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The European Food Safety Authority before European Courts

Some reflections on the judicial review of EFSA scientific opinions and administrative acts

*Alberto Alemanno**, *Stéphanie Mahieu***

This article, by tackling one of the most controversial issues surrounding the functioning of the European Food Safety Authority (EFSA), explores whether its scientific opinions and other administrative acts may be challenged before the European courts. The issue as to whether Community courts may review the legality of the acts emanating from EFSA remains today, not having being defined by the general regulation establishing the agency nor by case law, an open question. Therefore, after illustrating and analysing the existent case law, this article will engage in developments whose character will be mostly speculative. In so doing, it distinguishes between EFSA scientific opinions and EFSA administrative decisions, such as those concerning its public procurement activity or human resources management.

I. Introduction

EFSA is part of a legal and institutional framework progressively framed by a social, cultural, economic and political context distinctive for the agro-food sector¹. Being a linchpin of the important reform conducted in EU food law following the “BSE crisis”, EFSA was conceived as an independent authority entrusted with tasks mainly confined to risk assessment and communication², with the view of enhancing the confidence of consumers, of interested parties and of institutions in the system³. Risk management, including framing legislation

and implementation of controls, has been left to the Commission⁴.

The specific features of the agro-food sector find reflection in the scope of action, structure and related judicial accountability of EFSA as a Community agency. A comparative analysis of the “judicial accountability” of the different European agencies created in closed sectors also driven by externalities does not offer any decisive help in finding an answer to the question of the reviewability of EFSA opinions insofar as their constituent regulations provide for very different solutions⁵. Thus, for instance, Regulation (EC) No 1907/2006

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1 See S. Mahieu, *Le droit de la Société de l'alimentation. Vers un nouveau modèle de maîtrise des risques alimentaires et technologiques en droit communautaire et international*, op. cit., pp. 23-116.

2 See the White Paper on Food Safety, COM(1999) 719 final, 12 January 2000, pts. 30 and ss.

3 See recitals 18 and 35 of the preamble of Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (hereinafter: the ‘general food law regulation’ or, merely, the ‘Regulation’), OJ L 31, p. 1.

4 See recital 34 of the general food regulation and pt. 32 of the White Paper on Food Safety.

5 See D. Geradin, *The Development of European Regulatory Agencies: What the EU should learn from American experience*, *Columbia Journal of European Law* 11, (2004), p. 30 ss.

provides that the European Chemicals Agency (ECA), established for the purposes of managing and carrying out the technical, scientific and administrative tasks, comprises a Board of Appeal to guarantee processing of appeals for any natural or legal person affected by its decisions, and that an action may be brought before the European Courts, in accordance with Article 230 of the Treaty, “contesting a decision taken by the Board of Appeal or, in cases where no right of appeal lies before the Board, by the Agency”⁶. The European Medicines Agency (EMA) offers a second interesting point of comparison. Being also responsible for coordinating Member States’ pharmaco-vigilance activities, its “chief task” is – similar to EFSA – to provide Member States and Community institutions with the best possible scientific opinions relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use, so as to enable them to exercise the powers regarding the authorisation and the supervision of medicinal products⁷. General provisions of its constituent regulation rule the jurisdiction of the Community Courts concerning its contractual and non-contractual liability⁸, and expressly allow for lodging a complaint with the Ombudsman or bringing an action before the Court of Justice,

“under the conditions laid down in Articles 195 and 230 of the Treaty respectively”⁹, concerning the EMA decisions regarding access to documents taken pursuant to Article 8 of Regulation (EC) No 1049/2001¹⁰. Lastly, one could mention the Common Plant Variety Office (CPVO), which is responsible for the implementation and application of the EC regime allowing for the grant of industrial property rights valid throughout the Community¹¹. Its constituent regulation states that an appeal can be brought against its decisions to a Board of Appeal¹², and that direct actions or actions against decisions of the Boards of Appeal may be brought on appeal before the Court of Justice¹³.

So, while some of the constituent regulations of the European agencies explicitly provide that the acts adopted by the agency are challengeable under Article 230 EC¹⁴, some others entrust a specific chamber of the agency¹⁵ or the Commission¹⁶ with the task of reviewing the legality of the agency’s decisions. In the case of EFSA, the general food regulation, which establishes that agency, does not even contemplate the possibility of submitting its acts to legal review. A role for EC courts is envisioned exclusively in the area of contractual and non-contractual liability of EFSA where Article 47

6 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, p. 1, recitals 15 and 106, art. 75, par. 1, art. 76, par. 1, h), art. 91 to 94. The paragraph 2 of art. 94 states that should the Agency fail to take a decision, proceedings for failure to act may be brought before the European Courts in accordance with Article 232 EC. See also art. 101 of this Regulation, which lays down rules concerning the liability of the agency.

7 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, p. 1, recitals 19 and 30, art. 22 and ss., art. 47 and ss., and art. 57.

8 Regulation (EC) No 726/2004, art. 72.

9 Art. 73 of Regulation (EC) No 726/2004.

10 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents OJ L 145 p.43.

11 Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights, OJ L 227, p. 1, such as modified, 3rd recital.

12 Art. 67 of Regulation (EC) No 2100/94.

13 Art. 73 and 74 of Regulation (EC) No 2100/94.

14 See, for instance, 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 L36, 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.

15 Generally, this is the procedure that has been chosen for those agencies which have been entrusted with decision-making powers, such as Office for Harmonization in the Internal Market (OHMI) and the European Aviation Safety Agency (EASA). See, respectively, 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, and Regulation (EC) No 216/2008 of the European Parliament and the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC, OJ L 79, p. 1.

16 As mentioned above, this is the case, for instance, of the CPVO and corresponds to the model chosen for executive agencies. It provides generally for an administrative appeal before the Commission and the later possibility of filing an action for annulment. This is provided for by the Framework Regulation 58/2003 of 19 December 2002 laying down the statute for executive agencies to be entrusted with certain tasks in the management of Community programmes (OJ L 11) at Article 22(1).

of the constituent Regulation expressly establishes the jurisdiction of the European Courts¹⁷.

As a result, the question as to whether EFSA administrative acts, opinions or any other EC source of scientific advice may be challenged before the European courts is exclusively governed by the classic rules relating to actions for annulment (Article 230 of the EC Treaty). In examining which acts of EFSA are capable of forming the subject of an action for annulment, it is important to distinguish between EFSA scientific opinions and EFSA administrative decisions, such as those concerning its public procurement activity or the human resources management.

