Risk Assessment in the European Food Safety Regulation: Who is to Decide Whose Science is Better? *Commission v. France* and Beyond…

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A. Introduction

The outbreak of bovine spongiform encephalopathy (hereinafter BSE) in Europe has brought about serious tensions and fears – not only among consumers, but also among the national and European authorities responsible for risk management. Faced with the incapacity of the existing system to control the situation, on the one hand,[1] and the need to restore consumers' confidence on the other, the EU and national regulators felt obliged to repair the weaknesses as soon as possible. However, remedial actions undertaken at the time of the BSE crisis were not always the product of thorough consultations and they were often not well coordinated. Thus, they became a source of disagreement among the various actors in play. The case *Commission v. France*,[2] which I will examine more closely in this paper, illustrates such a conflict among the national and European scientific authorities. The judgment was delivered in 2001, but the problem of the successful integration of science into the regulatory decision-making process of the EU still remains unsettled. In this paper I will present suggestions as to how the situation could be influenced by the outcomes of recent reforms of European food safety law and the establishment of the European Food Safety Authority.

In the first part of the paper I will present a brief overview of the development of food safety law and policy in the European Union. In the second part, I will analyze the *Commission v. France* case. After a short description of the factual and legal background of the conflict, I will present the crucial points of the judgment of the European Court of Justice with special regard to the issue of risk assessment. This

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[1] *See* R. Miller, *As Germany Comes to Grip with Its Own Mad-Cow Crisis, Where Was the EU?*, 2 GERMAN LAW JOURNAL, No 2 (1 February 2001), *at* www.germanlawjournal.com.

[2] Case C-1/00, *Commission v. France*, [2001], ECR I-9989.

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particular issue will be analyzed in a broader context, with special emphasis placed on the possible developments in the area of science-based decision-making in the light of the reform of the European food regulation and administration.

I. Background to the Problem: Food Safety in Europe – Now and Then

The BSE crisis[3] has been the catalyst for several major changes in the European food safety regime and, therefore, in this paper, I shall treat it as a turning point in its history. Consequently, the following short presentation of the EU attitude towards the issue will be divided into two parts: before and after the outbreak of BSE.

The change in the European attitude towards food safety regulation can be illustrated very appropriately with the following quotation from the European Commission Green Paper on Food Law:

"Health protection in relation with consumption of foodstuffs is to be an absolute priority at any time and not only something to be looked at in emergency situation." [4]

II. European Food Safety Before the BSE Crisis

Food safety has proven to be a highly sensitive area of law and policy making. For decades, Member States have treated food issues as a matter of national competence. This is probably why the attitude taken by Europe towards food safety regulation was initially marked by general hesitance. This was partly due to a lack of any strong legal basis for any Community action in the field, but also to the awareness of the great importance attached to food issues at the national level. Consequently, most of the Community rules in the area were created on an *ad hoc* basis or were developed by ECJ jurisprudence,[5] and they were generally of a harmonizing and trade-facilitating character. So, until the outbreak of the food crises in the nine-

[3] Useful information on the nature of BSE, the BSE crisis and measures taken to control it can be found in a publication by the European Commission, DG XXIV: *BSE Guide. Information for consumers*. GIS-BSE (96) 7.5 or. (FR), 29.10 1996, *available at* http://www.europa.eu.int/comm/food/food/biosafety/bse/bse07_en.pdf, as well as in a FAQ section *at* http://www.europa.eu.int/comm/food /food/biosafety/bse/m03_3_en.pdf.

[4] Commission Green Paper on The General Principles of Food Law in the European Union, COM (97) 176 final.

[5] They were mostly cases concerning abuse of the common market freedom of movement of goods as well as misuse of safeguard measures by Member States.

ties, the Community did not develop a comprehensive food safety policy, but rather a complex maze of isolated sectoral rules.[6]

In the field of food regulation, the Community has traditionally resorted to committees,[7] which formally assisted with (but were in fact in charge of) both risk assessment and risk regulation. The three main committees active in this area were: the Scientific Committee on Foodstuffs (SCF),[8] composed of independent scientific experts; the Standing Committee on Foodstuffs (StCF),[9] consisting of national representatives; and the Advisory Committee on Foodstuffs (ACF),[10] incorporating the representatives of interest groups. Each of them had a precise function in the regulation process, which can be simplified by saying that risk assessment was carried by the SCF and risk management by the Commission, assisted by both the StCF and the ACF. From the functional point of view, the SCF was meant to provide scientific advice about the regulation process and the ACF was to inform the decision maker about the views of various stakeholders' groups. The StCF was created to safeguard the effectiveness of the regulation by ensuring the support of the Member States and their willingness to implement the decisions taken. It is the committees, with

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[6] *See* E. Vos, *EU Food Safety Regulation in the Aftermath of the BSE Crisis*, 23 JOURNAL OF CONSUMER POLICY 233 (2000); F. D. Lafond, *The creation of the European Food Authority. Institutional implications of risk regulation*, 10 EUROPEAN ISSUES 4 (November 2001).

