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The European Food Safety Authority at Five

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The European Food Safety Authority at Five

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The establishment of the much-awaited European Food Safety Authority is the most prominent innovation introduced by the recently reformed European regulation of food.1 Yet, the Authority merely represents one of the components of an entirely new strategy adopted by the European Union in relation to food safety2. Although pivotal to the functioning of the new food safety regime, the EFSA has not been vested with any regulatory power in the matter, which remains with the Commission and the Member States. However, although EFSA opinions have not been granted a direct regulatory authority and, accordingly, do not prime over national advice, they are likely to acquire a de facto legally binding value for both the EC and the Member states authorities when passing legislation. After briefly examining EFSA’s institutional architecture, this article will provide a detailed analysis of EFSA’s origins, of its institutional structure and powers by looking into its first five years of existence.

1. The genesis

There had been recurrent calls for the creation of a Community food regulatory agency long before the outbreak of the food scares which have outraged Europe3. At least until the mid-1990s, such suggestions were taken into serious consideration by the EC Commission4. They were subsequently abandoned5 before being revamped by the President of the EC Commission, Jacques Santer when appear-

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2 Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, in O.J. 2002 L31 (hereinafter: the ‘general food law regulation’ or, merely, the ‘Regulation’).

3 For an overview on the genesis of EFSA, see M. D. Matthee, Regulating Scientic Expertise with regard to Risks Deriving from Gene-

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ing before the European Parliament Temporary Committee of Enquiry into BSE\textsuperscript{6}. Only a month later, facing a motion of censure from the European Parliament for alleged mismanagement of the BSE crisis\textsuperscript{7}, the same Commission President Santer seemed to be more determined about the need to establish an independent European Food Agency modelled on the US Food & Drug Administration: “I also think that an independent agency, to meet the specific needs of the Community but based on the positive aspects of the United States Food and Drug Administration, should be considered. Compliance with the principle of subsidiarity, to which we are all attached, must not be used as a pretext for obstructing the emergence of a credible European health protection system, as a necessary follow-on from the single market”\textsuperscript{8}. 

From this moment on, most of the advocates of a European food agency crafted their proposals taking as a model the U.S. FDA, a very large and centralized agency in charge of risk assessment, risk management controls and inspections throughout the US, as well as risk communication\textsuperscript{9}. By relying on the great confidence that both US consumers and the food industry have in its activities, they played, not without some ambiguity, on the FDA analogy in order to gain consensus around their proposals for the creation of a not well-defined European-style FDA. While Health Commissioner Emma Bonino, after visiting the States in 1997, declared that the FDA was not a good model for Europe, mainly because of its lack of political independence\textsuperscript{10}, the EC Commission President Romano Prodi, in his first speech to the European Parliament, advocated the establishment of a “European FDA”\textsuperscript{11}.

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

The conundrum facing the Community in shaping the administrative powers of the agency has been effectively summed up by the following question: “to what degree should, could, or does ‘expertise’ replace legal, political and ethical criteria?”\textsuperscript{12} In other words, should the agency be invested with regulatory and enforcement powers similar to those of the U.S. FDA?

This question was central to the mandate given by the Commission to three leading European Scientists – James, Kemper and Pascal\textsuperscript{13} – who had “to consider the most effective system for providing

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  \item[6] He declared: “Our job is and will no doubt remain, in a spirit of subsidiarity, to monitor the monitoring mechanisms set up by our Member States and their operation, even if, personally I think that in the long term the creation of an agency modelled on the American Food and Drug Administration should not be ruled out”. See EP Temporary Committee on BSE – President Santer Statement of 15 January 1997.
  \item[7] In the European Parliament’s debate on the report by the Temporary Committee of Inquiry into BSE on the 18 February 1997, the Parliament called on the Commission to bring together all the activities spread out among the various directorates general within a single DG, to set up a framework directive on food law, to ensure the safety of the foodstuffs which circulate freely within the Community, to change the way in which scientific committees work, etc. See Debate in plenary session of the EP, 18 Feb. 1997, EU-Bulletin, 1-2, 1997, 163-6.
  \item[9] For a detailed examination of the FDA’s powers and administrative organisation, see P. Barton Hutt and R.A. Merril, Food & Drug Law, Cases and Materials, Ith., New York, Foundation Press, 1991, at 4-6; for an historical overview of the US food regulation, see P. Barton Hutt, A Historical Introduction, 45 FDC L.J, 17, (1990). For the purpose of our analysis, it is sufficient to know that the FDA is an institution under the responsibility of the Secretary of Health within the US Department of Health, it has 9,000 employees and monitors the manufacture, import, transport, storage and sale of a broad range of products throughout the U.S. It relies on about 2,100 scientists working in 40 laboratories throughout the country. It goes without saying that it is one of the most powerful administrative agencies in the world.
  \item[10] Among the other reasons she provided: FDA did not cover the primary products of meat, poultry and fish and it would be unrealistic at EU level to have an organization with a staff of 5,000. It is worth noting that the European Commission currently employs approximately 20,000 individuals.
  \item[13] This informal working group, composed of the three Professors and the four Secretaries, was referred to as “Future of Scientific Advice” (FSA) and the final report as “A European Food and Public Health Authority: The Future of Scientific Advice” (Brussels: Commission, 1999). 
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scientific advice which was independent, transparent, excellent and readily understood by non-experts” and to assess “whether an independent agency type structure could lead to further improvements in scientific advice at the EC level”\textsuperscript{14}. The “Future of Scientific Advice” report, presented by these three scientists, represented the first serious attempt to analyze the opportunity and desirability of establishing an independent agency by setting out the benefits and the drawbacks relating to the development of a system analogous to the U.S. FDA\textsuperscript{15}. Starting from the premise that it would be “unwise to continue to deal with issues of such immense public concern simply by devising an improved system within DG SANCO”, James, Kemper and Pascal expressed the need for “structural changes” in the way these issues are handled within the Community in order to recapture public confidence\textsuperscript{16}. They proposed the institution of a Brussels-based organization, to be called the European Food and Public Health Authority (EFPHA), with the combined scope of the U.S. Center for Disease and Control (CDC)\textsuperscript{17} and the Food and Drug Administration. Although the proposed agency would have shared some features with the U.S. FDA, it was conceived as being more “independent of political and industrial interests”\textsuperscript{18}. Stressing the importance of not artificially compartmentalising the analysis of risk between risk assessment and risk management, they decided not to confine the new organization to providing scientific advice. Rather, they promoted interaction between risk assessors (EFSA’s scientists) and risk managers (Commission services in charge of drafting legislation) from the beginning of the process when the questions are defined, to the final stage when the advice is translated into management proposals. In other words, under their proposal “in one bold brush” the Commission, the Council, and Parliament would have lost legislative and executive power to a regulatory authority\textsuperscript{19}. Finally, since “the current scientific advice relates to many areas in addition to those of food safety”, the Report underlined the importance of also including environmental and public health concerns within their proposed authority as “public health issues are in health terms a greater burden on society than the effects of poor food safety which has dominated thinking so far”\textsuperscript{20}. However, three month after the release of this report, the Commission published its White Paper on Food Safety\textsuperscript{21}, calling for the establishment of an independent agency, the European Food Authority (EFA), entrusted with a number of key tasks embracing: independent scientific advice on all aspects relating to food safety (risk assessment) and communication and dialogue with consumers on food safety and health issues (risk communication). Thus, the Commission, under the pressure of the Member States, who were reluctant to give up their involvement in the risk management stage by devolving food control powers to an independent food agency, clearly rejected the transfer of risk management powers from the Commission to the EFA as suggested by the James, Kemper and Pascal report. To justify this decision the White Paper raised “three very serious issues”\textsuperscript{22}:

– The transfer of regulatory powers to an independent Authority could lead to an “unwarranted dilution of democratic accountability”;
– The Commission must retain both regulation and control if it is to discharge the responsibilities placed upon it under the Treaties;
– An Authority with regulatory power could not be created under the current institutional arrangements of the EC, and would require modification of the existing provisions of the EC Treaty.\textsuperscript{23}

\textsuperscript{14} The full text of the mandate given to them has been made public at http://europa.eu.int/comm/food/fs/sc/ future_mandate_en.html
\textsuperscript{15} Philippe James, Francois Kemper, Gérard Pascal, A European Food and Public Health Authority: The Future of Scientific Advice in the EU, Report commissioned by the Director General of DG XXIV (now DG SANCO), Dec. 1999, 6.
\textsuperscript{16} Ibidem, at 15.
\textsuperscript{17} According to the report, the CDC “has a crucial influence in ensuring that activities of industrially sensitive issues such as those handled by the FDA are geared to public concerns”, 6. To know more about this institution see http://www.cdc.gov/.
\textsuperscript{18} Report, supra note 14, at 7.
\textsuperscript{19} See L. Buonanno, in Ansell C. and Vogel D. (eds.), What’ the Beef? The Contested Governance of European Food Safety, supra note 5, at 259 ss.
\textsuperscript{20} Report, supra note 14, at 6.
\textsuperscript{22} Ibidem, at 15.
\textsuperscript{23} Ibidem, at 17, para 33.
Although debatable\textsuperscript{24}, these arguments led to the definitive abandonment of the FDA analogy in the European food policy’s discourse: the FDA was no longer to be considered to be a valid model. Presenting the White Paper to the European Parliament majority party group, the EC Commissioner David Byrne said:

"Looking across the Atlantic, I saw the American public placed great confidence in the work of the US food and Drug Administration. An institution that was science-based. But also an institution that was involved in management and legislation. I concluded that such a model, while attractive in itself and clearly working for the US, would not be appropriate for the European scene. I wanted to ensure that risk assessment and risk management would be separated. Such an approach would be in line with the provisions of the Treaty, which entrusted management, and legislation, to the Commission, Parliament and Council\textsuperscript{25}.

Although the White Paper did not settle all aspects of the EFA’s activities\textsuperscript{26}, it sketched out the main features of the new agency, thereby paving the way to the publication of the first regulation’s proposal\textsuperscript{27}. The amended proposal\textsuperscript{28}, after completion of first reading by the EC Parliament and Council, was finally adopted on January 28, 2002\textsuperscript{29}.

