European Food Safety Authority

EXECUTIVE DIRECTOR

Parma, 31 MAY 2011
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Erminia Mazzoni
Chairman of the Committee on Petitions
European Parliament
60, rue Wiertz
1047 Brussels
Belgium

Re.: Your letter dated 27 April 2011 concerning Petitions No. 813/2008, 305/2010 and 436/2010

Dear Honourable Member of the European Parliament, dear Mrs Mazzoni,

Thank you very much for your letter dated 20 April 2011 in which you ask the European Food Safety Authority (hereinafter EFSA) to provide its considered position regarding the questions and allegations set out in three different petitions submitted to your Committee.

After careful consideration of the petitions and the exchanges of letters between the Petitioners and the European Commission, I am pleased to inform you that I did not find any breach of the principles or rules governing EFSA, with particular reference to the principles of transparency, openness, scientific excellence and independence, and to the legal framework applicable to the Authority[1].

With respect to the allegations outlined in the petitions, I would like to take this opportunity to clarify the measures put in place by EFSA over time to ensure the independence of its scientific outputs, decision making processes and experts, and to respond to those allegations.

1. EFSA's Governance

EFSA's governance as laid down in Regulation (EC) No 178/2002 provides a strong basis for the independence of the Authority. On the one hand, the functional separation of risk assessment from risk management ensures that EFSA's advice is free from political influence, while the allocation of EFSA's administrative and scientific powers to different internal bodies that check and balance the enactment of each other's attribution do ensure that the scientific processes are managed without undue influence from the other bodies.

[1] Such as Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as last amended.

In more detail, Article 24 of Regulation (EC) No 178/2002 foresees a Management Board, which is entrusted with the task of providing strategic directions, adopting the internal rules, the budget, the annual work programme, the statement of estimates of revenue and expenditure and the establishment plan; an Executive Director appointed by the Board, who is EFSA's legal representative, implements the strategic documents adopted by the Board and manages the daily operations of the Authority; an Advisory Forum, which advises the Executive Director regarding cooperation and networking with Member States' authorities; EFSA staff, who provide scientific and technical advice and secretarial support to the Scientific Committee and Scientific Panels; and the Scientific Panels and Scientific Committee, which adopt scientific opinions and other major scientific outputs.

EFSA's Management Board plays a crucial role in ensuring that the Authority acts independently. The members of the Board are appointed by the Council, in consultation with the European Parliament from a shortlist of candidates drawn up by the European Commission following a public call for expression of interest, plus a representative of the European Commission. By law, four of the members shall have a background in organisations representing consumers and other interests in the food chain[2]. Nonetheless, all members of the Board are appointed in a personal capacity: they are required to act independently in the public interest and refrain from any activity that could result in a conflict of interest or is likely to be perceived as such by the public[3]. Pursuant to the Rules of Procedure of the Management Board, their compliance with that obligation is ensured by the Chair of the Board, who is required to screen the declarations of interest to be submitted annually in writing by each member of the Board.

2. EFSA's scientific decision making

As far as the scientific processes are concerned, EFSA put in place several procedures and workflows to ensure the independence of its scientific experts, scientific bodies and outputs.

The members of EFSA's Scientific Committee, Scientific Panels and Working Groups, as well as other external experts contributing to the work of EFSA, are selected based on their scientific competence and expertise, and according to objective and transparent criteria set out in a call for expression of interest published on the Official Journal of the European Union, on EFSA's website and on other relevant scientific journals. Every effort is made to secure a proper geographical and gender balance, compatibly with considerations such as the diversity in the Scientific Committee or Scientific Panel of scientific expertise and disciplines of work. Furthermore, during the selection process, interests declared by the applicants are screened with a view to preventing the appointment of candidates with evident and significant conflicts of interest so that they are not appointed as members of EFSA's Panels and Scientific Committee. In addition, independent external evaluators and observers review the assessment of applications to ensure that the selection process is carried out in a correct, fair, consistent and coherent manner[4].

The Rules of Procedure[5] provide a procedural framework for the establishment and operation of the Scientific Committee, Panels and their Working Groups, covering issues such as the *quorum* for the adoption of outputs; the assignment of tasks to the Scientific Committee or Panels; the

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[2] Article 25 of Regulation (EC) No 178/2002.

[3] Article 37 of Regulation (EC) No 178/2002.

[4] For more information on the selection of EFSA's scientific experts, see http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.