[7] For complex analysis of the organization and functioning of the committee structure in the food sector, *see, e.g.*, SHAPING EUROPEAN LAW AND POLICY: THE ROLE OF COMMITTEES AND COMITOLOGY IN THE POLITICAL PROCESS (R. H. Pedler and G. F. Schaefer eds., 1996); C. Joerges, *'Comitology and the European Model?' Towards a Recht-Fertigungs-Recht in the Europeanisation Process*, *in* EUROPEAN GOVERNANCE, DELIBERATION AND THE QUEST FOR DEMOCRATISATION (E. O. Eriksen, C. Joerges and J. Neyer eds., ARENA Report No 02/2003); GOOD GOVERNANCE IN EUROPE'S INTEGRATED MARKET 501 (C. Joerges and R. Dehousse eds., 2002); C. Joerges, J. Neyer, *Transforming Strategic interaction into deliberative problem-solving: European Comitology in the Foodstuffs Sector*, 4 JOURNAL OF EUROPEAN PUBLIC POLICY 609 (1997); C. JOERGES, E. VOS, EU COMMITTEES: SOCIAL REGULATION, LAW AND POLITICS (1999); A. Maurer, *Committees in the EU system: A Deliberative Perspective*, *in* EUROPEAN GOVERNANCE, DELIBERATION AND THE QUEST FOR DEMOCRATISATION 337 (E. O. Eriksen, C. Joerges and J. Neyer eds., ARENA Report No 02/2003); E. VOS, INSTITUTIONAL FRAMEWORKS OF THE COMMUNITY HEALTH AND SAFETY REGULATION. COMMITTEES, AGENCIES AND PRIVATE BODIES (1999); E. Vos, *Reforming the European Commission: What Role to Play for EU Agencies*, 37 CMLREV. 1113 (2000).

[8] SCF was created on the basis of Commission Decision 74/234/EEC of 16 April 1974 relating to the institution of a Scientific Committee for Food, (1974) OJ L 136/1, later replaced by Commission Decision 97/579/EC of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety, (1997) OJ L 237/18.

[9] StCF was set up by Council Decision 69/414/EEC of 13 November 1969 setting up a Standing Committee for Foodstuffs, (1969) OJ L 291/9.

[10] ACF was originally established by Commission Decision 75/420/EEC of 26 June 1975, setting up an Advisory Committee on Foodstuffs, (1975) OJ L 182/35.

their problematic system of the organisation and functioning, that faced the most criticism for the Community's inefficiency in dealing with the BSE crisis.

The first *Report on Alleged Contraventions or Maladministration in the Implementation of Community Law in Relation to BSE*[11] issued by the European Parliament identified a series of problems on different levels, the effects of which were cumulative. It pointed out the main sources of problems, some of which are worth mentioning here. The first concerned the policy of disinformation applied by the Commission, not only with regard to the public, but also towards the other European institutions and national authorities.[12] The second concerned the way in which national interests managed to prevail over the interests of Europe.[13] The so-called "British thinking" phenomenon,[14] which had a great deal of influence on Commission decisions, occurred as a result of a number of British officials sitting on two committees operating in the field, namely, the Veterinary Scientific Committee, composed of highly regarded scientists, and the Standing Veterinary Committee, composed of national representatives. It transpired that their activities at that time were subject to intense political pressure and, as a result, neither independence nor transparency was at a premium.[15] The third important factor concerned the working methods of the Committees and the Commission and the ambiguity of their relations.[16] The lack of supervision and control, the lack of coordination, as well as the already-mentioned predominance of national and industrial interests in the decision-making processes were all highlighted.[17]

III. Influence of the BSE Crisis on the Development of the European Food Safety Policy

There is no doubt that it was the BSE crisis that forced the Community and Member States to face the problem of policy shortcomings and to take firm action to reform the European food safety system. One of the first steps was thus the creation of a

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[11] European Parliament, *Report on alleged contraventions or maladministartion in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and national courts*, 7 January 1997, A4-0020/97.

[12] *Id.*, at p.5-6.

[13] *Id.*, at p.9-11, 37-38, 40-41.

[14] *Id.*, at p.10.