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


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


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

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mission\textsuperscript{31}, as stated in recital 32 of the regulation, the scientific and technical basis of Community legislation relating to the safety of food and feed should contribute to the achievement of a high level of health protection within the Community. In other words, this regulation reflects the strong belief of the EC legislator according to which there is a tight connection between science based food safety legislation and the assurance of consumer confidence in the decision-making process underpinning food law.

Its mission also includes the provision of scientific advice on matters related to human nutrition, animal health and welfare and plant health.

In the exercise of these activities, the Authority shall act “in close cooperation with the competent bodies in the Member States carrying out similar tasks to those of the Authority”\textsuperscript{32}. This provision is crucial in understanding the raison d’être underpinning the creation of the Authority: EFSA has not been conceived as a pan-European scientific body aimed at imposing its scientific voice over national opinions in food matters, rather it aims at providing an independent European view which ideally complements Member States’ studies. Similarly, the Authority, the Commission and the Member States must cooperate to promote the effective coherence between risk assessment, risk management and risk communication functions. In the absence of clear indications within the regulation, it still remains to be seen how this cooperation will be realised in practice.

2. Tasks

From a reading of the list of tasks given to EFSA it seems to be clear that EFSA’s scientific activity cannot be reduced to the delivery of scientific opinions in response to questions posed by its (institutional) customers. Rather, EFSA’s scientific involvement breaks down into four main activities:

- providing scientific opinions, guidance and advice in response to questions submitted by the European Commission, the European Parliament or the Member States;
- assessing the risk of regulated substances, such as GMOs, pesticides and food/feed additives, following notification procedures and time schedules established by EC vertical legislation;
- monitoring of specific risk factors and diseases as well as identifying and characterising emerging risks;
- developing, promoting and applying new and harmonised scientific approaches for hazard and risk assessment of food and feed.

These tasks should be undertaken in conditions that respect the virtues of ‘independence’, ‘scientific and technical quality’, ‘transparency’ and ‘diligence’\textsuperscript{33}.

In accomplishing the first two tasks, the EFSA fulfils its main mission: to prepare and present scientific opinions. While in the former case the Authority acts in response to food safety questions addressed on a voluntary basis by the competent institutions, in the latter, EFSA’s intervention is requested by European vertical legislation. Thus, for instance, the legislative framework for the marketing of food additives\textsuperscript{34} and feed additives\textsuperscript{35}, being based on a positive list system, relies on EFSA’s assessment. Similarly, the new GMOs legislative regime provides for the risk assessment of GMO and derived food and feed to be carried out by EFSA\textsuperscript{36}. Given their character of lex specialis, this set of vertical legislation dealing with regulated substances determines the modalities of EFSA’s scientific intervention. In particular, these pieces of vertical legislation entrust the Commission (sometimes together with EFSA) with laying down the guidelines to be followed by risk assessors in conducting their assessment.

Where the vertical legislation does not require the Commission and/or the Authority to establish

\textsuperscript{31} In particular, Article 22 (7) states that “[t]he Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it”.

\textsuperscript{32} Article 22 (7) of the Regulation.

\textsuperscript{33} Article 22.7 Regulation 178/2002.


\textsuperscript{35} Since 18 October 2004, applications for authorising the placing and use of feed additives in the market are regulated in the European Union under Regulation (EC) No 1831/2003. EFSA is responsible for the scientific assessment of the feed additives.

these guidelines, these should be established by the Commission after consulting the Authority.\(^{37}\) In particular, the Commission should elaborate the guidelines governing the scientific evaluation of substances, products or processes which are subject, under Community legislation, to a system of prior authorisation or entry on a positive list, in particular where Community legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant.

Moreover, under Article 32 of the Regulation, the Authority is entitled to commission scientific studies necessary for the performance of its mission. In doing so, it should seek to avoid duplication with Member State or Community research programmes and shall foster cooperation through appropriate coordination. Finally, the Authority shall inform the European Parliament, the Commission and the Member States of the results of its scientific studies.

It is noteworthy that under Regulation 178/2002, the EFSA has received fewer functions than those originally provided for by the regulation as originally proposed\(^{38}\). In particular, the Authority is not responsible for the operation of the Rapid Alert System for food and feed established by this Regulation (which is under the Commission’s responsibility) and it has also lost its role in the communication on health-policy-related nutritional issues\(^{39}\).

III. Institutional framework

The Authority consists of:
1 a Management Board;
2 an Executive Director and his/her staff;
3 an Advisory Forum;
4 a Scientific Committee and Scientific Panels

1. Management Board

The Management Board is responsible for guiding EFSA’s activities and ensuring that the Authority carries out its mission and performs its tasks. Unlike other EC agencies\(^{40}\), it is not composed of representatives of all Member States, since Management Board Members are chosen for their independence, not for their connection to Member States: they are experts in their own right and collectively have a blend of expertise in the management of key organizations involved in food safety and in the most current issues within the area.

It chooses fourteen Members appointed by the Council in consultation with the European Parliament from a list (a ‘roster’) provided by the Commission\(^{41}\), plus a representative of the Commission\(^{42}\). Although the Council would have preferred to have the board formed solely by national representatives\(^{43}\), four of its Members “shall have a background in organizations representing consumers and other interests in the food chain”\(^{44}\). These Members inevitably represent a particular interest in the food sector since they retain their previous posts while sitting on the Board. Given the ‘free movement bias’ affecting EFSA’s foundations, it would appear to be advisable to increase the number of consumer representatives, who do not dispose of the same resources as the food industry to lobby the Commission or to

\(^{37}\) Article 30 (6) lett. b of the Regulation.

\(^{38}\) See supra note 26.

\(^{39}\) See Article 22 (h) and (k) of the amended proposal, supra note 152. However, EFSA remained invested with an important role in nutritional issues. In particular, EFSA involvement with health-policy-related nutritional issues began on January 19, 2007 following the entry into force of the first EC Regulation on the use of nutrition and health claims for foods. See Corrigendum to Regulation (EC) 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ 2007 L 123/1. To know more about the role of EFSA in nutritional issues and in the application of this regulation, see S. Valtuena Martinez, L. Heng, W. Gelbmann, A. Cavillier, P. Rodriguez Iglesias, The Regulation on Nutrition and Health Claim Made on Foods: Role of the European Food Safety Authority, European Food and Feed Law Review, 2/2007, at 76.

\(^{40}\) Within the other EC agencies, Members of the Board are appointed either by the Member States independently or by the Council on the basis of one member per Member State. See E. Chiti, The Emergency of a Community Administration: the Case of European Agencies, Common Market Law Review 37, at 309-342, 2000; see also K. Kanska, Wolves in the clothing of sheep? The case of the European Food Safety Authority, 24 European Law Review 2004, 713.

\(^{41}\) The representative of the Commission, until now SANCO’s Director General Robert Madelin, constitutes the most significant link between EFSA and the Commission. On this point, see S. Gabbi, The Interaction between risk assessors and risk managers. The case of the European Commission and the European Food Safety Authority, European Food and Feed Law Review, 3/2007, p. 131.

\(^{42}\) E. Vos, Mondialisation et régulation-cadre des marches – Le principe de précaution et le droit alimentaire de l’Union européenne, in 2-3 Revue international de Droit Economique (2002), 219 at 244.
carry out their own risk assessment in order to give greater balance to EFSA’s opinions.

The Board composition represents a significant and innovative institutional aspect aimed at ensuring “its independence, high scientific quality, transparency and efficiency”45.

After the Enlargement to 25 Member States, the number of members of the Board turned out to be much smaller than the number of Member States. However, in order to partly mitigate such under-representation, the Regulation provides that “the broadest possible geographic distribution within the Union” should be guaranteed within the Board46. Furthermore, Recital 41 of the Preamble dictates a “rotation of the different countries of origin of the Members of the Management Board without any post being reserved for nationals of any specific Member State”. To fully understand the meaning of such a provision, reference must be made to the BSE crisis when “the influence of “British thinking” on the Commission was increased by the presence of many persons of British nationality on the two committees operating in this field: the Scientific Veterinary Committee and the Standing Veterinary Committee”47.

This crisis clearly showed the need for a geographic rotation of Members, as different Member States not only have different interests as regards the food sector but also different perceptions as regards risk assessment.

As the term of office of the Board Members is four and six years (only for half of its Members), nationals of the new Members States of the May 2004 enlargement may not be appointed before 200748.

The Commission, after a widely publicized call for interested candidates, published a short list of suitable candidates on April 8, 2002. Those candidates who had a background in organizations representing consumers and other interests in the food supply chain were specifically identified on the short list from which 5, not 4 as provided in the text, were selected by the Council and they met for the first time on September 18-19, 200249.

2. Executive Director

Together with the Management Board, the regulation provides for the appointment of an Executive Director, who is the legal representative of the Authority, is in charge of the day-to-day management and is responsible for all staff matters.

Among its tasks, the most important is the design of the work programme of EFSA because, due to its limited capacity, the agency cannot deal with all possible issues within its mission. The Executive Director is therefore responsible for priority setting, as confirmed by Article 27 (3) stating that the “Director may also ask the Advisory Forum for advice on the prioritization of requests for scientific opinions”. Contrary to what was required by the original proposal, in designing the work program of EFSA, the Director is not required to obtain the agreement of the Commission, but simply to consult it. This undoubtedly reinforces his independence (as well EFSA’s independence) vis-à-vis the Commission.

As regards the term of office, the Director is appointed for five years by the Management Board on the basis of a list of candidates proposed by the Commission after an open competition. The Authority being a separate legal entity, independent of the other EC institutions, the Executive Director is not answerable to the Commission or other Community or national institutions, but to the sole Management Board. The entire responsibility for risk management decisions remains with the competent EC institutions (Commission, Council and Parliament) as established in the Treaty. However, he can be dismissed by the Board by a simple majority of votes.