[5] Decision concerning the establishment and operations of the Scientific Committee, Scientific Panels and their Working Groups, see http://www.efsa.europa.eu/en/keydocs/docs/paneloperation.pdf. See in more detail also *infra*, page 4.

creation of Working Groups; the attendance of observers to meetings; and public hearings. This ensures a harmonised processing of EFSA's scientific decision making workflows, thereby granting impartiality and objectivity in all scientific processes and preventing any form of discrimination. In that respect, EFSA has also invested a great deal of resources to develop a comprehensive body of good risk assessment practices and methodologies to guide the work of its Scientific Committee and Scientific Panels to ensure their opinions respect the highest scientific standards[6]. This represents an additional guarantee of the objectivity and impartiality of the scientific processes and standards followed by EFSA. Indeed, the fact that general good risk assessment practices and methodologies have been developed helps avoiding a case by case approach that could otherwise be detrimental to the impartiality of the work of EFSA's scientific experts.

As outputs are adopted by consensus or by the majority of the concerned experts, the risk of one viewpoint exerting an undue influence over the other members of the group is limited. EFSA's advice does not represent the views of any single expert or school of thought. Scientific matters are usually first debated in a working group, where a scientific output is drafted, endorsed and later shifted to the competent Scientific Panel or Scientific Committee, where the debate becomes more focused and drafts are discussed, amended and finally adopted. The quality of EFSA's scientific outputs is therefore also enhanced by ensuring a shared responsibility of all members of a Panel after deliberation in a dedicated Working Group.

To ensure the quality of its outputs and the reliability of its advice, EFSA disposes also of an internal capacity of data collection, validation and analysis as well as harmonising data collection methodologies to facilitate transfer of data to, and from, Member States and increasing the comparability of data. In relation to dossiers received from applicants seeking authorisation of products or claims, EFSA not only collects the data from publicly available sources but also directs the data requirements for applicants submitting dossiers.

3. Openness and Transparency

For what concerns the allegations that EFSA is not transparent enough in its scientific processes, I would like to clarify the following.

EFSA adheres to high transparency standards. All its scientific outputs are published and available on its website. The progress of a mandate can be checked at all times from receipt through to the adoption of the scientific output and can be freely accessed via the EFSA website, the Register of Questions database[7], meeting minutes and outcomes of public consultations. All documentation supporting the scientific decision-making process – draft assessment reports, Member State contributions etc. – are published alongside the final output. Finally, EFSA records minority views and publishes them in its scientific outputs to ensure that the full plurality of views is transparently reflected in its advice.

EFSA is also committed to openness to the civil society and regularly consults its stakeholders, partners and the public at large on key issues, both scientific and otherwise. Consultations contribute to enhancing the quality and completeness of EFSA's scientific outputs. Guidance documents lay down the data requirements/methodologies that will be used by Panels in carrying out risk assessments. In other words, risk assessment methodologies are discussed, debated, open to public scrutiny and not developed by the Panels in isolation. In addition, technical meetings

[6] For more information on the on EFSA's good risk assessment practices and methodologies http://www.efsa.europa.eu/en/efsahow/rapractice.htm.

[7] EFSA Register of Questions Database, see http://www.efsa.europa.eu/en/request/requests.htm

and workshops are organised with specific stakeholder groups and where appropriate are webcast live on EFSA's website[8].

In other words, contrary to what it seems possible to deduce from the petitions, EFSA's openness to civil society is not limited to the management of the Stakeholder Platform, and goes far beyond that.

4. EFSA's Policy on Declarations of Interests

EFSA, as an independent Agency created to provide scientific advice on all matters related to the safety of the food chain to Union risk managers, takes very seriously its mission to deliver high quality scientific advice. For this reason all the rules that guarantee the independence, objectivity and impartiality of the EFSA duties are scrupulously implemented day after day.

In October 2007, in accordance with the principle of independence laid down in Articles 22(7) and 37 of Regulation N° 178/2002, EFSA's Management Board adopted a *Policy on Declarations of Interests* (DOIs)[9] which laid down specific provisions for preventing conflicts of interest. To implement the policy, a set of comprehensive rules and procedures were drawn up[10], supported by a detailed *Guidance Document on Declarations of Interest*[11].

The DoI Policy is based on the principle that high quality scientific expertise is by nature based on prior experience, that interests are a natural and inevitable consequence of attaining scientific recognition at international level in a given field and that some of those interests may conflict with EFSA's aim to deliver objective scientific advice.

The Policy foresees a three-step screening process of Declarations of Interest submitted by scientific experts: depending on the roles, functions and relevant groups of the persons concerned, they are required to complete and submit (i) an annual DoI (ADoI); and/or (ii) a specific DoI (SDoI) linked to a specific subject matter (e.g. an application dossier) to be filled before each meeting; and (iii) an oral declaration of interest (ODoI) at the beginning of each meeting. ADoIs are posted by EFSA on its website, whereas SDoIs and ODoIs resulting into potential conflict of interest are recorded in the minutes of the relevant meeting.