[15] *Id.*, at p.10-11, 13, 16, 23.

[16] *Id.*, at p.16, 23-38.

[17] Compare *Report on alleged contraventions…*, *id.*, Part A.I.4, as well as E. Vos, *EU Food Safety in the Aftermath of the BSE Crisis, supra* note 6, at 231-233..

strong legal basis for Community actions in the field, embodied in the Amsterdam Treaty Amendment, which introduced a requirement for all Community policies and actions to ensure a high level of human health protection.[18] This means, as Lafond has correctly pointed out, that the aim is no longer merely to mitigate the side-effects of implementing the single market, but rather to deal with public health protection and consumer protection as fully acknowledged objectives of the European integration process.[19]

A radical change in the approach towards food safety regulation was also announced by the Commission in its Green Paper on General Principles of Food Law in the EU,[20] which was followed by the White Paper on Food Safety of 12 January 2000.[21] This new policy was aimed at covering the whole food chain and all stages of the decision-making process. Three pillars of risk regulation in the field of food safety were identified: risk assessment, risk management, and risk communication.[22] The creation of a European Food Authority was also proposed.[23]

Finally, these policy ideas resulted in the adoption of a new Regulation on the general principles and requirements of food law,[24] providing for a coherent conceptual approach to the issue. The Regulation treats food production as a continuum running from the primary production of animal feed to the supply of food for the end consumer. It also expressly introduces principles of food law, including the precautionary principle, and establishes the European Food Safety Authority as an independent source of scientific advice, information and risk communication. The Authority is expected, as a new scientific body, to provide the Commission with scientific advice in an independent, objective and transparent manner. It will also be the center of a network of national scientific institutions. In this way, the EFSA should

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[18] E. Vos, *id*., at 235-236. After the Amsterdam Amendment, the first sentence of Article 152. 1 EC reads: "A high level of human protecion **shall be ensured** in the definition and implementation of all Community policies and activities" (emphasis added). Amendment of Articles 95 and 193 EC follows the same direction.

[19] *See* F. D. Lafond, *supra* note 6, at 6.

[20] *Supra* note 4. .

[21] White Paper on Food Safety COM (1999) 719 final.

[22] *Id*., at p.8-9.

[23] *Id*., at p.14-21.

[24] 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 L 31/1, 1.2.2002.

enable Member States to become more closely involved in scientific matters and to establish and co-ordinate close co-operation between the Authority and the national scientific institutions. The Regulation indicates the division of responsibilities among food and feed business operators, the Member States, and the Community institutions.[25]

B. Judgment in the *Commission v. France* Case

I. Factual and Legal Background of the Case

First detected in the United Kingdom in 1986, BSE *(Bovine Spongiform Encephalopathy)* is one of the transmissible spongiform encephalopathies, which affect various animal species, in this case, cattle.[26] The first measures to combat this disease were taken by the British authorities in 1988,[27] and were later supplemented by Community action, starting in 1990.[28] Following the discovery of a possible link between BSE and a new variant Creutzfeldt-Jacob disease (vCJD), which affects humans, the Commission adopted Decision 96/239/EC,[29] temporarily prohibiting the export of live bovine animals, beef and veal, and their derivative products from the United Kingdom to the other Member States and third countries. The Decision provided for a constant revision of progress on the basis of the results of inspections and

[25] For further analysis of the influence of the BSE crisis on the development of the European food regulation, *see* F. D. Lafond, *supra* note 6; M. Hagenmeyer, *Modern food safety requirements – according to EC Regulation No 178/2002*, 4 ZLR 443 (2002); E. Millstone, *Recent developments in EU food policy: institutional adjustments or fundamental reforms?*, 6 ZLR 815 (2000); D. Chalmers, *'Food for Thought': Reconciling European Risks and Traditional Ways of Life*, 66 THE MODERN LAW REVIEW 532 (July 2003); S. Krapohl, *Risk Regulatoin in the EU between Interests and Expertise – The Case of BSE*, 10 Journal of European Public Policy 189 (April 2003); L. Buonanno, et. al, *Politics versus Science in the Making of a New Regulatory Regime for Food in Europe*, 5 EIoP (2001); E. RANDALL, POLICY AND PLANS: FORMULATING A FOOD SAFETY AND PUBLIC POLICY STRATEGY FOR THE UNION (2001), *available at* http://www.policylibrary.com/Essays/RandallEFARisk/EFArisk2.htm.

[26] For background information on the nature of the disease as well as some general surveys in it, *see* WHO FACT SHEET ON BSE, *at* http://www.who.int/mediacentre/factsheets/fs113/en/at. Regularly updated numbers of reported BSE cases, by country, are available on the website of the Office International Des Epizooties at: http://www.oie.int/eng/info/en_esb.htm.