II. European courts and scientific opinions

The application of the classic rules relating to actions for annulment, and notably Article 230 EC, to scientific opinions raises several problems. First, Article 230 EC does not contain any reference, neither explicit nor implicit, to acts of EFSA or any other European agency, scientific committee or source of expertise, among the institutions whose acts may be the subject of an action for annulment¹⁸. 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 rec-

ommendations and opinions, and (...) acts of the European Parliament intended to produce legal effects vis-à-vis third parties”¹⁹. Second, EFSA or any other source of scientific advice can hardly be assimilated to one of the institutions or bodies listed therein. Put differently, EFSA opinions or those coming from external sources do not, strictly speaking, come from one of those EC institutions listed in Article 230, paragraph 1, EC²⁰. Thirdly, being “preliminary or purely preparatory acts”, or a “procedural step in an ongoing decision-making process”²¹, 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”²². Last, but not least, not being addressed to any individual, scientific opinions could not be assimilated into Community decisions, but fall within the scope of the fourth paragraph of Article 230 which provide for very demanding standing requirements²³.

1. Where do we stand? A look at the case-law of the EU Courts

The FMC Chemical and Dow AgroSciences orders

It is by relying on these arguments that a series of recent orders delivered by the Court of First

17 According to this provision: “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”.

18 Article 230, 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”.

19 This obstacle per se would not appear insurmountable to the extent the ECJ, in the past, has shown to be ready to interpret broadly the category of acts reviewable under Article 230 EC. See Case 294/83, *Les Verts vs. 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 also acts not mentioned

in Article 230 EC are capable of forming the subject of an action for annulment.

20 It is by relying exactly on this textual argument that the CFI, in *Associazione delle cantine sociali venete*, has declared inadmissible an action for 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 on this judgment, see L. Raimondi, *Mediatore europeo e mezzi di ricorso giurisdizionale*, *Il Diritto dell’Unione europea*, 2004, p. 547 ss.

21 See the argument of EFSA in Case T-311/06, *FMC Chemical and Arysta Lifesciences/ EFSA* (2008), not reported, par. 27.

22 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 reported, par. 50.

23 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 when the challenge act is not a decision. Under the fourth paragraph of Article 230, an individual may institute proceedings against other acts only when these are “of direct and individual concern”. See Case 25/62 *Plaumann v. Commission* (1963) ECR 1963, at 95.

Instance (CFI) seem to rule out the possibility that EFSA scientific opinions may be judicially reviewed as such²⁴. The applicants in those cases were manufacturers and distributors within the European Union of active substances used in plant protection products. They had asked for the inclusion of substances in the list of authorised substances contained in the annex of Directive 91/414/EEC concerning the placing of plant protection products on the market²⁵. After having received the draft assessment report of the competent Member States according to the procedure laid down in Regulation (EC) No 451/2000²⁶, EFSA recommended that the active substance should not be included in the annex. The Commission then adopted a decision concerning the non-inclusion of the substance in the annex and the withdrawal of authorisations for plant protection products containing that substance. The applicants brought an action for annulment of the opinion of EFSA concerning the assessment of the substance and for compensation for the damage they allegedly sustained. In these orders, after having examined all the arguments adduced by the applicants concerning the nature of the contested acts, it was held that

“(...) the applicants have not produced evidence enabling it to be established to the requisite legal standard that the contested measure produces binding legal effects capable of affecting their interests by bringing about a distinct change in their legal position. (...) The application for annulment must therefore be declared inadmissible (...)”²⁷.

The CFI reached this conclusion after having explored different aspects of the nature of both EFSA’s powers and the measures at stake in the present case. The CFI first noted that the procedure for the evaluation of active substances, laid down in Regulation No 451/2000, was made up of successive stages at each of which Member States, EFSA and the Commission were assigned a specific role, and considered that only the directive or the decision finally adopted produced legal effects capable of affecting the interests of the notifiers²⁸. From that it concluded that the EFSA contested measure must be regarded as a preliminary step in the procedure for the inclusion or the non-inclusion of active substances in the annex of the relevant directive and, therefore, was not a measure against which proceedings for annulment may be brought²⁹.

More precisely, the CFI held that the applicants failed to show that the measure was intended to produce legal effects. It rejected the applicants’ argument on the ground that there was nothing in Regulation No 451/2000 to suggest that the Commission, having no discretion as to the inclusion of the active substance, was obliged to comply with EFSA opinions³⁰. Contrary to the plaintiffs’ claim, drawing from *Alliance for Natural Health and Others*³¹, the CFI held that the contested measure did not conclude the administrative stage of the evaluation of the active substance in question and that, as a result, they may not, as such, be the subject of an action for annulment³². Moreover, the applicants claim that EFSA’s review procedure is separate from the procedure for the assessment of

24 See orders of the CFI of 17 June 2008, Case T-311/06, *FMC Chemical and Arysta Lifesciences/EFSA* (2008), not reported, and Case T-397/06, *Dow AgroSciences/EFSA* (2008), not reported. See also orders of the President of the CFI delivered on March 1, 2007, case T-397/06 R, *Dow AgroSciences Ltd v. EFSA*, not reported, 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 reported.

25 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1). This legislation establishes the Community rules applicable to the granting and the withdrawal of authorisation to place plant protection products on the market. It provides that member States shall ensure that a plant protection product is not authorised unless (...) its active substance are listed in Annex I (art. 4).

26 The Commission Regulation (EC) No 451/2000 of 28 February 2000 laying down the detailed rules for the implementation of the second and third stages of the work programme referred to in Article 8(2) of Directive 91/414 organises the procedure for the evaluation of various active substances with a view

to their possible inclusion in Annex I to Directive 91/414.

27 Case T-311/06, *FMC Chemical and Arysta Lifesciences/EFSA* (2008), paras. 67 and 68, and Case T-397/06, *Dow AgroSciences/EFSA* (2008), paras. 59 and 60.

28 Case T-311/06, *FMC Chemical and Arysta Lifesciences/EFSA* (2008), paras. 45 and 49, and Case T-397/06, *Dow AgroSciences/EFSA* (2008), paras. 42 and 46.

29 Case T-311/06, *FMC Chemical and Arysta Lifesciences/EFSA* (2008), par. 50, and Case T-397/06, *Dow AgroSciences/EFSA* (2008), par. 47.

