans is approximately the same or the use of body weight scaling for interspecies comparisons.

<sup>56</sup> It is argued that in the EC food context, where the question of science policies has not specifically been addressed at regulatory level, the European Food Safety Authority is never simply conveying information, but is inevitably endorsing a particular ideological model of politics. Along these lines of thought, see Chalmers 2003: 543.

<sup>57</sup> CEC, Commission of the European Communities, *European Governance: A White Paper*, COM(2001) 428 final, 25 July 2001, Brussels; CEC, Commission of the European Communities, *Communication on the Collection and Use of Expertise by the Commission: Principles and Guidelines*, COM(2002) 713 final, 11 December 2002, Brussels; CEC, Commission of the European Communities, *The Operating Framework for the European Regulatory Agencies*, COM(2002) 718 final, 11 December 2002, Brussels.

<sup>58</sup> Most of the EFSA scientific panels are in the process of adopting guidance documents aimed at establishing a method for conducting risk assessment. Thus, for instance, the Scientific Panel on Genetically Modified Organisms has adopted a Guidance document for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use (The EFSA Journal (2006) 374, 1-115 Summary) and also a Guidance document for the risk assessment of genetically modified plants and derived food and feed (the EFSA Journal (2004) 99, 1-94).

<sup>59</sup> Although officials' attendance is subject to the condition that they “shall not seek to influence discussions”, it is likely that their mere presence at the meetings may in some cases influence the delivery of scientific opinions. Thus, the scientists, depending on the circumstances, may be inclined to deliver the anticipated opinion or they may fail to take due account of some scientific information available to them. According to Greenpeace, the latter has already happened in EFSA's assessment of the first two genetically engineered crops

submitted to its examination. Greenpeace has severely criticised European scientists for having ignored two critical scientific factors. See Alemanno 2007a: 213–215.

<sup>60</sup> For more on the relationship existing between EFSA and the Commission, see Gabbi 2007: 131 and Alemanno 2007b: 610–611, 627–629.

<sup>61</sup> A recent initiative has been launched by the European Consumer Safety Association (ECOSA) on the occasion of the Edinburgh Risk Assessment Conference. A working party has been established with the aim of developing a common nomenclature for risk assessors and a more standardised framework for the actual risk assessment process.

<sup>62</sup> The European Commission decided on 10 June 1997 to create a Scientific Steering Committee (SSC) in the field of consumer health and food safety. The detailed mandate of this Committee is available at <[http://ec.europa.eu/food/fs/sc/ssc/index\\_en.html](http://ec.europa.eu/food/fs/sc/ssc/index_en.html)>.

<sup>63</sup> Updated Opinion of the Scientific Steering Committee on Harmonisation of Risk Assessment Procedures, adopted on 10 April 2003, at 2.

<sup>64</sup> Case 247/84 Motte [1985] ECR 3887, para 20, in which the Court said that Member States must “take into account” the results of international scientific research, but where it also stated that “it must be emphasised that the Opinions of the Committee do not have binding force”.

<sup>65</sup> The Regulation, *supra* note 1, Article 22 (6).

<sup>66</sup> This conclusion deserves to be further elaborated by reference to those situations in which EFSA risk assessment is required by EC vertical legislation. In these circumstances, EFSA opinions enjoy the express status recognised by the legislation. Thus, for instance, under the GMO pre-market approval system, where the Commission decision is not in accordance with the EFSA opinion, the Commission must provide an explanation for the differences. See Article 7 of Regulation 1829/2003, *supra* note 44 (which reads: “[...] where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences”). See on this point Krapohl 2004: 532.

<sup>67</sup> Case 247/84 Motte [1985] ECR 3887, para 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>68</sup> The Regulation, *supra* note 1, Preamble (34) and (47), Article 22 (7).

<sup>69</sup> The Regulation, *supra* note 1, Article 30 (1).

<sup>70</sup> Although it is not expressly provided within the Regulation, this duty of cooperation must be read in light of Article 10 of the EC Treaty.

<sup>71</sup> The Regulation, *supra* note 1, Article 30 (3–4). This system recalls the compulsory notification system of draft technical regulations to the extent that it functions as a preventive

mechanism (sort of 'early-warning') aimed at solving *ex ante* any conflict arising between the national and European views of risk.

<sup>72</sup> The Regulation, *supra* note 1, Article 36 of the Regulation titled "Networking of organisations operating in the fields within the Authority's mission".

<sup>73</sup> The Regulation, *supra* note 1, Article 38.

<sup>74</sup> Article 4 of Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the field within the European Food Safety Authority's mission, *OJ L* 379. Under the same regulation, Member States are required to forward to the Authority, with a copy to the Commission, the names and details of the designated organisations, evidence that they comply with the criteria set out by Regulation 2230/2004 and details of their specific fields of competence.