[27] A summary of the chronology of BSE events in the United Kingdom indicating legal measures taken at the national level is available at the website of the Department for Environment, Food and Rural Affairs, *at* http://www.defra.gov.uk/animalh/bse/chronol.pdf; more detailed infrormation as well as a the full text of the Report of the BSE inquiry are available *at* http://www.bseinquiry.gov.uk.

[28] A chronological list of measures taken by the European authorities in order to combat the BSE problem can be found *at* http://www.europa.eu.int/comm/food/food/biosafety/bse/bse15_en.pdf.

[29] Commission Decision 96/239/EC of 27 March 1996 on emergency measures to protect against bovine spongiform encephalopathy, OJ L 78, 1996, p.47.

scientific studies. Thus, in March 1998, by Council Decision 98/256,[30] the ban was lifted with regard to certain meat and meat products from bovine animals slaughtered in Northern Ireland, and under the strict condition of the Export Certified Herds Scheme. A few months later, in the light of new inspections and scientific opinions, the Commission went on to adopt Decision 98/692,[31] which further enhanced the UK export possibilities by authorizing the export of meat and meat products from bovine animals born after 1 August 1996 and eligible under the newly established Date-Based Export Scheme (hereinafter the DBES). An animal was qualified as DBES-eligible if it had been born and reared in the UK and at the time of slaughter the following conditions were shown to have been met:

1) the animal had been clearly identifiable throughout its life, enabling it to be tracked back to the dam and herd of origin (its eartag number, date and holding of birth and all movement after birth were recorded either in the animal's official passport or on an official computerized identification and tracing system);
2) the animal was more than six months but less than 30 months of age;
3) the competent authority had obtained and verified positive official evidence that the dam of the animal had lived for at least six months after the birth of the eligible animal;
4) the dam of the animal had not developed BSE and was not suspected of having contracted BSE.

According to Commission Decision 1999/514,[32] 1 August 1999 was set as the date on which the dispatch of products was supposed to commence.

In French law, the ban on British beef and beef products was introduced by the ministerial order of 28 October 1998, establishing specific measures that would be applicable to certain products of bovine origin dispatched from the United Kingdom.[33] Therefore, the introduction of the authorization to import the DBES products in conformity with Decision 98/692 necessitated the amendment of the national law in question. Such a measure was drafted by the French government and

[30] Council Decision 98/256/EC of 16 March 1998 concerning emergency measures to protect against bovine spongiform encephalopathy, amending Decision 94/474/EC and repealing Decision 96/239/EC, OJ L 113, 1998, p.32.

[31] Commission Decision 98/692/EC of 25 November 1998 amending Decision 98/256/EC as regards certain emergency measures to protect against bovine spongiform encephalopathy, OJ L 328, 1998, p.28.

[32] Commission Decision 1999/514/EC of 23 July 1999 setting the date on which dispatch of bovine products under the date-based export scheme may commence by virtue of art 6(5) of Council Decision 98/256/EC, OJ L 195, 1999, p.42.

[33] JORF of 2 December 1998, p.18169.

submitted for obligatory consultation to the French Food Safety Agency - *Agence française de sécurité sanitaire des aliments* (hereinafter the AFSSA). On 30 September 1999, the AFSSA issued a negative opinion on the proposal.[34] The opinion was based on a report by a group of experts on transmissible sub-acute spongiform encephalopathies, which stated "having regard to current scientific knowledge and the epidemiological data now available to it, the group of experts expresses the opinion that the risk of Great Britain exporting infected beef and veal cannot be regarded as totally overcome."[35] The Commission expressed its surprise at the fact that the matter, having been established by the Community authorities, had been subsequently referred to the national scientific authority [in this case the AFSSA] and urged the French Republic to take immediate steps to comply with Decision 98/692. The French Republic forwarded the AFSSA opinion to the Commission and requested the Scientific Steering Committee (hereinafter the SSC) to examine it.[36] The Commission followed this request and forwarded the opinion, together with a set of questions to the SSC. After reexamining the opinions, the SSC concluded that the measures adopted by the United Kingdom made the risk from DBES products to human health at least comparable to that in the other Member States and that therefore there were no grounds for revising the overall conclusions of the SSC opinions, which were related directly to the rationale of the DBES.[37]

II. Proceedings

On 17 November 1999, the Commission issued a formal notice under Article 226 EC stating that by refusing to allow UK beef conforming to the Community requirements to be marketed in its territory after 1 August 1999, the French Republic had failed to fulfill its obligations under Community law. On 9 December, the French Government responded claiming that France was currently unable to lift the ban on British beef and veal. Five days later, the Commission issued a reasoned opinion calling on the French Republic to adopt, within five working days, the measures necessary to comply with its Community obligations. This time limit was later extended, at the request of the French Republic, to 30 December 1999. The French reply to the reasoned opinion, invoking the results of the AFSSA consultation,

[34] *See* http://www.afssa.fr/ftp/afssa/basedoc/a990930.pdf. The English text of the opinion is available at: http://www.afssa.fr/ftp/basedoc/aa19990930.pdf.