30 Case T-311/06, *FMC Chemical and Arysta Lifesciences/EFSA* (2008), paras. 51, 52 and 54 to 56, and Case T-397/06, *Dow AgroSciences/EFSA* (2008), paras. 48 and 49.

31 *Joined Cases C-154/04 and C-155/04 Alliance for Natural Health and Others* (2005) ECR I-6451.

32 Case T-311/06, *FMC Chemical and Arysta Lifesciences/EFSA* (2008), par. 59, and Case T-397/06, *Dow AgroSciences/EFSA* (2008), par. 52.

active substances by the rapporteur Member State and the Commission, insofar as EFSA is subject to the general food regulation and must comply with specific rules applicable to its internal procedures, was similarly rejected, this time in the light of the *IBM v Commission*³³ judgment. The CFI considered indeed that there was nothing in the Regulation to suggest that the contested measure was the “culmination of a special procedure” conducted before EFSA and that was not part of the ordinary procedure laid down in Directive 91/414 for the purposes of adoption by the Commission of an act which lays down its final position³⁴. Finally, the CFI veered from the applicants’ argument that EFSA’s task would be a typical example of delegation to an internal body of the power to adopt decisions having binding effects on third parties, so that its decisions would be subject to judicial review. The CFI decided instead that Regulation No 451/2000 did not imply that the power to adopt binding decisions has been delegated to EFSA, and concluded that “the Commission (had) not delegated to EFSA the power to adopt decisions having binding effects on third parties”³⁵.

The Pfizer Ltd. order

Interestingly, these orders follow in substance the same logic as that of *Pfizer Ltd*³⁶, wherein the CFI was called upon to review the legality of a Commission’s decision to initiate a referral to the EMEA. The CFI found in that case that the contested measure merely represented a preliminary stage in that procedure and therefore did not affect the legal position of the applicant³⁷. More precisely, the CFI reasoned that, since the consultative procedure represents only an intermediate stage which is intended to result in the adoption of a final decision, its validity may be appreciated at the time of any challenge directed at the final decision³⁸. As a result, the applicant was not considered as being deprived of judicial protection because of a dismissal of its action as inadmissible, since “it will be open to them to contest the validity of the consultative procedure should they bring proceedings against a final decision which is contrary to their interests and is based on the opinion of the (EMEA’s Committee for Proprietary Medicinal Products (CPMP)) and, if appropriate, to bring proceedings to recover any loss they may suffer”³⁹.

The Schering-Plough order

More recently, the European Courts have advanced even further their position vis-à-vis the issue of judicial review of scientific opinions. In *Schering-Plough*⁴⁰, the CFI, after having recalled that EMEA’s aim is to provide the Member States and the institutions with the best possible scientific advice on any question relating to the evaluation of the quality, the safety, and the efficacy of medicinal products for human or veterinary use, held that, insofar as the constituent regulation of EMEA provides for this agency only advisory powers⁴¹, the refusal by EMEA of an application of modification of placing on the market must be deemed to emanate from the Commission itself⁴². Therefore, such a refusal may be subject to an action directed only against that institution and the action must be dismissed as inadmissible insofar as it is directed against the EMEA⁴³.

2. The current debate: some reflections

This recent case-law seems to consistently dismiss the possibility of bringing an action for annulment against EFSA scientific opinions as such; and that

33 Case 60/81 *IBM v Commission* (1981) ECR 2639, paras. 10 and 11.

34 Case T-311/06, *FMC Chemical and Arysta Lifesciences/EFSA* (2008), paras. 63, 64 and 68 ; Case T-397/06, *Dow AgroSciences/EFSA* (2008), paras. 50 and 51.

35 Case T-311/06, *FMC Chemical and Arysta Lifesciences/EFSA* (2008), par. 66.

36 Case T-123/03, *Pfizer/Commission* (2004) ECR II-1631.

37 Case T-123/03, *Pfizer/Commission* (2004), paras. 26 and 27. In particular, Art. 26 reads as follow: « The Court finds that the contested measure does not definitively determine the position of the Commission on the question of the harmonisation of the Lipid SPCs, any more than it represents the culmination of a special procedure distinct from that intended to result in a decision on that harmonisation. The measure does no more than set in motion the consultative procedure described in paragraphs 3 and 4 above, and merely represents a preliminary stage in that procedure ».

38 Case T-123/03, *Pfizer/Commission* (2004), par. 29.

39 Case T-123/03, *Pfizer/Commission* (2004), par. 33.

40 T-133/03, *Schering-Plough/Commission and EMEA* (2007), par. 18.

41 Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, OJ L 214.

42 T-133/03, *Schering-Plough/Commission and EMEA* (2007), par. 22.

43 T-133/03, *Schering-Plough/Commission and EMEA* (2007), par. 23.

mainly insofar as they constitute only the intermediate stage of a procedure intended to result in the adoption of a final decision. Without intending to question such a conclusion, we would like to put the findings of these orders in perspective with EFSA's contemporary role. This contextualisation exercise of EFSA's activities might be decisive in view of a possible future evolution in the judicial review of EFSA scientific opinions.

To begin with, risk assessment, which is one of EFSA's main tasks in support of the risk management process⁴⁴, has acquired during recent times a central importance in economic and risk-generating activities⁴⁵. EFSA has been entrusted with extensive competences in this regards, as it can be brought to intervene in all fields having a direct or indirect impact on food and feed safety⁴⁶, as well as human nutrition, animal health and welfare, plant health, and GMOs⁴⁷. Moreover, EFSA opinions can be determinant not only in classic risk management processes applied in those fields, but also in the framework of ad hoc procedures like the mediation⁴⁸ or crisis management procedures⁴⁹.

More generally, the scientific opinions and risk assessments carried out by EFSA have acquired an increasing important role at national, EU and international level⁵⁰. Indeed, scientific assessments are

necessary under both EU⁵¹ and international law⁵² for legitimating a market restrictive measure intended to protect health or the environment. The general food regulation has established as a core general principle of national and European food law that "risk management shall take into account the results of risk assessment, and in particular, the opinions of (EFSA)"⁵³.