<sup>75</sup> Case T-13/99 Pfizer Animal Health v. Council [2002] ECR II-3305. See also the parallel case T-70/99 Alpharma v. Council [2002] ECR II-3495.

<sup>76</sup> See Article 7 of Regulation 1829/2003, *supra* note 44.

<sup>77</sup> The Regulation, *supra* note 1, Article 14 (9).

<sup>78</sup> The Regulation, *supra* note 1, Article 6 (3).

<sup>79</sup> The Regulation, *supra* note 1, Article 14 (1).

<sup>80</sup> Cases C-211/03, C-299/03 and C-316/03 to C-318/03, HLH Warenvertriebs GmbH [2005] ECR 5141, at 94.

<sup>81</sup> *Ibid.*, at 93.

<sup>82</sup> *Ibid.*, at 94.

<sup>83</sup> Article 17 of Council Regulation (EEC) No 302/93 of February 1993 on the establishment of a European Monitoring Centre for Drugs and Drug Addiction, *OJ L* 36, p. 1. This provision clearly states that "the Court of Justice shall have jurisdiction in actions brought against the Centre under the conditions provided for under Article 173 [now 230] of the Treaty". See also Article 15(3) of Council Regulation (EC) No 1035/97 of 2 June 1997 establishing a European Monitoring Centre on Racism and Xenophobia, *OJ L* 151, p. 1.

<sup>84</sup> Articles 57 and 63 of Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark, *OJ L* 11, p. 1.

<sup>85</sup> This is the case, for instance, of the Community Plant Variety Office (CPVO) as established by Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights, *OJ L* 227, p. 1.

<sup>86</sup> According to the Regulation, *supra* note 1, Article 47: "1. [t]he contractual liability of the Authority shall be governed by the law applicable to the contract in question. The Court of

Justice of the European Communities shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Authority. 2. In the case of non-contractual liability, the Authority shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or its servants in the performance of their duties. The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damage. 3. The personal liability of its servants towards the Authority shall be governed by the relevant provisions applying to the staff of the Authority”.

<sup>87</sup> Article 230 EC Treaty, paragraph 1, reads: “[t]he Court of Justice shall review the legality of acts adopted jointly by the European Parliament and the Council, of acts of the Council, of the Commission and of the ECB, other than recommendations and opinions, and of acts of the European Parliament intended to produce legal effects vis-à-vis third parties”.

<sup>88</sup> This obstacle would per se not appear insurmountable to the extent that the ECJ, in the past, has shown itself to be ready to interpret broadly the category of acts reviewable under Article 230 EC. See Case 294/83, *Les Verts v. Parliament*, ECR 1986, p. 1339 and Case 193-4/87, *Maurissen v. Court of Auditors*, ECR 1989, p. 1045. In these judgments the ECJ considered that insofar as the Community is based on the rule of law, acts not mentioned in Article 230 EC are also capable of forming the subject of an action for annulment.

<sup>89</sup> It is precisely by relying on this argument that the CFI, in *Associazione delle cantine sociali venete*, declared inadmissible an action for a failure to act directed against the European Ombudsman. Case T-103/99 *Associazione delle cantine sociali venete v. Médiateur européen and Parliament* [2000] ECR II-4165, paras 44-48. For a detailed analysis and comment of this judgment, see Raimondi 2004: 547 ss.

<sup>90</sup> Case 60/81 *IBM v. Commission* [1981] ECR 2639, paras 9-10 and order of 24 March 2006 in Case T-454/05 *R Sumitomo Chemical AGRO Europe and Philagro France v. Commission*, not published in the ECR, paragraph 50.

<sup>91</sup> Under Article 230 EC, judicial persons can easily challenge the legality of Community decisions when these decisions are *addressed* to them. However, the same article provides for a very demanding *locus standi* requirement where the act challenged is not a decision. Under the fourth paragraph of Article 230 EC, an individual may institute proceedings against other acts only when these are "of direct and individual concern".

<sup>92</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 II-4945, at 197.

<sup>93</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 II-4945.

<sup>94</sup> Thus, for instance, the Scientific Panel on Genetically Modified Organisms has adopted a Guidance document for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use (The EFSA Journal (2006) 374, 1-115 Summary) as well as a Guidance document for the risk assessment of genetically modified plants and derived food and feed (the EFSA Journal (2004) 99, 1-94).

<sup>95</sup> Orders of the President of the CFI delivered on March 1, 2007, Case T-397/06 R Dow AgroSciences Ltd v. EFSA and Cases T-311/06 R I, T-311/06 R II, T-312/06 R I and T-313/06 R FMC Chemical SPRL, Arysta Lifesciences SAS and Otsuka Chemical Co. Ltd, not yet reported.