[35] *See* Opinion of the panel of experts on transmissible sub-acute spongiform encephalopathies (TSSE) of 30 September 1999, attached to the AFSSA opinion, *available at* http://www.afssa.fr/ftp/basedoc/aa19990930.pdf, p.5.

[36] Full text of the SSC opinion is *available at* http://europa.eu.int/comm/food/fs/sc/ssc/out62_en.pdf.

[37] Technical aspects of the reasoning of the opinion of the SSC as well as the opinion of the AFSSA will not be analyzed in detail, because they seem to be outside the scope of this paper.

stated that serious doubts remained as to the risks presented by the products subject to the DBES. The French government maintained that the guarantees provided for in this case were ineffective, since they presupposed that products of UK origin were traceable in the other Member States, while the vast majority of the states were not prepared to ensure traceability. According to the French reasoning, by ignoring the above-mentioned factors and having lifted the ban despite them, the Commission had infringed the precautionary principle. In view of this reply, the Commission brought an action before the European Court of Justice.

Advocate General Mischo delivered his opinion on the case on 20 September 2001.[38] One of the issues discussed in great detail, which is of the greatest importance for this paper, concerns the authority of the SSC's opinions. This matter will be discussed in detail in the following section.

The main argument of the European Commission was that, under Article 249 EC, decisions are binding upon those to whom they are addressed. The Commission urged that Article 1 of Decision 1999/514, which set 1 August 1999 as the date on which dispatch of products subject to the DBES could commence, allowed the Member States no discretion as to that date and the conditions governing dispatch. A Member State, the Commission argued, therefore cannot, by relying on the scientific opinion of a national body, substitute its own assessment of the risk for the risk assessment developed by the Commission in accordance with its powers. The Commission also noted a second important consequence of Article 249 EC, which is of a more procedural nature, namely that a Member State cannot rely on internal legal reasons to unilaterally justify a failure to apply a decision. A Member State cannot therefore make its implementation of a decision subject to the condition that certain amendments are made to them.[39]

The French response to this was based on the assertion that the conditions for lifting the ban had not been met. France maintained that the Commission was not entitled to bring proceedings against it for failure to implement an unlawful decision while failing to ensure that the other Member States were complying with its fundamental elements. Given these circumstances, France claimed that it was enti-

[38] Opinion of Mr Advocate General Mischo delivered on 20 September 2001 in case C-1/00, *Commission v. France*, [2001], ECR I-9989.

[39] *See* the judgment, *supra* note 2, par.88-93. The Commission also raised additional arguments maintaining that in the present case the French Republic had breached Article 28 EC and Article 10 EC as well. Due to the limited scope of this paper, these arguments will not be discussed here, as they are of minor importance for the outcome of the case and in particular, for the main issue of my analysis.

tled to rely on Article 30 EC to prevent the import of the UK beef and veal.[40] This argument was supported by three detailed examples of the lack of fulfillment of the conditions for lifting the ban on British beef: (i) that the DBES had not taken new data into account (such as the discovery of a suspected case of BSE); (ii) that UK beef and veal did not comply with the conditions of the DBES; and (iii) that there was no system for tracing products subject to the DBES and that the Member States had refused to set up such a system, although it was a fundamental condition of the DBES. All three claims supported French concerns about the effectiveness of the DBES. They were, however, found by the Commission and the Court to challenge the validity of the decision itself, but not the arguments that the Commission presented before the Court. According to the ECJ, France could have used these arguments to challenge the validity of the decision, using the procedural means provided for in the Treaty. On the contrary, applicability of French arguments to confront the statements, which were presented by the Commission before the Court, could by no means have been accepted.