In February 1, 2003, Geoffrey Podger, former Chief Executive of the UK Food Standards Agency50, has been appointed as the first EFSA’s Executive Director. His appointment was certainly motivated by the role he played in UK food policy in the aftermath of the BSE crisis. After a pro tem-

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44 Article 25 (1) of the Regulation.
45 See recitals (40) and (41) of the Regulation.
46 Article 25 (1) of the Regulation.
47 Vos, supra note 42, p. 144. See also the Temporary Committee of Inquiry into BSE available at http://www.bseinquiry.gov.uk/evidence/tcb/sb.htm.
48 As of today, only one Member of a scientific committee comes from a new Member State. A list of the members is available at http://www.efsa.europa.eu/en/mboard/members.html.
50 Midday-express, October 2, 2002, Executive Director of the European Food Safety Authority nominated.
pore direction by the Dutch Koëter, on February 10, 2006 the EFSA Management Board officially nominated Catherine Geslain-Lanéelle as EFSA Executive Director.  

3. Advisory Forum

The Advisory Forum is the link between EFSA and the Member States. It is composed of representatives from competent bodies (e.g., national food agencies) in the Member States which undertake tasks similar to those of the Authority, these representatives being designated by each Member State.

Members of the Advisory Forum may not be Members of the Management Board. The Executive Director convenes and chairs the Forum, but a third of its Members may also initiate a meeting. The Forum has to meet at least four times per year and its meetings are open to the participation of Commission officials. Representatives from the European Parliament and other relevant bodies may also be invited to participate.

The Advisory Forum gives the Executive Director advice on all aspects of his tasks, and notably on making proposals for the EFSA’s work programme. The Director may also ask the Forum for advice on the prioritizing of requests for scientific opinions.

Being an organ totally unknown within the Community agency structure, it is the most original organ within the EFSA. In the words of the regulation, it constitutes "a mechanism for an exchange of information on potential risks and the pooling of knowledge".

The creation of this mechanism may be seen as responding to two different goals: one was reinforcing Member States’ participation in EFSA’s activities and the other to facilitate cooperation between the agency and the Member States.

In fact, being a forum, it aims at fostering cooperation between the national food bodies represented and the EFSA, thus avoiding conflicts arising amongst these entities in relation to specific scientific opinions. In particular, the Advisory Body also ensures close cooperation between the Authority and the competent bodies in the Member States to avoid duplication of EFSA’s scientific studies with Member States, to promote the European network of organizations operating within the fields of the Authority’s mission and where EFSA or a Member State identifies emerging risk.

The newly appointed Executive Director, being particularly aware of the key role that the Advisory Forum might play within EFSA’s mission, is showing great willingness to enhance the exchange of scientific information amongst the Advisory Forum Members and EFSA. In particular, she envisions that Advisory Forum members might become “the focal point for EFSA’s activities” in each Member State, thereby acting as “ambassadors for EFSA with the key players in the food chain at national level.”

4. Scientific Committee and Scientific Panels

The Scientific Committee and the eight permanent Scientific Panels, being responsible for providing the scientific opinions, constitute the core of the Authority. As mentioned above, these Committees used to be attached to the EC Commission and they emerged from the Commission reorganisation of its scientific advice which took place in 1997. Now they form part of EFSA.

The Scientific Committee, replacing the former Scientific Steering Committee, is responsible for the general coordination necessary to ensure the consistency in the scientific opinions of the different panels. In order to do so, it is entrusted with the
critical task of developing "working procedures and harmonisation of working methods". The realisation of this objective is crucial to the extent that, since EFSA advice represents the main basis for decision making in the food sector, risk managers and the public need to have access to the procedures through which the risks have been evaluated. Indeed, as will be argued below, the elaboration of harmonised transparent approaches to risk assessment is not only a prerequisite for a proper functioning of the Authority but will also be a decisive factor for EFSA’s success. Showing great awareness of this issue, EFSA has recently asked the Scientific Committee to provide guidance that would ensure transparency in the risk assessments carried out by EFSA’s scientific committees and Panels. One of the most relevant issues in relation to the objective of ensuring transparency in risk assessment is that of the terms of reference of scientific opinions, i.e. the information required to be included in EFSA’s scientific opinions.

Besides this horizontal competence, the Scientific Committee is also entrusted with a purely scientific activity: the provision of scientific advice on multi-sectorial issues falling within the competence of more than one panel. Here the Scientific Committee’s intervention pursues again the goal of ensuring consistency in scientific advice. For those issues which do not fall within the scope ratione materiae of any of the Panels, the Scientific Committee must set up a working group.

It is composed of the Chairs of the Scientific Panels and six independent scientific experts who do not belong to any of the scientific panels. The six independent experts are appointed by the Management Board.

As for the Scientific Panels, they are composed of independent experts who are not employees of the Authority. The following are the Scientific Panels, replacing five of the former DG SANCO Scientific Committees, which dealt with issues falling within the competence of EFSA, following the 1997 reform:

a) Panel on food additives, flavourings, processing aids and materials in contact with food (ACF);
b) Panel on additives and products or substances used in animal feed (FEEDAP);
c) Panel on plant health, plant protection products and their residues (PPR);
d) Panel in genetically modified organisms (GMO);
e) Panel on dietetic products, nutrition and allergies (NDA);
f) Panel on biological hazards (BIOHAZ);
g) Panel on contaminants in the food chain (CON-TAM);
h) Panel on animal health and welfare (AHAW).

The eight panels are responsible for providing the scientific opinions of EFSA. Their tasks are stated in similar terms to those of the former Scientific Committees. The Scientific Committee and the Panels can form working groups of additional experts on specialised subjects so as to draw on the best scientific advice available in the EC and, when necessary, beyond.

Following the entry into force of Regulation (EC) No 575/2006, an additional Panel was created, the Panel on Plant Health (PLH), to tackle an increasing number of requests for scientific assessment of plant health risks. The Panel brings together a wide range of expertise in the various fields relevant to plant health. EFSA’s Scientific Committee and Panels were reconstituted as of June 2006 in accordance with the procedure in place for renewing the Scientific Committee and Panels every three years.

All scientists sitting in the Committee and in the Panels are appointed by the Management Board on the proposal of the Executive Director on the basis of an open competition. Neither the Commission nor the Member States play a formal role in the selection process. One may wonder whether this mode of selection is capable of eliminating any risk of political (by the Commission) or economic (by

62 According to Article 28(2): “Where necessary, and particularly in the case of subjects which do not fall within the competence of any of the Scientific Panels, the Scientific Committee shall set up working groups. In such cases, it shall draw on the expertise of those working groups when establishing scientific opinions”.
63 Other (non-food related) scientific committees have been established by Decision 2004/210/EC of 3 March 2004, OJ L 66, at 45.
64 The full list of EFSA Panels is available at www.efsa.eu.int/science/catindex_en.html.
66 The first meeting was held in Parma on 13 and 14 June 2006.
67 Membership of each scientific panel is published on the website of EFSA.
industry) influence over the scientists. Some authors suggest that the short term of office (3 years) and the possibility for renewal of their appointment may allow their selection and reselection to be guided by political factors. It is undisputable that, by having the opportunity to assist in two selections of scientists during its 5-year term of office, the Commission may be tempted to influence the selection process. However, the most serious way in which the Commission could actually exercise some political influence on the selection of scientists may be represented by the attendance of Commission officials at the deliberations of the panels. This is expressly authorized by the Regulation, which states that "the representatives of the Commission’s departments shall be entitled to be present at the meetings of the Scientific Panels and their working groups." Commission officials actually attend all scientific panels’ meetings to "ensure a seamless interface between the scientific advisor and the decision makers." Although the participation of officials is subject to the condition according to which they “shall not seek to influence discussions”, it is likely that their mere presence at the meetings may in some cases influence the delivery of scientific opinions. Thus, the scientists, depending on the circumstances, may be induced to deliver opinions which are expected of them or they may fail to take due account of some scientific information available to them. According to Greenpeace, the latter is exactly what has already happened in the assessment made by EFSA of the first two genetically engineered crops submitted to its examination. This NGO severely criticized European scientists for having ignored two critical scientific factors.

The attendance of Commission officials at EFSA meetings is not bad per se, but it becomes so insofar as it tends to be unframed and non-transparent.

As EFSA’s role is to provide an independent scientific point of reference in risk assessment [...] enabling the Community institutions and Member States to take informed risk management decisions", it is crucial to its proper functioning to find an appropriate interface between risk assessment and risk management in decision-making. A clear understanding of this interface is also crucial for the Scientific Committee and Panels of independent experts, which have been established to provide the EFSA’s scientific opinions. We will illustrate in the last section of this article how both the EFSA and the Commission have become aware of this issue and which steps have already undertaken in order to address it.

Apart from this risk of political pressure over the scientists, the other source of influence may come from industry. Given the growing trend among multinationals to devote private resources to the financing of scientific education and academic research, scientists employed in the panels may still retain close ties with industry.

In light of the above, the system for ensuring the independence of EFSA’s Members set up by the Management, being based solely on “declarations of interests”, does not seem to be adequate to overcome the flaws inherent in the composition of EFSA’s organs.

The initial procedures for operation and cooperation of the Scientific Committee and the Scientific Panels have been laid down, in conformity with the Regulation, by the Decision concerning the establishment and operations of the Scientific Committees and Panels. Furthermore, rules on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred...
to it have been set up by Commission Regulation 1304/2003 of July 2003.77

Decisions are made by a simple majority vote, minority opinions are recorded with the name of the author and the main arguments supporting it.

Since June 2006, 191 scientists have been working for the EFSA Scientific Committee and Panels for a new three-year mandate78. Their selection resulted from an EFSA call for expressions of interest launched in November 2005 which, after closing in February 2006, had attracted a total of 874 applicants.