<sup>96</sup> Dow AgroSciences, *supra* note 95, at 39.

<sup>97</sup> Article 33(1) of the European Coal and Steel Community reads: “[...] The Court of Justice may not, however, examine the evaluation of the situation, resulting from economic facts or circumstances, in the light of which the Commission took its decisions or made its recommendations, save where the Commission is alleged to have misused its powers or to have manifestly failed to observe the provisions of this Treaty or any rule of law relating to its application”.

<sup>98</sup> This is settled case law. See, in particular, in the competition law field, Joined Cases 56/64 and 58/64 Consten and Grundig v. Commission [1966] ECR 299, at page 347; in the agricultural field, Case 55/75 Balkan-Import Export v. Hauptzollamt Berlin-Packhof [1976] ECR 19, at 8 and Case 98/78 Racke v. Hauptzollamt Mainz [1979] ECR 69, para 5; Case 265/87 Schröder [1989] ECR 2237, para 22; Joined Cases C-267/88 to C-286/88 Wuidart and Others [1990] ECR I-435, para 14; Case C-331/88 Fedesa and Others [1990] ECR I-4023, at 14; Case C-157/96 National Farmers' Union and Others [1998] ECR I-2211, at 39; in the civil servants case law, Case 9/82 Øhrgaard and Delvaux v. Commission [1983] ECR 2379, at 14; in the state aid field, Case C-225/91 Matra v. Commission [1993] ECR I-3203, at 24-25. However, it should be noted that in the field of competition law the CFI has recently shown that it was ready to perform an in-depth analysis of the Commission's decisions. See for instance, the Babyliis case, T-114/02 [2003] ECR II-1279.

<sup>99</sup> Decision 96/239/EC of 27 March 1996 on emergency measures to protect against bovine spongiform encephalopathy, OJ L 78.

<sup>100</sup> Case C-157/96, National Farmers' Union and Others [1998] ECR I-2211, para 39; referring to Case 98/78 Racke v. Hauptzollamt Mainz [1979] ECR 69, para 5.

<sup>101</sup> Case 138/79 Roquette Frères v. Council [1980] ECR 3333, para 25; Joined Cases 197/80 to 200/80, 243/80, 245/80 and 247/80 Ludwigshafener Walzmühle v. Council and Commission [1981] ECR 3211, para 37; Case C-27/95 Bakers of Nailsea [1997] ECR I-1847,

para 32; Case C-4/96 Nifpo and Northern Ireland Fishermen's Federation [1998] ECR I-681, paras 41 and 42; Case C-120/97 Upjohn [1999] ECR I-223, para 34; and Spain v. Council, cited at para 115 above, para 29 and, lastly, T-13/99, Pfizer, *supra* note 75, at 168.

<sup>102</sup> See Case C-120/97, Upjohn Ltd [1999] ECR 223, para 34. 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, at page 347. See, in particular, the most recent interpretation of this judgment in Case C-168/01 GlaxoSmithKline Services Unlimited v. Commission [2006] not yet reported, at 241 where it is said that: "the Court dealing with an application for annulment of a decision applying Article 81(3) EC carries out, in so far as it is faced with complex economic assessments, a review confined, as regards the merits, to verifying whether the facts have been accurately stated, whether there has been any manifest error of appraisal and whether the legal consequences deduced from those facts were accurate".

<sup>103</sup> See Case T-13/99 Pfizer Animal Health v. Council [2002] ECR II-3305, paras 168-69 and 323.

<sup>104</sup> Case C-286/02 Bellio F.lli Srl v. Prefettura di Treviso [2004] not yet reported.

<sup>105</sup> Case C-286/02 Bellio F.lli Srl v. Prefettura di Treviso [2004], para 61.

<sup>106</sup> Case C-198/03 P, Commission v. Ceva/Pfizer [2005], not yet reported.

<sup>107</sup> *Ibid.*, at 75.

<sup>108</sup> While the EC judiciary shows itself to be quite deferential in examining the EC's efforts to attain a high level of protection of health, through the adoption of food (and feed) safety regulations, when it comes to the Members States' use of science in pursuing health protection goals, it adopts a more intrusive approach. In particular, the Courts are demanding in assessing whether the contested measure is adequately backed up by credible scientific evidence. For a possible explanation of this phenomenon, see Alemanno 2007a: 325-336.

<sup>109</sup> Case T-13/99 Pfizer Animal Health v. Council [2002] ECR II-3305.

<sup>110</sup> See also the parallel case that concerned the same decision, revoking the authorization of some antibiotics as growth promoters: T-70/99, Alpharma Inc. v. Council [2002] ECR II-3495. For a comment on these two judgments, see *ex multis*, Walker 2003: 207-208; Vos 2004; Mariatte 2002: 12; Gonzalez Vaqué 2002: 925, n. 13 and Alemanno 2002: 842.