Finally, in the judgment delivered on 13 December 2001, the European Court of Justice declared that the French Republic had failed to fulfill its obligations under Decision 98/256 and Decision 1999/514, in particular by refusing to allow the marketing in its territory after 30 December 1999 of products subject to the DBES, which are correctly marked and labeled.[41]

III. Key Issues

It seems from the above considerations that the main argument pressed by the French Republic in the pre-court phase of the dispute, concerning the differing opinions of the European and the national risk assessment bodies, was no longer prioritized by the defendant before the Court. According to some French commentators, France could have been far more successful had it invoked the precautionary

[40] *Id.*, at par.94. Article 30 EC allows Member States to introduce prohibition 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 archeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. More on Article 30 EC, *see* P. CRAIG AND G. DE BURCA, EU LAW. TEXTS, CASES, MATERIALS 626-636 (2003); J. STEINER AND L. WOODS, TEXTBOOK ON EUROPEAN COMMUNITY LAW 239-255 (5th ed. 2003); C. BERNARD, THE SUBSTANTIVE LAW OF THE EU. THE FOUR FREEDOMS 64-85 (2004); S. WEATHERHILL AND P. BEAUMONT, EU LAW. THE ESSENTIAL GUIDE TO THE LEGAL WORKINGS OF THE EUROPEAN UNION 525-559 (1999).

[41] *See* the judgment in the case, *supra* note 2, par.142.

principle. This, indeed, would have been quite logical in these circumstances. Not doing so, it enabled the Court to ignore the principle entirely.[42]

Nevertheless, since the primary purpose of this paper is to consider the problem of conflicting scientific opinions in risk assessment, I will now take a closer look at the issues of science and precaution, which were of the focal point of the pre-court stage of the proceedings. I will therefore concentrate on those parts of the reasoning where the authority of the SSC's opinions was discussed. Let me start by comparing the views of the parties, the Advocate General and the Court on this point.

The European Commission made a clear and straightforward statement on the matter, declaring that "a Member State cannot, by relying on the scientific opinion of a national body, substitute its own assessment of the risks for that carried out by the Commission in accordance with its powers" and that the AFFSA's opinions were contradicted by those of the SSC.[43] The Commission, however, did not manage to present any satisfactory scientific arguments that would justify this position. In fact, in the Advocate General's opinion presenting the Commission's position, no reference is made to any arguments having been raised by the Commission on this issue. It could have been primacy or supremacy, but an immediate question would have to be: primacy of what? Law? This, however, is not a legal question. Science? There seems to have been no legal basis for Community scientific supremacy. These questions could have been asked before but they were not. Perhaps there was no willingness on either side to bring such heavy artillery to the debate. Maybe none of them had enough confidence in their own arguments. Eventually, France decided not to engage in a discussion on this issue at all. It did not even formally contest this statement before the Court.

The French Republic, as described above, did not formally contest this statement before the Court. Nevertheless, in the French reply to the reasoned opinion, the French view on the issue can be clearly understood as contrasting sharply with that of the Commission. It stated that the French authorities, following observations made by the AFFSA, had serious doubts as regards the risks linked to UK meat covered by the DBES, which made an immediate lifting of the ban appear premature.[44] It was strongly emphasized that the decision to refrain from lifting the ban was taken "in the light of the AFFSA's findings that refusal was justified" and "driven by the sole concern of public health and consumer safety".

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[42] *See* T. Hamoniaux, *Principe de precaution et refus de la France de lever l'embargo sur la viande bovin britannique*, L'ACTUALITE JURISPRUDENTIELLE, DROIT ADMINISTRATIVE 164-169 (Février 2002).

[43] *See* the judgment in the case, *supra* note 2, par.78.

[44] *Id.*, at par.35.

Advocate General Mischo, however, firmly supported the view of the Commission on this point, stating that

"where a decision by it [the Commission] may be justified by the authority of the SSC's opinion, a Member State cannot take refuge behind the opinion issued by a national scientific body in order to oppose it, at least where, as was the case here, the national body's objections subsequent to the SSC's opinion relied upon by the Commission when taking its decision have been submitted to the SSC for consideration and held unfounded by it. (…) it cannot be accepted that, once the SSC has been informed of that matter, examined it and found it to lack pertinence, the Member State in question may challenge the scientific authority attaching to the SSC's opinions, unless it proves a malfunction at the level of that body."[45]

And the ECJ? The Court refrained from addressing the issue altogether. While the French switched to a completely different line of defense, the Court took only the new arguments into consideration, thereby ignoring the issue of science and risk assessment by different bodies.[46] Why was this? Did the Court choose an easy path or did this have more to do with its reluctance to take unpopular decisions and to become involved in a battle of sciences? This would seem rather surprising, since, in the history of the ECJ's jurisdiction, the Court has generally been quite willing to take any opportunity to assert itself on issues where the existence of its right to take a stand has not been completely clear.[47] Is it at all possible that the ECJ was in fact implicitly admitting its lack of competence in this case?