5. Resources: personnel and budget

The Authority’s activities are funded from the Community budget based on a proposal from the Commission and approved by the budgetary authority of the Council and the Parliament. The Community’s contribution is used in a number of areas covering science, communications, institutional relations and administration. Much of the focus is currently on recruitment – especially of the scientific staff required to carry out the important increase in risk assessments entrusted to the Authority. Although in principle it is up to EFSA to determine how to use the available resources, some limits exist to this freedom. Thus, for instance, a recent amendment to the Regulation has introduced a provision according to which EFSA is to seek an opinion of the budgetary authority if it intends to implement a project which “may have significant financial implications for the funding of the budget”79.

The Authority will employ up to 350 people in the coming years, with a budget of approximately 47 million80. It may be interesting to observe that, by comparison, the Food Standards Agency in the UK has a staff of 570 for food safety functions only, and its annual budget is approximately € 140 million.

Unlike other agencies such as the OHMI, EFSA does not currently collect user fees from industry to fund its activities. However, DG SANCO launched on 15 November 2006, a consultation to gather the views of interested parties on the possibility of enabling the European Food Safety Authority (EFSA) to receive fees for processing authorisation files81. Collecting these fees may contribute to EFSA’s financial independence, since Article 16 of the Framework Financial Regulation provides that if the balance of accounts of the agency is positive, the EFSA has to repay to the Commission only the amount up to the subsidy granted, but all the amounts exceeding the subsidy may be kept as revenue in its budget for the next financial year82.

Finally, as a European public body, EFSA must respect EC regulations on procurement and budgetary matters in the conclusion of contracts for the purchase of goods and services. In compliance with these regulations, EFSA is required to publish an annual list of contracts awarded with a value below the application threshold of the EC Public Procurement Directives as well as of the annual list of awarded building contracts. EFSA annual financial reports are available on the EFSA website83.

IV. Operation

1. Risk assessment: Scientific Opinions

As previously seen, EFSA’s primary responsibility is to provide scientific advice in the areas falling under its broad competence. To fully understand EFSA’s operation it is therefore important to analyse who is entitled to ask the Authority for a scientific opinion, when the Authority may or should refuse such a request, which is the procedure applied by the Authority to requests for scientific opinions referred to it and, finally, what is the legal status of EFSA’s scientific opinions. Some special attention has also to be devoted to EFSA’s role within the Rapid Alert System.

77 Commission Regulation 1304/2003 of July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it, JO L 185, p. 6.
78 The full list of the chosen scientific experts who accepted their nomination, together with the report outlining the procedure followed for evaluation of the candidates, is available at www.efsa.eu.int/science/catindex_en.html.
80 See 2006 EFSA Annual Report.
81 See Article 45, Fees received by the Authority. The consultation paper can be found at: http://ec.europa.eu/food/consultations/index_en.htm.
Whilst the basic rules governing the operation of the Authority are contained in Regulation 178/2002, some have been introduced by Commission Regulation 1304/2003 of July 2003 laying down the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it.84

We start this analysis by turning to the question of referral to the Authority.

a. Referral to the EFSA

Unlike the previous system where only the Commission could request advice from the Scientific Committees, the EFSA may respond to requests for scientific advice from a variety of entities. Besides the Commission, Member States, national food authorities and the EC Parliament are entitled to address EFSA to obtain a scientific opinion in relation to food and feed safety issues.85 This is vital to the EFSA in establishing itself at the centre of the networks as originally envisaged by the White Paper.

Where consultation is mandatory under Community law,86 the Commission continues to have exclusive authority to obtain scientific advice from EFSA. In these circumstances, the Commission is legally obliged to consult the Authority.

Furthermore, the Authority may refuse the request for an opinion if the background information explaining the scientific issue is not given, the Community interest is lacking87 or there are no new scientific elements justifying the re-examination.88

Furthermore, the EFSA, acting ex officio, may carry out scientific assessment on any matter that may have a direct or indirect effect on the safety of the food supply, including matters relating to animal health, animal welfare and plant health.89 This Authority’s self-tasking activity contributes not only to strengthening EFSA’s scientific respectability but also EFSA’s independence.90

The Authority is also entitled to give scientific advice on non-food and feed GMOs, and on nutrition, particularly in relation to Community legislation.

The Authority is also authorized to modify a request for an opinion, or refuse it, when it is unclear, different requests are made on the same issues or when it has already delivered a scientific opinion on the specific topic.91 In these circumstances, the finalised request, as agreed to by the applicant, must be forwarded to the scientific committee or a permanent scientific panel of the Authority for preparation of an opinion.

Against this backdrop, it may be noted that the Authority exercises broader tasks than those entrusted to the previous scientific committees, notably in the area of data collection. In that regard, Article 33, paragraph 4, allows the Authority to transmit

“to the Member States and the Commission appropriate recommendations which might improve the technical comparability of the data it receives and analyses, in order to facilitate consolidation at Community level”.

Opinions issued by the Scientific Committee and Scientific Panels are subject to mandatory public disclosure as soon as possible after adoption92, provided that their publication does not violate the prohibitions against disclosure of proprietary information and of personal data.93 However, EFSA’s scientific opinions relating to foreseeable health effects can never be kept confidential.94

If we look at the Register of requested opinions listing all scientific opinions asked of EFSA during the first years of its existence (from 2003 to mid-
In all these circumstances, justification for the refusal shall be given to the institution or the Member State that made the request. However, whenever the request falling into one of these categories belongs to the Commission, EFSA may ask it for additional information or propose an amendment to the request, thus rendering less likely the refusal of its request for a scientific opinion. To achieve this objective, the exercise of such a power presupposes the existence of an effective dialogue between the risk managers within the Commission and the scientists. Although the interactions between Commission officials and EFSA scientists have been quite poor and controversial so far, there are encouraging signs showing a serious commitment from both institutions to improve the status quo\textsuperscript{104}. In any event, the formal recognition by both

\textsuperscript{95} The register for requested opinions and own-initiative opinions has been established by Commission Regulation 1304/2003 of July 2003 (on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it) "to ensure sound management" (see preamble (3)). It must be accessible to the public and allow the progress of requests for opinions to be followed with effect from the date on which they are received. See its article 2. It is available at http://www3.efsa.europa.eu/register/qr\_datedreceipt\_1\_en.html

\textsuperscript{96} Around 35 by the end of July 2005.

\textsuperscript{97} See the Register of requested opinions available at www.efsa.eu.int/register/qr\_applicants\_1\_en.html

\textsuperscript{98} Cases C-211/03, C-299/03 and C-316/03 to C-318/03, HLH Warenvertriebs GmbH [2005] not yet published, at 89-94.

\textsuperscript{99} Ibidem, at 90-91.

\textsuperscript{100} Ibidem, at 91.

\textsuperscript{101} Article 29, paragraph 4, of the Regulation.

\textsuperscript{102} Article 29, paragraph 2 and 4, of the Regulation.

\textsuperscript{103} Article 29, paragraph 4, of the Regulation.

\textsuperscript{104} While on the EFSA side, the Scientific Committee has recently set up a working group devoted to the transparency in risk assessment, on the Commission's side, SANCO's Director General has proposed the adoption of a joint format designed to facilitate the interactions between risk managers and risk assessors and the publication of annual report that would provide a feed-back on the quality of scientific opinions issued by EFSA during the previous year. On these initiatives, see S. Gabbi, The Interaction between risk assessors and risk managers. The case of the European Commission and the European Food Safety Authority, European Food and Feed Law Review, 3/2007, p. 134.
institutions of the importance of such a dialogue already represents a step in the right direction.

Regulation 1304/2003 on the procedure applied by EFSA to requests for scientific opinions referred to it has recognised some new hypotheses for refusal. Thus, the Authority shall not issue a scientific opinion in the event of requests from applicants not authorised to ask EFSA for a scientific opinion under Community legislation or requests for opinions on matters which are part of the Authority’s mission. Unlike the cases referred to in Regulation 178/2002, those introduced by this regulation do not allow the Authority to decide whether or not to provide a scientific opinion, but actually prevent it from doing so. To fully implement the duty of refusal imposed on EFSA in the first case, Member States are supposed to inform the Authority of the “government authority or authorities authorised to request scientific opinions from the Authority”.

Finally, under the transparency requirement imposed on EFSA’s activities, the Authority is supposed to make public all requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

bb. Time limits and emergencies
Community vertical legislation, such as, for instance, Regulation 2065/2003 on smoke flavourings used or intended for use in or on foods and Directive 1829/2003 on genetically modified food and feed, generally provides that, in giving its opinion, the Authority must respect a time limit of six months as from the receipt of a valid application.

Where Community legislation does not already specify a time limit for the delivery of a scientific opinion, the Authority shall issue scientific opinions within the time limit specified in the requests for opinions, except in duly justified circumstances.

In particular, Regulation 1304/2003 establishes that, in as far as Community (vertical) legislation does specify a time limit for such a delivery, the applicant may stipulate a deadline by when the opinion is required, giving the reasons. Where the Authority cannot meet this deadline, it should inform the applicant, explain the reasons and propose a new deadline. Should the applicant not stipulate a deadline, the Authority should inform the applicant of the anticipated time needed to deliver the opinion.

There are special rules governing the time limits in case of emergencies. In particular, EFSA is supposed to take the measures necessary to ensure that a request or an own-initiative opinion is delivered as soon as possible where the information accompanying the request testifies to an urgent need for a scientific opinion. Urgent need exists either when there is an emerging risk likely to constitute a serious risk to human or animal health or the environment and likely to have a Community dimension or when the Commission looks for a more detailed scientific basis for managing a serious risk to human or animal health or the environment.

cc. Transparency requirements for scientific advice
The regulation provides for several provisions establishing transparency requirements for the scientific opinions. Transparency is a must for EFSA, especially in the light of its objective of restoring consumer confidence in food safety.

All its activities, according to Article 38, have to be carried out with a high level of transparency, meaning that not only the agendas and minutes of the meetings of its scientific bodies shall be made public but also the opinions, including minority opinions.