If, despite such an increasing importance, EFSA opinions continue not to be considered as legally binding, their impact on the outcome of the decision-making procedure is substantial, if not determinant. Indeed, some recent food regulations explicitly require the Commission to take EFSA opinion into account and, if Commission's draft decision is not in accordance with the opinion of EFSA, to « provide an explanation for the differences »⁵⁴. Practically speaking, it can be observed that, in the field of pre-market approval procedures, most of Commission decisions follow EFSA opinions. In point of fact, one may wonder whether the Commission or any other decision-making body would be well-equipped to depart from the outcome of the scientific opinion without becoming subject to the criticisms of the public, i.e. the addressee of those measures adopted in contrast with the available scientific advice. This seems particularly true in

44 See notably art. 50, par. 2, of the Regulation. For an introduction to the main steps of risk assessment, see A. Hagen Meyer, Risk Analysis in accordance with Article 6, Regulation (EC) No. 178/2002, EFFL, 3/2006, p. 146 ss.

45 For an analysis of the role of the risk assessment and, more generally, the risk analysis in EU and international regulations and case-law in the agro-food sector and risk-generating technological activities, see S. Mahieu, *Le droit de la Société de l'alimentation. Vers un nouveau modèle de maîtrise des risques alimentaires et technologiques en droit communautaire et international*, op. cit., pp. 55-75, 117-272, 133-272, 333-352, 381-396, 626-629 and A. Alemanno, *Trade in Food – Regulatory and Judicial approaches in the EC and the WTO*, op. cit., pp. 78-105, 391-401.

46 Art. 22, par. 2, of the Regulation.

47 Art. 23, par. 5, of the Regulation.

48 Under this procedure, after a Member State has referred to the Commission a measure taken by another Member State in the field of food safety which it sees as being either incompatible with the general food regulation or likely to affect the functioning of the internal market, and if an agreement cannot be reached, EFSA can be requested by the Commission to deliver an opinion on any relevant contentious scientific issue. See Art. 60 of the Regulation.

49 It is "in close cooperation with" EFSA that the Commission shall draw up a general plan for crisis management in the field of the safety of food and feed, which shall notably specify the practical procedures necessary to manage a crisis (see art. 55 of the Regulation).

50 On the legal status of EFSA opinions, see A. Alemanno, *The European Food Safety Authority at Five*, EFFL, 1/2008, p. 16 ss.

51 In *Alpharma*, cited above, the European judge recognised the principle that, when European institutions have to proceed to complex technical and scientific assessments, a risk assessment is a prerequisite to the adoption to any preventive measure (paras. 168 and 211). See also *Alliance for Natural Health*, cited above, paras. 72-73.

52 SPS agreement puts risk assessment at the basis of the adoption of SPS measures ; see Art. 2.2, 3.3, 5.1 and 5.2 SPS. See also *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, DS 26 and 48, and *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, DS 291, 292 and 293, 26 September 2006.

53 Art. 6, par. 3, of the Regulation.

54 See, for instance, Art. 7, par. 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, OJ L 268, p. 1; Art. 17, par. 1, of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods OJ L 404, p. 9; Art. 10, par. 1, and Art. 35, par. 1, of Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, p. 1, as well as Article 11, par.2, Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ, L 338, p. 4.

the light of the demanding requirements to which EU courts have subject the exercise of such a possibility. Indeed, according to the CFI in Pfizer:

- “the statement of reasons must be of a scientific level at least commensurate with that of the opinion in question:
 - (i)n such a case, the institution may take as its basis either a supplementary opinion from the same committee of experts or
 - other evidence, whose probative value is at least commensurate with that of the opinion concerned.
- (i)n the event that the Community institution disregards only part of the opinion, it may also avail itself of those parts of the scientific reasoning which it does not dispute”⁵⁵.

In any event, the duty imposed on the risk manager (be it the Commission or another entity) to provide an explanation for the reasons justifying a departure from the opinion will make it possible for the courts to understand whether that opinion has been taken into account and which « other legitimate factors » have been considered.

The growing importance of these opinions and their de facto legally binding character has been further confirmed by the case law in recent times. Following an application for interim measure introduced by France, the CFI decided to suspend the relevant provision of a Commission regulation introducing less restrictive measures of surveillance and eradication in relation to certain spongiform encephalopathies, as compared with those laid down in Regulation (EC) No 999/2002⁵⁶. According to the plaintiff the new scientific elements relied upon by the Commission to justify the introduction of these less restrictive measures ignore the scientific uncertainties which continue to surround the risk of transmission to human beings of transmissible spongiform encephalopathies (TSE) other than bovine spongiform encephalopathy (BSE). As the existence of such uncertainties clearly stem from the available scientific opinions, such as that carried out by EFSA, France claims a breach, at the risk assessment stage, of the precautionary principle by the Commission. The Court, after reminding that “in the context of the application of the precautionary principle, a risk assessment was a prerequisite for the adoption of the contested provisions”⁵⁷, stated that

“ (...) the weight of the applicant’s claim regarding the error committed by the Commission in the risk assessment must be evaluated principally in the light of the opinion of EFSA and its Scientific Panel”⁵⁸.

Against this backdrop, it went on by indicating that “(...) recital 9 in the preamble to (the contested Regulation) expressly refers to the conclusions of the (EFSA) opinion, but conceals a part of it which seems to call in question the Commission’s dual premise on which the contested provisions are based, namely, that TSEs other than BSE cannot be transmitted to humans and that the discriminatory tests are reliable. (...) It should be pointed out that the Commission, in (the contested Regulation), not only expurgated without justification part of EFSA’s conclusions but also reproduced incorrectly that part of the conclusions which it retained.”⁵⁹

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

“(I)n those circumstances, the claim that the Commission infringed the precautionary principle by committing an error in the risk management requires an in-depth examination which may be carried out only by the court adjudicating on the merits”⁶⁰.

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

In the light of the above, it is becoming more and more obvious that, not only from a legal standpoint but also from a practical perspective, EFSA opinions increasingly contribute to frame Commission’s decisions in this sector, both through their compulsory integration in the decision-making procedure and through the growing importance of their im-

55 Case T-123/03, Pfizer/Commission (2004), paragraph 199.

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

57 Case T-257/07 R, France/Commission (2007) not yet reported, par. 70.

58 Case T-257/07 R, France/Commission (2007) not yet reported, par. 71.

59 Case T-257/07 R, France/Commission, (2007) not yet reported, paras.72 and 75.

60 Case T-257/07 R, France/Commission, (2007) not yet reported, par. 86.

pact on the final decision to be adopted. Although these scientific opinions do not formally bind the Commission, they indisputably provide it with the evidence of scientific assessment necessary to determine, “in full knowledge of fact”, the appropriate measure to ensure a high level of health protection, as required not only by Article 2 of the general food Regulation but also by the Treaty itself (Article 95 EC). Therefore, whenever the scientific opinions are vitiated or have not been fully taken into account, their illegality will reflect on the subsequent decision which might be subject to judicial review. Notwithstanding their expressed “non-binding legal nature”, it has been established, along the same logic, in *Artegodan*, with reference to the scientific opinions given by the Committee for Proprietary Medicinal Products (CPMB), that they 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”⁶¹.