Such a reluctant approach towards conflicts of science seems to have become somewhat traditional. Both the ECJ and the Court of First Instance consistently avoid giving this particular problem due diligence. Neither the famous *Pfizer*[48] and

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[45] Opinion of AG Mischo, *supra* note 38, par.120-121.

[46] In the judicial stage of the Article 226 proceedings the ECJ has full jurisdiction to consider all the issues *de novo*. It is not just a review of the reasoned opinion. The scope of the proceedings, however, is limited to the infringements specified in it. *See* T. C. HARTLEY, THE FOUNDATIONS OF EUROPEAN COMMUNITY LAW 315-316, 431 (5th ed. 2003).

[47] *See, e.g.*, a discussion in A. ARNULL, THE EUROPEAN UNION AND ITS COURT OF JUSTICE 38-40 (1999).

[48] Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, [2002], ECR II-3305. For comments on the decision, *see* K. H. Lauder, *The Introduction of the Precautionary Principle into EU Law: a Pyrrhic Victory for Environmental and Public Health Law? Decision–Making under Conditions of Complexity in Multi-Level Political Systems*, 40 CMLREV. (2003), C. MacMaolain, *Using the precautionary principle to protect human health: Pfizer v. Council*, 28 ELREV. (2003), O. Segnana, *The Precautionary Principle: New Developments in the Case Law of Court of First Instance*, 3 GERMAN LAW JOURNAL No.10 (1 October 2002), *at* www.germanlawjournal.com.

Alpharma[49] rulings, nor the more recent *Monsanto*[50] judgment, have successfully addressed the issue. Although the matter of scientific uncertainty was common to all three cases, in all three of them the Courts failed to tackle the really problematic questions. As Dabrowska has correctly pointed out, commenting on the *Monsanto* judgment, "the Court, whilst giving legal meaning to scientific notions did not specify what is meant by scientific experts or which the relevant scientific bodies might be. The Court's judgment is open to criticism in that it did not establish more clearly what is to be understood as the 'most reliable scientific evidence available' or identify the relevant Community scientific institution(s). (…) Had the Court raised this issue, its ruling would be more complete and could have contributed more to the notion that consumers may be well protected even in an integrated, transnational, market."[51]

C. Conclusions: Who Can Decide Whose Science is Better?

For many, the case *Commission v. France* might illustrate nothing more than a situation where the national authorities of a Member State hid behind the lab coats of their scientists and invoked scientific analysis in order to avoid fulfilling common obligations under Community law. On the other hand, it must also be perceived as an example of a failure by the European regulators to legitimize their decision to an extent that would convince all the Member States. The most important question to be asked in this context is whether the new legal and institutional food safety architecture offers any remedies to these failures. I will attempt to answer this question by trying to hypothesise whether the deliberation on *Commission v. France* would be different if it were to take place now. There can be no doubt that Regulation 178/2002 and the EFSA have introduced a new dimension to the debate, but the question is whether it would make any significant difference in this particular case? In my opinion, it would.

As Randall has correctly pointed out, one of the essential lessons of the BSE crisis is that there are limits to the part that science can play in the formulation of public policy and that even the best science cannot relieve policy-makers of the responsibility of taking decisions in the face of the unknown and of uncertainty.[52] Even if

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[49] Case T-70/99, *Alpharma Inc. v. Council*, [2002], ECR II-3495.

[50] Case C-236/01, *Monsanto Agricoltura Italiana SpA and Others v. Presidenza del Consiglio dei Ministri and Others*, judgment delivered on 9 September 2003, not yet reporter in the ECR.

[51] P. Dabrowska, *GM Foods, Risk, Precaution and the Internal Market: Did Both Sides Win the day in the Recent Judgment of the European Court of Justice?*, 5 GERMAN LAW JOURNAL No 2 (1 February 2004), at www.germanlawjournal.com.

[52] *See* RANDALL, *supra* note 25, p.1.

sufficient arguments to legitimize risk assessment are developed, the extent to which science can be "democratized" is limited. It is thus the responsibility of the democratic system of government to protect the lives and health of citizens, and decisions about the acceptable level of risk cannot be taken solely by experts who are unaccountable to the public. As the Court of First Instance pointed out in its judgment in the *Pfizer* case: "scientific legitimacy is not a sufficient basis for the exercise of public authority".[53] Joerges and Neyer refer to the main suggestion of the European food law reformers in a very clear and straightforward manner, indicating that one of the paths to improving the input legitimacy of risk regulatory systems is to differentiate stringently between risk assessment and risk management, where risk assessment could be viewed as an attempt to arrive at scientifically sound judgments and risk management is the task of transforming assessments into policies by taking due account of non-scientific concerns.[54]