Moreover, the information on which EFSA opinions are based must also, in principle, be made public without delay. Nevertheless, confidential information for which a confidential treatment has been requested shall not be divulged by EFSA, with the exception

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105 Commission Regulation 1304/2003 of July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it, JO L 185, p. 6.
106 Article 3, paragraph 1 of the Regulation.
107 Ibidem, Article 9 of the Regulation.
108 See Article 38, paragraph 1, lett. g) of the Regulation.
110 See Article 6(1) of Regulation 1829/2003 on genetically modified food and feed, OJ L268, p. 1.
111 Article 29(3) of the Regulation.
112 Article 38(1) lett. c) of the Regulation.
113 Article 39, paragraph 3 of the Regulation provides that “[b]y way of derogation from Article 38, the Authority shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public if circumstances so require, in order to protect public health.”
that conclusions of the scientific opinions delivered by the Authority relating to foreseeable health effects shall on no account be kept confidential. Any other non-confidential information concerning the mission of the Authority shall rapidly be made public. Wide access to documents in its possession shall equally be ensured.

Finally, the Authority’s right to issue own-initiative opinions is also subject to the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it which has been laid down by Regulation 1304/2003.

b. The legal status of the EFSA’s Scientific Opinions

Although EC institutions are expressly required to take EFSA’s opinions into account when drafting a Community measure, the Authority lacks formal authority to reach binding resolutions on potentially contentious scientific issues. In other words, similar to the old scientific committees, it does not have the final word in case of diverging scientific opinions between its own decisions and those issued by other bodies. This may be inferred from Article 30 of the Regulation which, while establishing a procedure aimed at solving problems arising from “diverging scientific opinions”, attributes neither an authoritative nor a mediating role to EFSA, but simply duties of “vigilance” and “cooperation”. This outcome is, at least on its first appearance, surprising if analysed in light of EFSA’s ambition to become “the point of reference in risk assessment” for the whole Community.

More precisely, under the Regulation, the Authority has to exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the opinions issued by national food agencies or other bodies carrying out similar tasks. Where there is a conflict between its opinion and those of bodies carrying out similar tasks, the EFSA must contact the body in question to ensure that all relevant scientific information is shared and to identify potentially contentious scientific issues. Where accommodation is not possible despite EFSA’s effort and the body is either a Community agency, a Commission Scientific body or a Member State body, the Authority is “obliged to cooperate” with the aim of resolving the differences or present a joint document, which will be made public, identifying the uncertainties and the “contentious scientific issues”. This system recalls the compulsory notification system of draft technical regulations to the extent that it functions as a preventive mechanism (sort of ‘early-warning’) aimed at solving existing any conflict arising between the national and European views of risk.

A prima facie reading of these provisions clearly shows that EFSA has not been entrusted with the power to act as the ultimate body of scientific advice in the European Union. To understand the

114 Article 39(3) of the Regulation.
115 Article 22 (6) of the Regulation.
116 This conclusion deserves to be further elaborated by looking at those situations where EFSA risk assessment is required by EC vertical legislation. In these circumstances, EFSA opinions enjoy the express status recognised by the legislation. Thus, for instance, under the GMO pre-market approval system, where the Commission decision is not in accordance with the EFSA opinion, the Commission must provide an explanation for the differences. See Article 7 of Regulation 1829/2003 (which reads: “...where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences”). See on this point S. Krapohl, Credible Commitment in Non-Independent Regulatory Agencies: A Comparative Analysis of the European Agencies for Pharmaceuticals and Foodstuffs, in European Law Journal 10 (5), p. 532.
117 Case 247/84 Mote [1985] ECR 3887, para 20, where the Court said that Member States must “take into account the results of international scientific research”, but it also stated that “it must be emphasised that the Opinions of the Committee do not have binding force”.
118 Preamble (34) and (47), Article 22 (7).
119 Article 30 (1) of the Regulation.
120 Article 30 (2) of the Regulation.
121 Although it is not expressly provided within the Regulation, this duty of cooperation must be read in light of Article 10 of the Treaty.
122 Article 30 (3-4) of the Regulation.
practical consequences stemming from this decision, one may remember the crisis involving France and the United Kingdom regarding the Commission’s decision to lift the embargo on beef exports in July 1999, two years after the BSE outbreak.125 The French Food Safety Authority (AFFSA) and the EC Commission Scientific Steering Committee strongly differed on the scientific interpretations of the risks associated with beef. France, relying on its scientific opinion, refused to lift the embargo on British beef in contravention of the EU scientific data and the EC Commission brought France before the European Court of Justice, claiming a violation of EC law.126 This case clearly exemplifies the likelihood that, in spite of the high degree of integration within the EU food safety arena, conflicts may arise in the future between national authorities and the EFSA on contentious scientific issues.

The introduction of a mere duty of co-operation does seem to fall short in providing an effective answer to the fundamental question as to the relationships between EFSA and the national authorities responsible for food safety issues. The institution of an Advisory Body, as a mechanism of exchange of information between the national authorities and EFSA, is unlikely to prove decisive in overcoming the difficulties arising from diverging scientific opinions. In light of the above, the current regulatory framework and the institution of the EFSA cannot realistically be expected to put an end to the competition in scientific matters pertaining to food among national authorities in the Member States. This is notwithstanding the committed declaration by the EFSA Deputy Executive Director that EFSA should not “compete with the excellent science in the Member States”127.

Finally, the abovementioned provisions certainly cast some doubts on the possibility that EFSA will become “the scientific point of reference for the whole Union”, as announced by the Regulation.

Most of these considerations found confirmation in the recent GMO Austrian cases where the Austrian authorities, claiming to be entitled to create a GMO-free zone, tried to obtain a derogation, on the basis of Article 95(5), from the marketing in its territory of an authorised GMO under directive 2001/18.128 Not being successful, the Austrian authorities challenged the Commission decision rejecting the ban on the use of genetically modified organisms in Upper Austria (Land Oberösterreich) by relying on their own scientific assessment.129 The CFI has rejected the Austrian action to the extent that it did not provide new scientific evidence justifying the creation of a GMO-free zone in Upper Austria.130

Another interesting recent case showing a conflict between scientific assessments performed at Community level and others of different origin is Agrarproduktionen Staebelow.131 After a test had been carried out on a slaughtered bovine animal from Staebelow’s holding gave a positive test result for BSE, 50 animals within the cohort of this animal were identified. Against this backdrop, the German authorities ordered the immediate slaughter of these animals in application of Regulation (EC) No 999/2001. Staebelow lodged an objection against that order but it was declared to be unfounded. In a preliminary ruling from a German Court, the ECJ was asked to judge on the proportionality of the obligation to slaughter the cohort of the infected animal as imposed by Regulation No 999/2001.132 In particular, Staebelow relied on the scientific evidence stemming from various scientific articles to demonstrate that the slaughter of animals made no appreciable difference to the possibility of BSE.
infection and therefore that measure was inappropriate. The ECJ uphold the validity of the Regulation, by stating that:

“As follows from the fourth recital in the preamble to that regulation, the rules which it lays down are based on various scientific opinions which recommend that the exposure of animals and humans to infected animal products be avoided. The state of scientific knowledge in that regard at the time of adoption of that regulation is apparent, in particular, from the 2001 Joint WHO/FAO/OIE Technical Consultation on BSE, cited above, in which it is stated that ‘scientific consensus confirms that food is the main avenue of exposure’ to BSE (p. 4 of that consultation)”

On this basis, the Court ruled that the challenged regulation, requiring the slaughter of the cohort of an infected bovine animal, did not infringe the principle of proportionality.

By not endowing EFSA opinions with scientific supremacy over national scientific studies, the Regulation promotes an alternative method of tackling the issue of diverging scientific opinions between the EFSA and the national scientific bodies. In order to prevent the emergence of scientific controversies, EFSA is required to promote European networking of organisations operating in food safety risk assessment. More specifically, the official aim of such networking is “to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices.” To this end, the Management Board, acting on a proposal from the Executive Director, is required to draw up a list to be made public of competent organisations designated by the Member States which may assist the Authority, either individually or in networks, with its mission. Member States are not free in designating their competent organisations, but have to abide by the criteria set out by Regulation 2230/2004 laying down detailed rules for the implementation of the general food regulation with regard to the network of organisations operating in the fields within the European Food Safety Authority’s mission. Such an external control of the national bodies which are potentially members of the network is justified insofar as EFSA may entrust certain tasks to these organisations. In particular, the Authority may require them to provide some preparatory work for scientific opinions, scientific and technical assistance, collection of data and identification of emerging risks.

Member States are required to forward to the Authority, with a copy to the Commission, the names and details of the designated organisations, evidence that they comply with the criteria set out by Regulation 2230/2004 and details of their specific fields of competence. In particular, for the purposes of application of Regulation 1829/2003, Member States must communicate the names and details of the competent organisations in the field of safety assessment of genetically modified foods and feeds.

After consulting the Commission, the Authority is also required to lay down harmonised quality criteria for the performance of tasks which it entrusts to the organisations on the list, in particular (a) the criteria to ensure that tasks are performed to high scientific and technical standards; (b) the criteria relating to the resources which may be allocated to the performance of tasks; and (c) the criteria relating to the existence of rules and procedures for

133 Case C-504/04, Agrarproduktion Staebelow GmbH against Landrat des Landkreises Bad Doberan, ECR I-1679, at para 42.
134 Article 36 of the Regulation titled “Networking of organisations operating in the fields within the Authority’s mission”.
135 Article 38 of the Regulation.
138 Under Article 1(1) of Regulation 2230/2004, the criteria that the national authorities must satisfy in order to become full members of the network are the following: (a) they must carry out scientific and technical support tasks in the fields within the mission of the [...] the Authority, especially those with a direct or indirect impact on food or feed safety; in particular, these tasks must include the collection and analysis of data connected with risk identification, exposure to risks, risk assessment, food or feed safety assessment, scientific or technical studies, or scientific or technical assistance for risk managers; (b) they must be legal entities pursuing public interest objectives, and their organisational arrangements must include specific procedures and rules ensuring that any tasks entrusted to them by the Authority will be performed with independence and integrity; (c) they must possess a high level of scientific or technical expertise in one or several fields within the Authority’s mission, especially those with a direct or indirect impact on food or feed safety; (d) they must have the capacity to operate in a network on scientific actions as referred to in Article 3 of this Regulation and/or the capacity to perform efficiently the types of task referred to in Article 4 of this Regulation which may be entrusted to them by the Authority.
139 Article 4 of Regulation 2230/2004.
ensuring that specific categories of tasks are carried out with independence, integrity and respect for confidentiality.\textsuperscript{140}

This sort of network activity is not without precedent\textsuperscript{141} and it plays a vital role within EFSA’s operation. In fact, the establishment of this network is necessary in order to support EFSA’s scientific activities, in particular in conducting scientific opinions.