Conflicts can only be assessed by considering whether the specific interests declared by a person are compatible with the concrete tasks and roles to be assigned to him or her by EFSA,

A special procedure for identifying and handling potential conflict of interests has been implemented. In case a Panel member or other EFSA expert is found to be in potential conflict of interest with respect to certain activities, past or present, or dossiers, and that situation cannot otherwise remedied, appropriate measures are taken to avoid that a conflict of interest occurs. These range from the exclusion of the expert from voting on a certain matter to his or her exclusion from all EFSA activities.

Thus far, this has resulted in the exclusion of 24 experts from all EFSA activities; of 280 experts from the drafting of certain outputs, and of 53 experts from the discussion of specific agenda items.

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[8] For example, the workshop on draft guidance for GM plant comparators - Webcast available http://www.efsa.europa.eu/en/events/event/gmo110331.htm or the meeting on gut and immune function health claims, see http://www.efsa.europa.eu/en/press/news/nda101206.htm.

[9] EFSA Policy on Declarations of Interest, see http://www.efsa.europa.eu/en/keydocs/docs/doipolicy.pdf.

[10] Implementing Act to the Policy on Declaration of Interests: Procedure for Identifying and Handling Potential Conflicts of Interest, see http://www.efsa.europa.eu/en/keydocs/docs/doiconflicts.pdf.

[11] Implementing Act to the Policy on Declaration of Interests: Guidance Document on Declarations of Interest, see http://www.efsa.europa.eu/en/keydocs/docs/doiguidance.pdf.

According to a benchmarking report delivered by a contractor and assessing Conflict of Interest/DoI policies of other risk assessment bodies, the Authority's Policy stands out as the real benchmark in terms of policies regulating Conflicts of Interests[12].

Nonetheless, the Authority has made and continues to make significant investments in tools to facilitate the implementation, monitoring and enforcement of the DoI screening system[13]. The effective implementation of DoI procedures has been validated by a number of both independent and internal reviews performed from 2008 to 2011 by contractors[14] and auditors.

In these months, EFSA is in the process of reviewing its approach to Independence of its scientific decision making process, and later in the year this may also result in further refinements to the procedure aimed at preventing CoIs.

Further to this, I am pleased to inform you that a Code of Conduct for scientific experts is currently being developed by EFSA in order to formalise the way EFSA experts should discharge their duties, with the ultimate goal of avoiding misunderstandings about those aspects.

5. Re. the legal framework applicable to EFSA staff

As regards allegations directed to EFSA staff, I would like first to clarify the difference between persons employed by the Authority as staff members, and experts cooperating on a voluntary basis outside an employment scheme. The latter constitute the category of experts who compose EFSA's Scientific Committee, Scientific Panels and their Working Groups, cooperate with EFSA voluntarily, receiving only reimbursement for the expenses they incur in and compensation for the time they devote to EFSA; conversely, the former work full time for EFSA, are paid by the Authority and are subject to the same Staff Regulations applicable to the European Commission and the vast majority of Union Institutions, bodies and agencies[15].

For what concerns the rules applicable to EFSA staff, as you may know already, the Authority does not have much discretion: it is bound by the Staff Regulations adopted by the Council and by implementing measures of those Regulations that have to be cleared by the European Commission before adoption.

Therefore, EFSA staff is hired on fixed terms contracts following a transparent selection procedure that foresees both written and oral examinations, under the scrutiny of a Panel of staff members already employed by EFSA, another fellow agency or another Union Institution. EFSA staff are fully subject to the obligations of avoiding conflicts of interest during their time at EFSA, being impartial and fair, behaving professionally and respecting the confidentiality of data acquired in the context of their work at the Authority. EFSA staff are trained to act in accordance with high standards of ethics and integrity. In order to implement in the most effective way the obligation foreseen in the Staff regulations of avoiding conflicts of interest for the duration of their contract with EFSA, staff members dealing with scientific matters are required to complete

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[12] Comparison between the tools ensuring EFSA's independent scientific advice and the instruments in use by organizations similar to EFSA, final report, February 2011.

[13] EFSA has invested more than €0.6 mil and three full-time staff equivalents in the development of an electronic DoI tool, and annually the Authority allocates an estimated three full time equivalents and €180 k budget to the screening of DoIs and related administrative tasks.

[14] Independent report of factual findings in connection with the implementation of EFSA policy on Declarations of Interests in certain Scientific Panels.

[15] Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community, as last amended.

an ADoI, which is then screened by the Appointing Authority and used as a basis for preventing the occurrence of CoIs.