Secondly, EFSA’s non-role in the framework of risk management is also relevant in the debate regarding the judicial review of its acts. The lack of risk management powers of EFSA can be explained by the historical context surrounding its creation and derives heavily from the Commission’s restrictive interpretation of the *Meroni* judgment⁶² – as recently recalled by the CFI itself⁶³ – which establishes the conditions under which a delegation of powers could

be granted to agencies. Indeed, the Commission in the White Paper on Food Safety, by drawing on the so-called *Meroni* doctrine, pointed out: the unwarranted dilution of democratic accountability that a transfer of management and regulatory powers to an independent authority in the food sector would imply; the necessity that the Commission would retain regulation and control functions to discharge the responsibilities placed upon it under the Treaties, and the Treaty provisions modification that such a transfer of regulatory power would require⁶⁴. Therefore, if the model of the US’s Food and Drug Administration (FDA) was taken into account during the reflection process leading to the creation of EFSA⁶⁵, it was found preferable that EFSA “would have to respect the principle of separation of risk assessment and risk management and should respect the existing policy and legal responsibilities of the Commission, European Parliament and Council”⁶⁶. However, even though EFSA’s powers have been limited to risk assessment and communication by its constituent regulation, the White Paper on Food Safety does not exclude “a possible future extension of its competencies (to be) considered in the light of the experience with the functioning of (EFSA) and the confidence gained in its operation, including a possible need to change the Treaty”⁶⁷.

Contrasting EFSA limited powers with the tasks entrusted with other agencies set up in close related fields can bring another interesting dimension to the issue. If EFSA shows analogies with the functioning of some other agencies, the CPVO, the EMEA and the ECA seem, in some respects, to benefit more from increased implementation and quasi-judicial powers than EFSA.

This should not come as a surprise since, as is well-known, the ad hoc setting up of those agencies does not proceed from a common reflection, what explains their rather disparate organisation⁶⁸. This situation calls for comment on the need of more homogeneity in the minimum standards of judicial review and remedies for challenging the measures of the agencies, for greater coherence in their organisation, interaction and accountability in the procedural regime applicable to them. Indeed, these agencies intervene in close related fields and operate under a common jurisdictional order. Being aware of the necessity to ensure coherence, effectiveness and accountability in the creation, operation and control of “regulatory” agencies, such as EFSA, in accordance with the principles of good governance⁶⁹, the Com-

61 Joined Cases T-74/00, 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, par. 197.

62 ECJ, 13 June 1958, *Meroni* vs. High Authority, 9/56, ECR 1957/1958, p. 133, paras. 40 and 44.

63 See Case T-311/06, *FMC Chemical and Arysta Lifesciences/EFSA* (2008), par. 66.

64 See pt. 33 of the White Paper on Food Safety.

65 See, for instance, pt. 39 of the White Paper on Food Safety.

66 Proposal for a regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food, COM(2000) 716 final, 8 November 2000, explanatory memorandum, p. 14. On the relationship between risk EFSA and the European Commission, see S. Gabbi, *The Interaction between Risk Assessors and Risk Managers*, EFFL, 3/2007, p. 129 ss.

67 Pt. 44 of the White Paper on Food Safety.

68 E. Chiti, *The Emergence of a Community Administration: the case of European Agencies*, 37 *Common Market Law Review*, (2000), p. 309-343.

69 Draft Interinstitutional Agreement on the operating framework for the European regulatory agencies, COM(2005) 59 final, 25 February 2005, p. 2.

mission has itself proposed an inter-institutional agreement on the operating framework for the European regulatory agencies. Having stated that a European “regulatory” agency does not necessarily have the power to enact binding legal norms⁷⁰, the Commission expressed therein that “(a)ctions may be brought before the Court of Justice for the annulment of acts carried out by an agency which are legally binding on third parties, for failure to act and for damages caused by any agency in the course of its activities”⁷¹. Such new rules, when adopted, would however only apply, at first, to future agencies created under the EC Treaty⁷².

Another evolution should also be taken into account. Technological and scientific progress has progressively blurred the lines among the different categories of activities and products with which the different agencies, cited above, are entrusted. As a result of this phenomenon, provisions of the relevant constituent regulations establish mechanisms aiming to avoid confusion between the regulations’ scope of application⁷³ or conflicts of opinion among the different agencies “carrying out a similar task in relation to issues of common concern”⁷⁴, and to promote cooperation and support among them⁷⁵. Not surprisingly, a number of cases have been introduced concerning market hindrance caused by problems of qualification of products as foodstuffs or as pharmaceuticals⁷⁶. If these cate-

gories of products and activities retain differences in terms of, for instance, risk perception and cultural sensibility, it remains that the blurring of the frontiers among them may question the opportunity to maintain such differences of logic, structure and accountability of the agencies that conduct their assessment.

3. The current debate: some speculations

Some possible developments on EFSA’s status before EU courts might be predicted by looking into the existing case law. Thus, it is worth noting that the CFI, in the Dow AgroSciences and FMC Chemicals orders, cited above, has been called upon reviewing only a particular category of EFSA acts, i.e. those adopted within the framework of pre-market approval legislations. This set of vertical legislations establish, conformingly to their own nature, specific multi-stages and inter-institutional procedures for placing specific substances on the market⁷⁷. As a result, one might observe that, in its final reply to FMC Chemicals and Arysta Lifesciences’s claims⁷⁸, the CFI took care to take to expressly limit the scope *ratione legis* of its findings to the relevant legislation examined in specie⁷⁹. Indeed, it held that its conclusion that the application for annulment

70 Draft Interinstitutional Agreement on the operating framework for the European regulatory agencies, p. 4.

71 Draft Interinstitutional Agreement on the operating framework for the European regulatory agencies, pt. 31. The communication from the Commission “The operating framework for the European Regulatory Agencies”, 11 December 2002, COM(2002) 718 final, provides that “Guarantees are needed ensuring that the regulatory agencies respect the principles of the institutional system of which they form a part, and the specific regulations applicable to them. Provision must therefore be made for appeal by the Member States or the institutions to the Court of Justice for confirmation of any breach of these principles and rules by the agencies and annulment of any acts vitiated by such breaches. More specifically, in the case of the decision-making agencies, compliance with the general legality principle includes the requirement to provide for appeal by interested third parties to the Court of First Instance or, in the future, to a specialised tribunal, to request the annulment of decisions taken by the agency –possibly reviewed by the internal boards of appeal –in respect of those third parties, or for a declaration of failure to act, in the event of unjustified absence of a decision.” (p. 13)

72 Draft Interinstitutional Agreement on the operating framework for the European regulatory agencies, p. 3, recital 3, and pt. 2.