Taking this differentiation between the "scientific" risk assessment and the "non-scientific" risk management as a starting point for further analysis, it can be assumed that the European Food Safety Authority can provide European rule-makers with a stronger and more legitimate scientific basis, with as much democratic flavor as it is possible to achieve in scientific deliberation. There is thus a fair chance that the establishment of the EFSA will greatly contribute to enhancing the value of European science, and this should make it easier for the regulators to justify the Europeanization of scientific decisions and for the Member States to accept EU supremacy in this particular field. It can also raise public confidence in European science. However, it also seems to me that much depends on the public perception of the nature of the EFSA. If its creation is perceived as a merely superficial change in name and organizational structure of a body that remains essentially the same as in previous decades, its influence on the legitimization of European science will be negligible. If, on the other hand, the creation of the EFSA by means of a Regulation convinces the public that this was the result of a conscious democratic process in which the Member States decided to hand matters of risk assessment over to an EU body and to accept its supremacy, it will indeed be of great importance to the issue of scientific conflicts. One should also bear in mind that the legitimacy of scientific assessment depends to a great extent on the way in which its deliberation is organized.[55] To allow a fair assessment of risk, the best possible solution is to ensure that

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[53] *Pfizer*, *supra* note 48. For more deliberation on the issue, *see* T. Christoforou, *The precautionary principle and democratizing expertise: a European legal perspective,* 30 SCIENCE AND PUBLIC POLICY 205-211 (June 2003); C. Joerges and J. Neyer, *Politics, risk management, World Trade Organisation governance and the limits of legalisation*, 30 Science and Public Policy 219-225(June 2003).

[54] *See* Joerges and Neyer, *supra* note 53, p.220.

[55] R. Dehousse, *Misfits: EU Law and the Transformation of European Governance*, *in* GOOD GOVERNANCE IN EUROPE'S INTEGRATED MARKET, *supra* note 7, p. 207.

the formal conditions for delivering scientific advice are complied with, and these involve transparency, consideration and excellence. In this sense the EFSA seems to be a genuine step forward, as well as making it possible to rationalize the delivery of scientific advice.

Another important innovation introduced by the Regulation establishing the EFSA is a conflict resolution mechanism, which is to be used whenever a divergence of scientific opinion arises.[56] According to Article 30, the European Food Safety Authority will exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks. Where such a substantive divergence over scientific issues has been identified and the body in question is a Member State body, the Authority and the national body are obliged to cooperate with the aim of either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data, which will then be made public. The introduction of such a provision into the Regulation indicates that the regulators recognized that the problem of varying scientific opinions required a solution. In this sense it can certainly be seen as a step forward. Nevertheless, it places the EFSA in the position of watchdog, rather than giving it any supremacy over conflicting national opinions. That is, it obliges the EFSA to seek and encourage compromise without entitling it to have the final word. Therefore other related questions arise: Will this be enough? Can one compromise on the outcomes of scientific expertise? This concept appears to be rather awkward, but let us hope it is possible to accomplish such compromises. Since neither the Commission nor the European Court of Justice has managed to arrive at a conclusion over how to deal with conflicts of science, with the Commission showing no readiness to negotiate and the Court showing no willingness to take a stand, maybe the EFSA can offer a satisfying solution. After all, who is to decide about science if not scientists themselves?

On 21 April 2004, the Scientific Panel on Biological Hazards of the European Food Safety Authority issued an opinion[57] on the application of the United Kingdom for Moderate Risk BSE Status according to World Organization for Animal Health standards. The Authority based its findings on modeling assumptions and calcula-

[56] *See* Article 30 of Regulation 178/2002, *supra* note 24.

[57] For details consult Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the Application of the United Kingdom for Moderate Risk BSE status,(Question No EFSA-Q-2003-013), delivered on 21 April 2004, The EFSA Journal (2004) 55, 1-3 and Report of the Working Group on the application of the United Kingdom for moderate BSE risk status, *available at* http://www.efsa.eu.int/science/biohaz/biohaz_opinions/426/opinion_biohaz_09_georisk_ej55_report_en1.pdf.

tions submitted by the UK authorities. This, however, was possible only after the Panel had checked whether the methodology used to calculate the absolute incidence of BSE in the UK cattle population was statistically sound. The Panel decided that the method was indeed statistically sound and concluded that the BSE risk in the United Kingdom was moderate and comparable with that of other Member Sates. So, does this mean that there is light at the end of the tunnel?

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