For what concerns former EFSA employees, the Authority has to comply with Article 17 of the Staff Regulations, according to which in case a former employee informs EFSA of his or her intention of engaging in an occupational activity, the Appointing Authority may forbid him or her from taking up that duty, or accept that under certain conditions, should that activity be found in conflict with the interest of the Authority. In that respect, however, due account should be taken of the fact that EFSA staff are hired under a temporary contract.

6. The risk assessment process of Genetically Modified Organisms

In relation to the risk assessment of genetically modified organisms, EFSA's GMO Panel applies the strict criteria laid down in the EU regulatory framework in relation to GMOs[16]. This is reflected also in the Panel guidance documents describing the data requirements applicants have to comply with when submitting their dossiers, such as all the necessary studies on human and animal safety and on environmental impact. The guidance documents were adopted by the Panel following an open public consultation aimed at gathering the views of EFSA's stakeholders and of the public and improve and complete the scientific base for the guidance. Finally, the Panel regularly reviews its guidance documents taking into account scientific developments and experience gained through its risk assessments.

For what concerns the allegations according to which EFSA would base its scientific opinions regarding dossiers submitted in the context of authorisation procedures of GMOs exclusively on data presented by applicants, I would like to highlight that the GMO Panel does not satisfy itself with those data. Rather, it frequently asks applicants for further scientific information, study results or clarifications before processing their applications: as a matter of fact, this happens in approximately 95% of the cases.

In addition to the clarifications and additional data provided by the applicant, EFSA takes into account other sources of information. Indeed, EFSA consults national competent authorities, the EFSA GMO Panel takes all published information into account, welcomes peer reviewed research results available in scientific literature including independent reviews of raw data derived from applicants' studies and is mindful to consider any other relevant scientific information made available. As far as the confidentiality of data submitted by applicants in the context of the assessment process, and public access to those data, is concerned, I take this opportunity to clarify that according to Article 30 of Regulation (EC) No 1829/2003 of the European Parliament and European Council of 22 September 2003 on genetically modified food and feed, EFSA complies with the administrative decisions taken by the European Commission on the confidentiality claims put forward by each applicant. In other words, EFSA has no say on whether certain data should be considered as confidential or as publicly available.

As regards the replicability of studies and field trials, I would like to underline that EFSA requirements for field trial design specify experiments that include internal repetitions within each test site – in order to secure that the data are generated according to scientific standards and are sound[17]. EFSA and Member States in NCAs verify the GMO safety testing by scrutinizing

[16] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/E, as last amended; and Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, as last amended.

[17] The Scientific Opinion on Statistical considerations for the safety evaluation of GMOs describes in details the principles and different possible scenarios. In particular design of field trials is covered in Section 2 (pages 9-14).

data submitted in a dossier as well as the analyses (e.g. statistical analysis of the data) and the results. Additional information is requested from the applicant where needed.

Finally, in petition 813-08, the petitioner encourages "greater involvement by Member States in (GMO) risk assessments…". EFSA is perfectly aware of the importance that contributions and involvement of Member States in its work have in order to improve the quality of its outputs and avoid unnecessary duplications or waste of limited resources. This is reflected in EFSA's "*Technical Report on Scientific Cooperation between EFSA and Member States: Taking Stock and Looking Ahead*"[18]. As regards in particular the GMO domain, over the last three years EFSA has developed substantially the level of interaction with MS's National Authorities competent for that sector. For instance, during the assessment the GMO panel shares the full contents of each application with over 200 experts belonging to the different NCAs. As a consequence, for each application under assessment the GMO panel receives many comments and proposals from a European wide NCA network of experts; it organises regularly specific or bilateral meetings with MS experts; it manages networks of those national administrations, where views are constantly and regularly exchanged.

Finally, pursuant to Article 30(2) of Regulation (EC) No 178/2002, EFSA exercise constant vigilance for the early identification of potential divergences with those to be expressed by the MS's NCAs. In case a potential or actual divergence is identified, EFSA is committed to resolve that divergence or to publish a document outlining the reasons for that difference.

I trust that the above has addressed your questions and requests and I remain at your disposal for further information or clarifications.

Yours sincerely,

Catherine Geslain-Lanéelle

Chapter 1.8 on general statistical principles and in particular in sub-section 1.8.7 on statistical analysis of field trials. Chapter 1.8 of the NTO opinion is similar to chapter 2.3.3. of the overall ERA Guidance.
In the Guidance on the environmental risk assessment of genetically modified plants adopted in 2010, field trials are mostly addressed in chapter 2.3.3 on general statistical principles (design, analysis, etc). However, field trials are also referred to in chapter 2.3.1 on choice of comparators and chapters 3.1 (persistence and invasiveness) and 3.4 (NTOs).

[18] Available at http://www.efsa.europa.eu/en/supporting/pub/97e.htm.