73 For instance, article 2 of Regulation (EC) No 1907/2006 provides that its rules on registration, evaluation and authorisation do not apply to substances used in medicinal products for human or veterinary use or in food or feedingstuffs (including additives)

provided they fall within the scope of the relevant Community legislation on medicinal products or food.

74 Art. 95, par. 1, Regulation (EC) No 1907/2006. See also art. 59 and 85 of Regulation (EC) No 726/2004.

75 Art. 110 of Regulation (EC) No 1907/2006. For an interesting introduction to mechanisms of cooperation and networking between EFSA and national authorities and scientific committees, see R. O’Rourke, *Scientific Conflict, the EFSA and a Common Risk Assessment*, EFFL, 4/2007, p. 197 ss.

76 See, for instance, Case C-211/03, C-299/03 and C-316/03 to C-318/03, *HLH Warenvertrieb and Orthica* (2005) ECR I-5141 and the more recent Case C-319/05, *Commission/Germany* (2007), not yet reported.

77 For a detailed analysis of the role, main features and provisions of EU pre-market approval legislations and procedures applicable in the agro-food sector and to risk-generating technological activities, with a specific application to biotech products, see S. Mahieu, « Le droit de la Société de l’alimentation. Vers un nouveau modèle de maîtrise des risques alimentaires et technologiques en droit communautaire et international », *op. cit.*, pp. 355-380, and 425-526.

78 Case T-397/06, *Dow AgroSciences/EFSA* (2008), not reported and Case T-311/06, *FMC Chemical and Arysta Lifesciences/EFSA* (2008) not reported.

79 Case T-311/06, *FMC Chemical and Arysta Lifesciences/EFSA* (2008) not reported, par. 44.

was inadmissible “(was) based on an analysis of the procedure referred to in Article 8 of Regulation No 451/2000”⁸⁰.

This approach, showing great wariness by the Court in ruling out any action against EFSA, has been further confirmed by the following conclusive statement contained in FMC Chemicals:

“there (was) no need to rule on EFSA’s contention that the (CFI) has no jurisdiction to rule on an application under the fourth paragraph of Article 230 EC for the annulment of one of EFSA’s acts.”⁸¹

Although the CFI has deemed, in the name of procedural economy, not to examine EFSA’s reviewability under Article 230 EC, it stems from the case-law that the Courts have consistently construed their reasoning by taking into account, often explicitly, the principle of effective judicial protection. In the case of an EFSA opinion, being a preliminary stage in a procedure leading to a final decision, it is considered that the applicant is not deprived of judicial remedies since the legality of the scientific opinion can be examined when the final decision based upon it is challenged. But,

then, one may legitimately wonder whether the same solution would, and should, apply to EFSA opinions intervening outside of the scope of such pre-market approval legislation⁸². Would such scientific opinions qualify as preliminary acts adopted in a formal and institutionalized procedure intended to lead to a final and challengeable decision? Probably not.

From these developments it can be expected that there will be an evolution either in the legislation or in the case-law (or in both) towards a clarification of the issue of judicial review of EFSA – and more generally, Community agencies – acts. In this respect, the recently-reformed regulation on materials and articles intended to come into contact with food provides expressly for an administrative review mechanism for « any act adopted under, or failure to exercise, the powers vested in the Authority by this Regulation »⁸³. According to this ad hoc mechanism, the Commission may be invested with the power to administratively review EFSA’s acts, or omissions, falling within the scope of this Regulation. It is argued that, though limited to EFSA’s activities within the food materials area, the introduction of such an administrative review might improve EFSA’s accountability vis-à-vis third parties. As a result, it might be tempting to call upon the amendment of the general food regulation in order to generalise such an administrative review mechanism to all EFSA’s acts. However, though pursuing a legitimate purpose, this reform might endanger the institutional separation that has been drawn between EFSA and the European Commission by the same constituent Regulation.

Interestingly, some cases having already laid down the conditions for judicial review of the acts adopted by a scientific committee, though not EFSA, they could be used as inspirational source in order to elaborate some further criteria in the framework of a judicial review of EFSA scientific opinions. In *Artegoda*⁸⁴, a case concerning a Commission decision of withdrawal of marketing authorisations of certain medicinal products for human use, the CFI, subsequently confirmed by the ECJ⁸⁵, held that EC courts may be called upon to review the formal legality of an agency’s scientific committee’s opinion as well as the Commission’s exercise of its discretion⁸⁶. Although the CFI has stated that it cannot “substitute its own assessment for that of the (scientific committee)”⁸⁷, it held that it

80 Case T-397/06, *Dow AgroSciences/EFSA* (2008), pt. 79 and Case T-311/06, *FMC Chemical and Arysta Lifesciences/EFSA* (2008), par. 87.

81 Case T-397/06, *Dow AgroSciences/EFSA* (2008), pt. 60; Case T-311/06, *FMC Chemical and Arysta Lifesciences/EFSA* (2008), par. 68.

82 See in particular Articles 29 of the Regulation, which expressly entrust EFSA with an ex officio power to carry out scientific assessment on any matter that may have a direct or indirect effect on the safety of food supply, including matters relating to animal health, animal welfare and plant health. To know more on EFSA self-tasking activities, see A. Alemanno, *Trade in Food*, op. cit., pp. 184186. See also the analogous power entrusted to EFSA within the framework of its risk communication tasks. As a recent example of EFSA’s opinion delivered outside of a pre-market approval procedure, see, in the framework of Commission’s current reflecting on the development of its policy in the area of animal cloning, the Scientific Opinion of the Scientific Committee on a request from the European Commission on Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals. *The EFSA Journal* (2008) 767, 1-49.

83 See in particular Article 14 of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ, L 338, p. 4.

84 Joined Cases T-144/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00 and T-141/00 *Artegoda a.o. v. Commission* (2002) ECR II-4945.