<sup>111</sup> Contra, see Peel 2004: 43 who argues that "Although the Court stressed that regulatory authorities must have at their disposal scientific information which is sufficiently reliable and cogent to allow them to understand the ramifications of the scientific questions raised and to make a decision on policy measures in full knowledge of the facts, the CFI displayed a

“strongly deferential attitude when reviewing the institutions’ interpretation of the scientific material and their judgments as to the existence of genuine scientific uncertainty”.

<sup>112</sup> These antibiotics were used as growth promoters, with the useful side effect of preventing certain animal diseases.

<sup>113</sup> Case T-13/99 Pfizer Animal Health v. Council [2002] ECR II-3305, at 322.

<sup>114</sup> *Ibid.*, para 162.

<sup>115</sup> *Ibid.*, para 323.

<sup>116</sup> *Ibid.*, para 393.

<sup>117</sup> Case 192/01 Commission v. Denmark [2003] ECR 9693.

<sup>118</sup> Case C-24/00 Commission v. France [2004] ECR I-1277.

<sup>119</sup> Case C-270/02 Commission v. Italy [2004] ECR I-1559.

<sup>120</sup> Case C-41/02 Commission v. Netherlands [2004] ECR I-11375.

<sup>121</sup> EFTA Court of 5 April 2001, Case E-3/00 Efta Surveillance Authority v. Norway, in EFTA Court Report 2000/2001, p. 73, para 30. For a comment of this case, see Alemanno 2001: 947-950.

<sup>122</sup> Commission v. Italy, *supra* note 119, para 24.

<sup>123</sup> Commission v. France, *supra* note 118, para 61.

<sup>124</sup> EC Statute Article 25.

<sup>125</sup> ECJ Rules, Article 49 and CFI Rules, Article 70.

<sup>126</sup> Case 10/55, Mirosevich v. High Authority [1954-56] ECR 333.

<sup>127</sup> Case 12/68, X v. Audit Board [1969] ECR 109.

<sup>128</sup> Case 24 and 34/58 Chambre syndicale de la Sidérurgie de l'Est v. High Authority [1960] ECR 281.

<sup>129</sup> Case 48/69 ICI Ltd v. Commission [1972] ECR 619.

<sup>130</sup> Case C-169/84, Société CdF Chimie Azote et Fertilisants SA [1990] ECR 3083.

<sup>131</sup> Case 204/80 Procureur de la République v. Vedel [1982] ECR 465.

<sup>132</sup> See on this point McGarity 2003: 155.

<sup>133</sup> For an introduction to peer-review and to the different types of peer involvement, see, e.g., Office of Management and Budget, Final Information Quality Bulletin for Peer Review, 15 December, 2004 and Patterson, Mekk, Strawson, Liteplo 2007: 1609-1621.

<sup>134</sup> As a result, publications and awards that have not undergone peer review are likely to be regarded with suspicion by scholars and professionals in many fields.

<sup>135</sup> See the Final Information Quality Bulletin for Peer Review by the Office of Management and Budget (OMB), December 2004, at 2.

<sup>136</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (*OJ L 230*, p. 1-32) was required to be implemented by Member States from 26 July 1993. The peer-review process is managed by EFSA's Pesticide Risk Assessment Peer Review Unit (PRAPeR).

<sup>137</sup> *Methanex Corp. vs. the United States of America*, Final Award of the Tribunal on Jurisdiction and Merits, in the matter of an international arbitration under chapter 11 of the north American free trade agreement and the UNCITRAL arbitration rules (Sagarika 2006: 110-114).

<sup>138</sup> The text of the NAFTA Agreement is available at <<http://www.nafta-sec-alena.org/>>.

<sup>139</sup> This substance is a key component in MTBE (methyl tertiary butyl ether), which is used to increase oxygen content and act as an octane enhancer in unleaded gasoline.

<sup>140</sup> In particular, the plaintiff argued that the California ban was tantamount to an expropriation of the company's investment; a violation of NAFTA's Article 1110, and was enacted in breach of the national treatment (Article 1102) and minimum international standards of treatment (Article 1105) provisions. By relying on these arguments, Methanex sought financial compensation from the United States to the amount of over \$900 million U.S.

<sup>141</sup> *Ibid.*

<sup>142</sup> The Regulation, *supra* note 1, Article 6 (3).

<sup>143</sup> Most of the EFSA scientific panels are in the process of adopting guidance documents establishing a method of conducting risk assessment. Thus, for instance, the Scientific Panel on Genetically Modified Organisms has adopted a Guidance document for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use (The EFSA Journal (2006) 374, 1-115 Summary) and also a Guidance document for the risk assessment of genetically modified plants and derived food and feed (the EFSA Journal (2004) 99, 1-94).

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