By showing to be ready to play its role of ‘watchdog’ of scientific assessments within Europe, EFSA’s Management Board has recommended in June 2006 the development of greater cooperation and networking between the authority and its counterparts in the Member States. This is one of EFSA’s key priority for the period 2007-2012\textsuperscript{142}. Following this recommendation, the EFSA’s Advisory Forum established a Working Group on Co-operation and Networking which a drafted a Strategy which has subsequently been endorsed by the Management Board in December 2006. The idea behind this Strategy is that only through close collaboration on scientific issues, through greater dialogue and effective communication, it will be possible to enhance a sense of common ownership of scientific activities. This document provides for a framework for cooperation and networking between the Member States and EFSA with the final aim to finalise work to establish a common approach to risk assessment throughout Europe. The strategy recognises the following four priority areas for the establishment of a common approach to risk assessment: (a) exchanging and collecting scientific data and information; (b) sharing risk assessment practices; (c) contributing to the harmonisation of methodologies for risk assessment and (d) promoting coherence in risk communication.

To implement this programme, it is foreseen that Advisory Forum members establish EFSA’s ‘focal points’ in the Member States as regards the national networks composed of risk managers, national authorities, research institutes, consumers and other stakeholders in the field of risk assessments on food and safety; nutrition; animal health and welfare; plant protection and plant health. The Advisory Forum will also develop a list of projects as part of further strengthening the cooperation and networking between the Member States and EFSA.

The clear goal pursued by the Strategy is to lower the number of cases of scientific conflict by preventing them from arising. It remains to be seen whether this objective will be attained in the near future. Although EFSA had to deal with only three divergent Opinions\textsuperscript{143}, where its experts differed in their advice from a national authority, it may not be ruled out that, as shown by the judgments mentioned above, more cases could arise in the future\textsuperscript{144}.

**Indirect legal effect**

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

EFSA, being at the centre of the collection and communication of scientific information, has the potential to create a new information network through which it may become the leading competent source for all EC actors.

As for the EC institutions, the recent Pfizer Animal Health judgment has clearly established a general duty to consult the available scientific reports prepared by experts on behalf of the EC\textsuperscript{145}. The EC institutions would be allowed to depart from this duty only in those exceptional circumstances where equivalent scientific evidence can be found and a justification for relying on it is provided. There are therefore good reasons to believe that these constraints on the possibility of departing from scientific evidence will be maintained by the EC courts with regard to EFSA’s opinions by transforming them into de facto authoritative measures. In other words, it is likely that within the new food safety regime it will be more and more difficult for

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143 EU Food Law, June 29, 2007.

144 For an overview on the specific issue of conflicting scientific opinion, see R. O’Rourke, Scientific Conflict, the EFSA and a Common Risk Assessment, European Food and Feed Law Review, forthcoming 2007.

the EC institutions to exercise their discretion beyond the boundaries drawn by a scientific administrative network led by an independent and authoritative authority such as EFSA. This is proven by directive 1829/2003 governing the marketing of GMO foods within the EC, where it provides that, should the Commission decision not be in accordance with an EFSA opinion, the Commission must “provide an explanation for the differences”\textsuperscript{146}.

It is submitted then that the EFSA’s opinions are likely to acquire some authoritative value vis-à-vis national decision-makers as well. Although the Regulation introduces the presumption that, in the absence of specific Community provisions, all food is deemed to be safe where it complies with the specific national provisions of the country where it is marketed\textsuperscript{147}, the same regulation imposes on Member States the duty to take account of the results of risk assessment, particularly the opinions of the Authority, when regulating the food sector. In sum, while domestic authorities are not procedurally required to consult the EFSA, they are still required to abide by its scientific opinions in passing new legislation\textsuperscript{148}. It would therefore seem impossible for the national authorities to derogate from the EFSA’s opinions without giving some reasons justifying their rejection.

The Authority’s position also has the potential to acquire some legal significance for private parties. As seen above, the Regulation also imposes a general obligation on private business operators engaged in production, processing and distribution to ensure that food placed on the market is safe\textsuperscript{149}. Any breach of this duty gives rise, at least in principle, to two separate violations of EC law: breach of the general obligation to ensure that food is safe, established by article 14 of the regulation, on the one hand, and violation of the Product Liability Directive on the other\textsuperscript{150}. Although national courts are not required to consult the Authority when investigating such violations, they are likely to rely on its scientific opinions. In other words, if the EFSA has issued an opinion suggesting that a product is unsafe, it would be extremely difficult for a private individual to prove the opposite.

Finally, EFSA’s opinions can also produce some legal effects vis-à-vis national courts. In HLH Warenvertiebs, where the ECJ had expressly been asked to determine whether the scientific opinions of that Authority may have binding force on the national courts, it has been held that “[a]n opinion delivered by that Authority, possibly in a matter forming the subject-matter of a dispute pending before a national court, may constitute evidence that that court should take into consideration in the context of that dispute.”\textsuperscript{151}

Notably, the Court has stated that national courts should ascribe to such an opinion the same value as that accorded to an “expert report”\textsuperscript{152}. Thus, EFSA’s scientific opinion may be susceptible to acquiring a legal status similar to that of scientific expertise requested by the same national courts of third parties. Although not binding per se, the scientific report “should be taken into consideration in the context of the dispute.”\textsuperscript{153}

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

2. Risk communication

Communicating on risks associated with the food chain is a key part of the EFSA’s mandate. This is because, by communicating on risks in an open and transparent way based on the independent scientific advice of its scientific expert panels, EFSA may contribute to regaining public confidence in the way food risks are assessed.

In the light of the above, the Regulation entrusts the Authority with the duty to communicate, on its own initiative, the “results of its work” by acting in
close collaboration with the Commission and the Member States “to promote the necessary coherence in the risk communication process”\textsuperscript{154}. However, the Commission remains entrusted with the communication of risk management decisions, even though they are based on scientific opinions of the Authority.

As a result, while EFSA’s mission includes communication of scientific information on risks, the Commission is responsible for communicating risk management measures. This shared responsibility in relation to risk communication makes EFSA’s attempts to communicate about its scientific outcomes particularly difficult. This is especially true to the fact that, in developing public communication, EFSA will seek to translate scientific evidence into accessible and meaningful communications, addressing the needs of key audiences. In so doing, it is almost inevitable for EFSA to go beyond the mere reporting of its scientific opinions and, thus, to make reference to some possible risk management options.

The seriousness of the flaws stemming from the existing shared competence in relation to risk communication powers has recently been proven during the methyl mercury episode\textsuperscript{155} and the first Avian Influenza crisis. In the latter situation, following the publication of a scientific opinion conducted by EFSA\textsuperscript{156}, Herman Koëter, at that time EFSA’s Acting Director, declared that

> “We don’t have any evidence that the virus can be transmitted through food. But we can’t exclude it, either. If you don’t eat raw eggs and always cook poultry thoroughly, there should be no problems”\textsuperscript{157}.

In so doing, Mr Koëter did not merely communicate to the public the outcome of EFSA scientific opinion, but he unequivocally suggested well-defined consumer risk management options, such as not eating raw eggs and cooking poultry thoroughly. By doing this, EFSA clearly went well beyond its mandate in risk communication, thereby encroaching on the Commission’s powers. In fact, it clearly appeared from the media that the Commission did not really appreciate EFSA’s move.

As a result, the newly-appointed Executive Director has dramatically modified the EFSA structure by putting, for the first time, its scientific activities on a equal footing with risk communication tasks\textsuperscript{158}.

Although prima facie surprising, the decision to devote to risk communication the same amount of attention that is given to risk assessment is perfectly in line with the rationale underpinning the creation of the Authority. EFSA has been established not only to ensure food safety, but especially to promote consumer confidence.

In the light of the above, the challenge for EFSA when exercising its risk communication competence is to disseminate complex scientific information in a consumer-friendly way in order to become the indispensable port-of-call for the most up-to-the-minute data on risk. To this end, under the umbrella of the Advisory Forum, EFSA has set up a Communication Working Group to facilitate message development and co-ordination with Member States as well as the sharing of best practices in the area of risk communications\textsuperscript{159}. The Communications Working Group works with the communications departments of the national food safety agencies to build a more collaborative and informed approach to communicating risks in the food chain and to promote coherence of food safety messages across the Community. To this end it regroups the heads of the communication units from all the national food safety authorities in Europe and is chaired by the Communications Director of EFSA. Meeting four times annually, the group seeks to share best practice and facilitate consistent risk communications messages in Europe. Moreover, since 2005, EFSA’s Advisory Group on Risk Com-

\begin{itemize}
\item \textsuperscript{154} Article 40 of the Regulation.
\item \textsuperscript{155} For an insightful illustration of this case, see Gabbi, supra note 42, p. 129-131.
\item \textsuperscript{156} The Scientific Panel on Animal Health and Welfare (AHAW) of the European Food Safety Authority (EFSA) has carried out a scientific evaluation on the animal health and welfare aspects of Avian Influenza (AI). This opinion has been considered at the Panel’s meeting on 13-14th September 2005 with a view to providing additional scientific support to the European Commission and Member States in addressing this issue.
\item \textsuperscript{157} As reported by several newspapers and other media, such as the Daily Mail (available at http://www.dailymail.co.uk/pages/live/articles/health/healthmain.html?in_article_id=166607&in_page_id=1774 &ito=1490), FOX News (available at http://www.foxnews.com/story/0,2933,173450,00.html) and News Scotsman (available at http://news.scotsman.com/international.cfm?id=2146272005).
\item \textsuperscript{158} The organigramme of EFSA is available at http://www.efsa.europa.eu/etec/media/efs/about_efs/structure/126.Pat.0001.File.dat/comm_efsorganigr_en.pdf
\item \textsuperscript{159} See http://www.efsa.eu.int/advisory_forum/working_groups/165_en.html.
\end{itemize}
munication (AGRC) has been established, which is comprised of seven risk communication experts and provides advice to the EFSA Executive Director on risk communications and issues specific to the work of EFSA.\footnote{160}

Besides the above described difficult cooperation with the Commission, EFSA also acts in close collaboration with the national authorities and the Member States to promote the necessary coherence in the risk communication process, especially with regard to public information campaigns.\footnote{161}

The main objective pursued by the EFSA's risk communication policy is to ensure that the public and any interested parties are rapidly given objective, reliable and easily accessible information, in particular with regard to the results of its work.