85 Case C-39/03 P *Commission v. Artégoda e.o.* (2003) ECR I-7885.

86 Joined Cases T-144/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00 and T-141/00 *Artegoda a.o. v. Commission* (2002), par. 199.

87 Joined Cases T-144/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00 and T-141/00 *Artegoda a.o. v. Commission* (2002), par 200.

may nonetheless review the proper functioning of the committee, the internal consistency of the opinion and the statement of reasons contained therein⁸⁸. In *Alpharma*, the CFI, facing an application for annulment of a Council regulation leading to the withdrawal of the authorisation of certain antibiotics from the list of the authorised additives in feedingstuffs, after recalling that judicial review of the way the Community institutions undertake a scientific risk assessment and evaluate highly complex scientific and technical facts “must be limited”⁸⁹, stated that a

“scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures”⁹⁰.

In the framework of this procedural examination, the CFI then proceeded to examine “whether the risk assessment carried out by the Community institutions in the present case (...) is vitiated by the errors alleged by *Alpharma*”⁹¹, but did not find any such error. Also, in *Alliance for Natural Health and others*, the CFI held that “the administrative and financial burdens involved in presenting files seeking (modifications of the positive lists) and the way in which the criteria of safety and bioavailability set out in the (relevant legislation) are applied by (EFSA) when considering individual files”⁹² are factors that may “be advanced in support of an action for annulment of a final decision refusing an application for modification of the positive lists or an action for damages against (EFSA) under Article 47(2) of Regulation No 178/2002”⁹³.

Should the Courts deepen this approach vis-à-vis EFSA’s scientific opinions, by engaging into a procedural scrutiny of EFSA’s acts and declaring their competence on all those acts which are not an «intermediate step», they might rely on the growing number of guidance documents which are prepared by the EFSA’s scientific panels in order to define their own way of conducting risk assessment⁹⁴. These documents may potentially provide a useful legality benchmark in reviewing the proper conduct of the panel when carrying out the risk assessment.

III. European courts and EFSA administrative acts

Besides the issue of the judicial review of scientific opinions, another open question relates more generally to the reviewability of EFSA administrative acts. Thus, for instance, to what extent may one bring an action against EFSA’s decisions relating to its growing procurement activity?

1. Where do we stand? A look at the case-law of the EU Courts

The European Dynamics order and the pending case

This question was expected to be answered in *European Dynamics*, wherein the applicant seeks the annulment of EFSA’s decision rejecting its bid for the software and services establishing an “Extranet” between the Member States’ national agencies, EFSA and the Commission⁹⁵. The CFI having concluded that there was no need to adjudicate on this case since the call for tenders was cancelled by EFSA before the lodging of the application, it has not examined the admissibility of the action leaving open this question to future cases. However, the CFI took care to indicate in one of its findings in that case that “the lapsing of the (EFSA decision rejecting the tender), which gave rise to its eradication from the Community legal order, is equivalent in effect to a judgement annulling that decision, without prejudice to the right of the applicant to

88 Ibidem.

89 Indeed, “the Community judicature is not entitled to substitute its assessment of the facts for that of the Community institutions, on which the Treaty confers sole responsibility for that duty. Instead, it must confine itself to ascertaining whether the exercise by the Community institutions of their discretion in that regard is vitiated by a manifest error or a misuse of powers or whether the Community institutions clearly exceeded the bounds of their discretion”(Case T-70/99, *Alpharma v. Council* (2002), par. 180).

90 Case T-70/99, *Alpharma v. Council* (2002), par. 183.

91 Case T-70/99, *Alpharma v. Council* (2002), par. 184.

92 Joined Cases C-154/04 and C-155/04 *Alliance for Natural Health and Others* (2005), par. 87.

93 Joined Cases C-154/04 and C-155/04 *Alliance for Natural Health and Others* (2005), par. 88.

94 Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants containing stacked transformation events Adopted on 16 May 2007, 16 May 2007, *The EFSA Journal* (2007) 512, 1-5.

95 Case T-69/05 *European Dynamics S.A. v EFSA* (2007), not reported.

contest, if necessary, in separate proceedings the lawfulness of the decision to cancel the call for tenders⁹⁶. It finally observed then that

“the fact that the applicant could no longer succeed by means of this action for annulment and would probably be time-barred from bringing a new action for annulment of the decisions taken by the EFSA following the cancellation of the disputed call for tenders does not preclude it from submitting, if appropriate, an application for compensation of the damage which it might claim to have incurred as a result of the allegedly unlawful conduct of the EFSA throughout the contested tendering procedure”⁹⁷.

By so doing, the CFI would seem to recognise the possibility of seeking not only judicial review of EFSA –and more generally Community agencies –acts cancelling a call for tenders, but also compensation of the damages suffered as result of those acts. Therefore, the possibility of an action for annulment against EFSA administrative acts may seem to be open today.

The same applicant who has triggered this order has recently lodged another action seeking the annulment of EFSA’s rejection of a bid of European Dynamics to another call for tender. This case is actually pending before the CFI⁹⁸.

The Sogelma/European Agency for Reconstruction case

In the meanwhile, the issue of European Courts’ jurisdiction to rule on an application under Article 230 EC for the annulment of one of administrative acts of European agencies, such as EFSA, is likely to be tackled by the CFI in Sogelma/EAR. In this pending case, the applicant asks for the annulment of the decision of the European Agency for Reconstruction (EAR) cancelling a tender procedure and launching a new tender procedure for works consisting in the identification and clearance of military ordnance⁹⁹. This case might indeed offer an opportunity to deal with the question of the judicial

review of agencies set up on the basis of community secondary legislation.

2. The current debate: some reflections

In the light of the above, it appears that one may reasonably expect that judicial review of this kind of agency acts be expressly acknowledged in the future case law insofar as these decisions, unlike scientific opinions, could not be considered as mere preparatory acts, but rather legally binding decisions producing effects vis-à-vis third parties. However, it must be pointed out that the general food regulation does not textually support such a conclusion, since it does not expressly foresees the applicability of Article 230 EC in these circumstances but rather provides that only disputes relating to contractual and non-contractual liability of EFSA can be brought before EC courts¹⁰⁰. In other words, there seems to be a lack of a textual basis for arguing in favour of the enforceability of EFSA administrative acts before EC Courts. But this is not necessarily compelling in establishing European courts’ jurisdiction over EFSA administrative acts. Indeed, because of the attention constantly paid to ensuring access to justice against EU acts, European courts may be led to recognising the judicial reviewability of EFSA administrative acts by the fact that there would not be any other means than article 230 EC to challenge these decisions.

However, it cannot be excluded that, from a procedural standpoint, the conclusions reached in the recent Eurojust judgment may be extended to the admissibility of the action relating to EFSA’s administrative acts. In this recent judgment, the ECJ has held that

“(…) it is for the applicant to choose the legal basis of its action and not for the Community judicature itself to choose the most appropriate legal basis (see, to that effect, Case 175/73 *Union syndicale and Others v Council* (1974) ECR 917, and the order of the Court of First Instance in Case T-148/97 *Keeling v OHIM* (1998) ECR II-2217). It is clear from the examination of the action that the applicant brought it under Article 230 EC. The admissibility of that action must therefore be examined in the light of that provision.

As is clear from Article 230 EC, the Court ‘shall review the legality of acts adopted jointly by the European Parliament and the Council, of acts of the

96 Case T-69/05 *European Dynamics S.A. v EFSA* (2007), par. 53.

97 Case T-69/05 *European Dynamics S.A. v EFSA* (2007), par. 63.

98 Case T-457/07 *European Dynamics S.A. v EFSA*, pending (see JO 2008, C 51 p. 47).

99 Pending Case T-411/06, *Sogelma/EAR*.

100 See Article 47 of the Regulation.

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’.

Clearly, the acts contested in the present action are not included in the list of acts the legality of which the Court may review under that article¹⁰¹.

Yet, while it is undisputable that the plaintiff is the dominus litis of the procedure, this outcome would be difficult to reconcile with the principle established in the recently proposed Draft Interinstitutional Agreement on the operating framework for the European regulatory agencies, cited above, under which “(a)ctions may be brought before the Court of Justice for the annulment of acts carried out by an agency which are legally binding on third parties, for failure to act and for damages caused by any agency in the course of its activities”¹⁰². This outcome would be even more difficult to reconcile with the principle of effective judicial protection in the Community legal order and the “general scheme of the Treaty” which is “to make a direct action available against ‘all measures adopted by the institutions’ (...) which are intended to have legal effects”¹⁰³. In that regard, it must be outlined that the Court itself, in Eurojust, tempered its findings by observing, as regards the right to effective judicial protection in a community based on the rule of law which, in the view of the applicant, requires that all decisions of a body with legal personality subject to Community law be amenable to judicial review, that “the acts contested in this case are not exempt from judicial review.”¹⁰⁴

IV. Conclusion

Our analysis shows an apparent progressive consecration of the principle of effective judicial protection as the polar star guiding the Courts when called upon adjudicating the controversial issue of admissibility of an action for annulment directed against EFSA as well as other agencies acts. This principle which is expected to find application both vis-à-vis administrative and scientific acts stemming from EFSA seems to have enlightened the Court’s case-law developed as of today. It remains to be seen whether it will lead, as it might reasonably be expected, the European courts to declare their competence even vis-à-vis those acts which, being enacted outside of pre-market approval procedures, do not qualify as « intermediate acts ».

In any event, it is predicted that the principle of effective judicial protection, provided that it will be consistently followed, will be the main criteria capable of giving rise to an interesting convergence of the conditions of judicial review of EFSA and other agencies acts, thus injecting greater coherence within the Community system of agencies.

Indeed, as our analysis has shown, there is a clear scope for clarification of the rules governing judicial review of EFSA’s acts. The European Courts have an important role to play in this respect. Since the *Warenvertriebs*¹⁰⁵ case and the case-law analysed here above, the European Courts have already specified some aspects of EFSA compe-

101 Case C-160/03 Kingdom of Spain v Eurojust, ECR I-2077, paras. 35-37.

102 Draft Interinstitutional Agreement on the operating framework for the European regulatory agencies, presented by the EC Commission, 25/02/05, COM(2005) 59 final.

103 Case C-294/83, *Les verts v Parliament* (1986), par. 24.

104 Case C-160/03 Kingdom of Spain v Eurojust (2005), par. 41. Indeed, Eurojust staff are to be subject to the rules and regulations applicable to officials and other servants of the European Communities, so that the candidates for the various positions in the contested calls for applications had access to the Community Courts under the conditions laid down in Article 91 of the Staff Regulations (par. 42).

105 In this case the Court concluded that it does not appear from the wording of article 9 of Commission Regulation (EC) No 1304/2003 of 11 July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it (OJ 2003 L 185, p. 6) that the national courts are among the ‘authorised’ ‘government authorities’ to which it refers, and that, therefore, as the Community rules stand, national courts may not refer questions on the classification of products to the European Food Safety Authority (Case C-211/03, , C-299/03 and C-316/03 to C-318/03, *HLH Warenver-*

trieb (2005), Rec. I-5141, paras. 91-92). The Court also held that EFSA opinions, although not binding, “may constitute evidence that the court would have to take into consideration as such” (par. 94), and ascribed to them “the same value as that recognized to an expert report” (par. 93). Although in *HLH Warenvertriebs* the question has arisen as to whether national courts may review the legality of EFSA’s scientific opinions, neither the opinion of the A.G. nor the judgment itself have tackled this issue (see Opinion of A.G. Geelhoed, Case C-211/03, *HLH Warenvertriebs* (2005) par. 98). However, the possibility for a national court to review the legality of a scientific opinion delivered by EFSA may be rendered controversial because of the ECJ’s monopoly on the legality review of EC acts under the *Foto-Frost* jurisprudence (Case 314/85, *Foto-Frost* (1987) ECR p. 4199). According to this case law, national jurisdictions do not have the power to declare acts of the Community institutions invalid and, accordingly, when they consider the arguments put forward by the parties to be well founded, they are supposed to refer questions of validity to the ECJ by means of a preliminary preference. The duty of referral to the ECJ has recently been confirmed in Case C-461/03 *Gaston Schul Douane-expediteur BV v Minister van Landbouw, Natuur en Voedselkwaliteit* (2005), ECR I-10513, and that “even where the Court has already declared invalid analogous provisions of another comparable regulation”.

tence and accountability. However, some aspects related to EFSA scope of intervention, effects and nature of its acts as well as their judicial reviewability still need further clarification. The importance of the reflection that has to take place in this regard will certainly shine beyond the framework

of EFSA to the broader and increasing sphere of influence of the other Community agencies. Should the legislator show itself not to be ready to engage into such a badly needed reflection, there is no doubt that the European Courts, were inundated by dozens of applicants, will step in and adjudicate.