Although prima facie surprising, the recent decision to devote to risk communication the same amount of attention that is given to risk assessment is perfectly in line with the rationale underpinning the creation of the Authority. EFSA has been established not only to ensure food safety, but especially for promoting consumer confidence.

It may be predicted that it is also against the latter objective that EFSA's legitimacy will ultimately be tested. Notwithstanding these laudable efforts, the modest communication budget (9% of the overall budget of the Authority) seems to cast some doubts on the attainment of this goal.\footnote{162}

V. The interactions between EFSA and the Commission

As it stems from the establishment of the Authority itself, the European legislator has opted not solely for a functional separation of the risk management from the risk assessment but also for an institutional separation between these two main components of risk analysis.

The first five years of existence of EFSA have shown that this ‘double-strengthened’ separation may give rise to tensions between the two entities to which those tasks are entrusted.

Besides the problems that have previously been highlighted in relation to the handling of the shared task of risk communication, the interpretation originally given to the principle of separation between risk assessors and risk managers has been so radical, from both sides, as to render impossible any attempt (réduire à néant) of dialogue between the two entities. In particular, this strict interpretation of the principle has been even worsen by, on the one side, EFSA which did not hesitate to test its own autonomy vis-à-vis its parent DG (so-called “DG de tutelle”), and on the other side the Commission which could not prevent itself from showing its muscles in front of the newly-created body.\footnote{163}

Today, following a few years of difficult coexistence, both EFSA and the European Commission seem to have finally become aware of the importance of an ongoing interaction between them, thus finally showing their willingness to fully implement those provisions which require EFSA to cooperate closely with the Commission.\footnote{164} Indeed, by showing some sensitivity to this growing trend of questioning the appropriateness of drawing a clear-cut distinction between the purely technical assessment of risks by scientists and the management of these risks by decision takers, the same general food regulation expresses the need, not without some ambiguity, to strengthen the “link between risk assessors and risk managers” in order to promote coherence and transparency between the risk assessment, risk management and risk communication functions.\footnote{165} This attempt to move towards a more fluid model of risk analysis which eschews formal conceptual distinctions and focuses on multiple inputs to the decision-making process, communication and public participation aims at ensuring that risk assessment addresses the right questions and that the answers are properly interpreted in risk management.

There are signs showing that both entities are undertaking several initiatives aimed at addressing some of the initial problems they had to face in their daily interactions. While the first years of

\footnote{160} The terms of reference of this body are available at http://www.efsa.europa.eu/efsa/about_eufsa/communicating_risk/adv_group_risk_comm/1160.Par.0027.pdf. Its members rank among the most famous experts in risk communication and are Jesus Contreras, University of Barcelona; Claude Fischler, CNRS, CETSAH, EHESS, Paris; Baruch Fischhoff, Carnegie Mellon University; George Gaskell, London School of Economics; Ragnar Löfstedt, King's College, London and Professor Ortwin Renn, University of Stuttgart.

\footnote{161} Article 40 (3) and (4) of the Regulation.

\footnote{162} EFSA Report 2006, p. 53.

\footnote{163} Gabbi, supra note 42, p. 129.

\footnote{164} Ibidem.

\footnote{165} Recital (35) of the Preamble.
EFSA’s existence have clearly shown the need for an effective interaction, one must make sure that these new mechanisms do not compromise the ontological underpinning for the establishment of the authority: ensuring both a functional and an institutional separation between risk assessment and risk management. It is suggested that this entirely legitimate process may strip the ‘functional separation’ between risk management and risk assessment of its original goal: purity of scientific assessment and accountability of risk managers. In other words, there is a need to find ways for risk assessment and risk management to interact efficiently, while at the same time maintaining appropriate functional separation.

This is the challenge currently facing the European food safety regulatory governance.

To give one but an example of the above described risk of compromising the principle of separation when favouring the interaction between risk assessors and risk managers, one may look at the recent proposal to create a Steering Committee, composed of risk managers, risk assessors and stakeholders’ representatives, which should draft the terms of reference of requests of scientific opinions. It is submitted that endorsing this opinion would inevitably put at stake the entire philosophy underpinning the separation between risk assessors and risk management, by offering them an opportunity to even mingle with industry representatives, the most motivated stakeholders in the food arena.

If an enhanced cooperation between risk assessors and risk management is becoming an indisputable need for a successful European food governance, any initiative to meet this goal should not compromise the original rationale underpinning the establishment of the Authority: purity of scientific assessment and accountability of risk managers.

Along this line of thought, it is regrettable that the recent Commission’s Consultation paper on whether EFSA should receive fees for processing authorisation files does not contain any appreciation on the impact that such a reform may have on the relationship existing between these two entities.

VI. Conclusion

In order to assess the success of EFSA within the context of the new European Food Safety regime, one has to verify whether this Authority has provided a credible answer to the most pressing questions among policy-makers and lawyers: whose science to use?

The creation of the EFSA and the enactment of the new food policy regime stem directly from the food scares that slapped Europe at the end of the 1990s. It would certainly have taken longer for the Community to conceive this reform if several food scandals had not rendered its system of governance “contested”, by showing the absence of a centralized European scientific assessment and a unifying text setting out the fundamental principles of EC food law. By producing a collapse of public trust in the European institutions, the contested governance of European food safety has not only accelerated this reform, but it has considerably helped EC food law to get rid of its original sin, its pro-market-bias, by illustrating the importance of assuring the safety of the products in free circulation throughout the Community. Under the new policy, only foodstuffs that are safe, wholesome and fit for consumption can be placed on the market for consumers.

By ceasing to be a fragmented area of Community law, European food law is based for the first time on comprehensive legislation covering the entire ‘farm to fork’ distribution chain and directly enforceable in all the EC Member States.

The role of EFSA in the implementation of the new food regime is far removed from that of the FDA within the U.S. context. This is due not only to the authorities’ different missions and diverging regulatory universes, but also to the conflicting per-


168 By “contested governance”, Ansell and Vogel mean a “pervasive conflict in policy arenas that goes beyond politics-as-usual to challenge who should make decisions and where, how and on what basis they should be made”. In other words, “[c]ontested governance entails a significant challenge to the legitimacy of existing institutional arrangements.” See C. Ansell and D. Vogel, What’s the Beef? The Contested Governance of European Food Safety, supra note 5.
ceptions of risk developed by their respective citizen-consumers\textsuperscript{169}. Risk analysis being the Grund-norm of the new regime, one could have expected the EFSA to become the scientific authoritative body for the whole Union and having the final word in all contentious scientific matters. But Member States did not want to make the Authority an oracle of Delphi spelling out the “truth” in all scientific matters. Rather they wanted to preserve the right of their national food agencies to carry out scientific studies, thus expressing their specific perception of a certain risk. In the words of EFSA:

“EFSA does not want to compete with the excellent science conducted in the Member States. On the contrary, it is eager to work with scientists from all Member States to share data and results from scientific studies and to harmonize national approaches to risk assessment, as appropriate. EFSA’s scientific opinions do not supersede any national opinion; they provide an independent European view which ideally complements national opinions. EFSA’s scientific opinions provide an authoritative reference for European risk assessment, and where EFSA risk assessments are required by EC legislation, it is EFSA’s opinion which prevail”\textsuperscript{170}.

While this approach is likely to bring about conflicts among Member States, it expresses the European attempt to defend its cultural patrimony and culinary richness against the mounting trend towards the obliteration of local traditions led by the multinational producers of processed food\textsuperscript{171}. Accordingly, in case of diverging opinions between the EFSA and national food authorities, it is up to the EC courts, and not to the EFSA, to solve these conflicts by striking a balance between the universal and the local values. However, there are encouraging signs showing that this kind of judicial involvement could be strongly reduced in the near future. By showing to be ready to play its role of “watchdog” of scientific assessments within Europe, EFSA’s Management Board has developed a “Strategy for Cooperation and Networking between the EU Member States and EFSA” by turning its imple-


\textsuperscript{170} Front cover article by H. Koëter, EFSA Deputy Executive Director and Director of Science, in EFSA news, 2/2004.

\textsuperscript{171} Contra, D. Chalmers, “Food for thought”: reconciling European risks and traditional ways of life, supra note 116, p. 533 who argues that the new legal regime will “probably reterritorialise conflicts so that these endemic and irresolvable disputes become reconfigured along European versus particularistic fault lines, with local groups either arguing a right to consume a food that is considered dangerous under EU law or to be protected from exposure to a product that is considered safe under EU law”.


\textsuperscript{173} Alemanno, supra note 169, pp. 237-258.

Wine Labelling: Future Perspectives

Luis González Vaque* and Sebastián Romero Melchor**

At the beginning of July 2007, the Commission presented a “Proposal for a Council Regulation on the common organisation of the market in wine and amending certain Regulations”. This document is part of the continuing Common Agricultural Policy (CAP) reforms of 2003. It takes into account Community policies related to sustainable development, agreed at the Goteberg European Council, on greater competitiveness in the relaunched Lisbon Strategy and on Simplification and Better Regulation for the CAP.

I. Introduction

The Commission’s proposal nearly covers all the aspects of the pre-cited common market organisation (CMO). Nevertheless, in the present paper we exclusively refer to the measures that are foreseen in the said document related to the labelling and, in this field, we will also briefly analyse the references made to the designations of origin and geographical indications of wines [which is dealt with in Chapter III of Title III (“Regulatory measures”) of the proposed Regulation].

Before delving further into the topic, it is worth underlying that one of the Commission’s planned objectives is precisely to achieve a clearer, more coherent and therefore more market oriented wine classification and labelling. Moreover we would like to remind you that the said Community Institution [bearing in mind that the concept of EU quality wines is based upon a geographical origin approach (quality wine produced in a specific region), and that this approach is currently being confirmed, adapted, promoted, and enhanced worldwide] already announced in the Communication “Towards a sustainable wine sector” its intention to “... revise the current quality regulatory framework, with a view to enhancing the conformity of EC quality policy as regards international rules”.

II. Labelling

1. Establishing a unique framework

The Commission proposes to simplify the labelling provisions by setting up a single legal framework applying to all the different categories of wine and particulars relating to them. It would be tailored to the expressed needs of consumers and more consistent with the wine quality policy. In particular, this would involve:

- transferring the competence from the Council to the Commission;
- the use of a single legal tool for all wines by complementing the rules in the horizontal labelling Directive 2000/13/EC which horizontally regulates the labelling of food products as appropriate to meet the particularities of the wine sector as regards compulsory and optional labelling needs;
– improving the flexibility of the labelling policy, in taking into account the WTO policies: by removing the distinction between the rules on labelling wines with and without geographical indications, and, most importantly, facilitating the indication of vine variety and vintage on wines without geographical indication status but which abide by certain requisites on appropriate traceability; and
– ensuring health and consumer information and protection, fully informing the consumer of the origin of the product, which will imply the adoption of labelling provisions on traceability7.

2. Definition of labelling

In article 47 of the Regulation proposed by the Commission, labelling is defined as “any words, particulars, trademarks, brand name, pictorial matter or symbol placed on any packaging, document, notice, label, ring or collar accompanying or referring to a given product”. The fact that the proposed text does not refer to the definition appearing in Directive 2000/13/EC (whose applicability is confirmed in article 488) could be considered as an inconsistency which will hinder the transposition on wine labels of such effective concepts as the presentation inherent to labelling, etc.

3. Compulsory information

Labelling of the products abiding by the future Regulation shall contain the following compulsory particulars:
– the category of the grapevine product (wine, liqueur wine, sparkling wine, aerated sparkling wine, etc.9);
– the actual alcoholic strength by volume;
– an indication of provenance of the wine;
– an indication of the bottler; and
– an indication of the importer in the case of imported wines.

For wines the labels of which include the protected name of a designation of origin or geographical indication, it would be compulsory to specify:
– the terms protected designation of origin or protected geographical indication; and
– the name of the protected designation of origin or protected geographical indication in question.

In the case of these wines, the reference to the category of the grapevine product may be omitted when the name of the protected designation of origin or protected geographical indication is displayed on the label.

However, it will not be necessary to include the terms protected designation of origin or protected geographical indication in the following cases:
– where a national specific designation as regulated by national law is displayed on the label; and
– where, in exceptional circumstances10, the name of the protected designation of origin or protected geographical indication is displayed on the label.

4. Optional information

According to article 50 of the Regulation proposed by the Commission, some labels may contain the following optional particulars:
– the vintage year;
– the name of one or more wine grape varieties;
– terms indicating the sugar content; or
– terms referring to certain production methods;

For wines with the protected designation of origin or geographical indication, some labels may include references to:
– traditional terms other than the designations of origin and geographical indications which desig...
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nate the production or ageing method or the characteristics, colour, type of place of the wine concerned; or
– the Community symbol indicating the protected designation of origin or geographical indication.

It is remarkable that whilst in Regulation No 510/2006 the Community symbols associated with the protected designation of origin or geographical indication are included in the compulsory particulars (when the names of the "protected designation of origin" or "protected geographical indication" are not displayed on the label), such a symbol is merely optional for wines...

5. Languages

The topic of "Languages" is dealt in Article 51, which provides that «compulsory particulars [...] shall, where expressed in words, appear in one or more of the official languages of the Community». However, "the name of a protected designation of origin or geographical indication or the national specific designation shall appear on the label in the official language or languages of the Member State where the wine originates".

This provision raises certain doubts over the possible movement of wines bearing indications, which are incomprehensible for consumers of the Member State in which they are marketed... We suppose the Council will amend it.

III. Indication of the geographic origin

1. A new approach

The Commission’s new approach in this field is in line with the general objectives set forth to change the wine sector’s Community regime by proposing to:
– consolidate the reputation of Community quality wine as the best in the world; and,
– recover old markets and winning new ones in the Community and worldwide; and,
– create a wine regime that operates through clear, simple and effective rules that balance supply and demand; creating a wine regime that preserves the best traditions of Community wine production, reinforcing the social fabric of many rural areas, and ensuring that all production respects the environment.

2. And new definitions...

Recital No 24 of the Commission’s proposed Regulation insists that the concept of quality wines in the Community is based, among other things, on the specific characteristics attributable to the wine’s geographical origin. Moreover, "such wines are identified for consumers via protected designations of origin and geographical indications although the current system is not fully developed in this respect".

The alternative system proposed by the Commission is fundamentally based upon the common notions of designation of origin and geographical indication, which are defined in article 27.1 of the abovementioned Regulation as follows:
– designation of origin: the name of a region, a specific place or, in exceptional cases, a country used to describe a wine, a liqueur wine, a sparkling wine, an aerated sparkling wine, a semi sparkling wine or a wine of overripe grapes that complies with the following requirements:
i) its quality and characteristics are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors;

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12 See article 8.2 of the Regulation No 510/2006 quoted in the previous footnote.

13 See also article 50 of the proposed Regulation in the document COM(2007) 372 final quoted in note 2 supra.


15 Our emphasis.

16 See also Recital No 24 of the proposed Regulation in the document COM(2007) 372 final quoted in footnote 2.
ii) the grapes from which it is produced come exclusively from this geographical area;  
iii) it is obtained from vine varieties belonging to Vitis vinifera.

– Geographical indication: an indication referring to a region, a specific place or, in exceptional cases, a country, used to describe a wine, a liqueur wine, a sparkling wine, an aerated sparkling wine, a semi sparkling wine or a wine of overripe grapes which complies with the following requirements:
   i) its quality, characteristics or reputation are essentially attributable to its geographical origin;
   ii) at least 85% of the grapes used for its production come exclusively from this geographical area;
   iii) it is obtained from vine varieties belonging to Vitis vinifera or a cross between the Vitis vinifera species and other species of the genus Vitis.

Yet, according to article 27.2:

"Traditional names shall be considered as a designation of origin where they:
   a) designate a wine;
   b) refer to a geographical name;
   c) fulfil the conditions referred to in points (i) to (iii) of paragraph 1(a)\(^{17}\)."

3. Coexistence of new and old designations

Brevitatis causa, we shall not deal with the various procedural requirements to comply with when filing an application for the protection of certain names by means of including them in the category of Community designations of origin or geographical indications\(^{18}\).

In any case, we consider it useful to refer to article 44 of the future Regulation, according to which: "1. Wine names, which are protected in accordance with Article 54 of Regulation (EC) No 1493/1999 and Article 28 of Regulation (EC) No 753/2002, shall automatically\(^{21}\) be protected under this Regulation. The Commission shall list them in the register provided for in Article 39.  
2. Member States shall, in respect of the designations of origin and geographical indications referred to in paragraph 1, transmit to the Commission:"

a) the technical files as provided for in Article 28(1);  
b) the national decision indicating their validity.

3. Names referred to in paragraph 1, for which the information referred to in paragraph 2 is not submitted by 31 December 2010, shall lose protection under this Regulation. The Commission shall take the corresponding formal steps to remove such names from the register provided for in Article 39.

4. By way of derogation from Article 43, it may be decided, until 31 December 2013, on the initiative of the Commission and in accordance with the procedure referred to in Article 104(1), to cancel protection of designations of origin or geographical indications referred to in paragraph 1 of this Article if they do not meet the relevant conditions for protection".

IV. Conclusion

It is surely too early as yet to reach definite conclusions. However, we consider it praiseworthy that, at last, it is a question of eliminating "differences between the laws of the Member States on the labelling of wine products [which] may impede the smooth functioning of the internal market"\(^{22}\). Furthermore, it appears coherent that the applicability, with horizontal character, of Directive 2000/13/EC should be maintained, considering that, "experience has shown that a differentiation in

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\(^{17}\) In other words, its quality, characteristics or reputation are essentially attributable to its geographical origin, with its related natural and human characteristics; the grapes used for its production come exclusively from this geographical area; and is obtained from vine varieties belonging to Vitis vinifera.


\(^{19}\) Council Regulation (EC) of 17th May 1999 through which is established the common organisation of the market in wine (OJ L 179, 14th July 1999, p. 1).


\(^{21}\) Our emphasis.

\(^{22}\) See Recital No 35 of the proposed Regulation in document COM(2007) 372 final quoted in note 2 supra.
terms of labelling rules according to the category of wine product is not expedient.23

If the communautarisation of wine labelling is welcomed, the one of the regime applicable to designations of origin and geographical indications is equally suitable. As far as the latter is concerned, the Commission’s proposal presents several positive aspects such as, for instance, foreseeing that “protection should be open to designations of origin and geographical indications of third countries where these are protected in their country of origin”24. On the contrary, some authors have criticised the fact that the Commission believes that “in order to preserve the particular quality characteristics of wines with a designation of origin or a geographical indication, Member States should be allowed to apply more stringent rules in that respect”25.

23 Ibidem, Recital No 38.
24 Ibidem, Recital No 27.
25 Ibidem, Recital No 25 (see also: MARTÍNEZ JAVALAMBRE, op. Cit. note 18 supra, 16-17).