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European Food Safety Authority

OFFICE OF THE EXECUTIVE DIRECTOR AND MANAGEMENT BOARD

Review of EFSA's Policy on Declarations of Interest: a Reflection Paper

1. Introduction

Since its inception, the European Food Safety Authority has put in place a range of initiatives to safeguard its independence which were formalised in September 2007 in a *Policy on Declarations of Interest (DOIs)*[1]. The policy included a three-year revision clause, hence the reason for the current review. To inform that review, this Reflection Paper seeks to critically analyse the lessons learned in implementing the policy and identify possible improvements and new approaches.

EFSA was established as the Union's independent risk assessment body for food and feed safety in 2002 as part of a wide-ranging reform of European food safety policy in response to a series of damaging food crises in the late 1990s and early 2000s. Its most critical commitment is to provide independent scientific advice of the highest quality to Europe's risk managers. The 2000 Commission *White Paper on Food Safety* recognised the fundamental importance of having an independent Authority[2] with a legal personality separate from the EU institutions. The separation of science from policy was seen as critical in rebuilding public confidence in European food after the BSE and dioxin crises in particular. EFSA's Founding Regulation (Regulation (EC) No 178/2002[3]) emphasised the functional separation of risk assessment and risk management and enshrined the interrelated core values of independence, scientific excellence, transparency, and openness. With a dual mandate of risk assessment and risk communication, EFSA issues scientific advice on food and feed safety to underpin European food policy and communicates on risk to a wide range of target audiences.

Unlike many of its international counterparts, EFSA relies heavily on external expertise from academia, research organisations and national food safety agencies to generate its scientific advice; for example, more than half of its Scientific Panel members come from the national food safety agencies. Public-private partnerships are an established feature of European research funding and hence many of the scientists who contribute to EFSA will inevitably have links with the private sector. As EFSA is obliged to ensure that its scientific advice is objective and unbiased, this places the onus on experts to actively consider any professional or personal interests or affiliations that might influence their objectivity and on EFSA to ensure that its system for managing interests is effective and rigorously implemented.

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

[2] European Commission: *White Paper on Food Safety* (2000), see http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf

[3] Article 37 of Regulation (EC) no 178/2002 of the European Parliament and of the Council of 28 January2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L31 of 1 February 2002.

A number of recent controversies have put the spotlight on the science underpinning public policies and run the risk of undermining confidence in science-based decision making. These include the alleged manipulation of climate change data and claims of undue influence by the pharmaceutical sector on the manufacture of the influenza A H1N1 vaccine. The *Eurobarometer Survey Report on Science and Technology (2010)*[4] reflects the public's concern in relation to independence; it indicates that 41% of Europeans have little confidence in the independence of scientists because of the work they do with industry. The agro-food sector is not immune from criticism and EFSA's independence has been called into question on a number of occasions most frequently in relation to genetically modified organisms (GMOs). The majority of respondents to a 2010 survey on attitudes towards EFSA among key partners and stakeholders[5] viewed EFSA as an organisation with "as much independence as can reasonably be expected" and with a "focus on avoiding conflicts of interest working very well". Independence, objectivity and high standards of professional conduct by all those involved in the activities of EFSA are crucial for its reputation because "no matter what seems to be the 'right' decision for those involved in the advisory process, it is essential that interested parties and the public at large are themselves convinced that decisions are sound"[6] and therefore trust the process that led to that advice.

2. Implementation of the Founding Regulation: Policy on DOIs

2.1 Legal provisions underpinning the independence of EFSA's scientific advice

EFSA's Founding Regulation stipulates that members of the Management Board, Advisory Forum, Scientific Committee and Panels, external experts taking part in the Working Groups of the Scientific Committee and Scientific Panels and the Executive Director shall undertake to act independently. Article 37 of that Regulation imposes on them the obligation to make a declaration of commitment and an annual declaration of interests "indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence".

The Founding Regulation includes several other measures critical to the independence of the Authority's scientific outputs, notably: the appointment by the Council of a Management Board with the "highest standards of competence" to act in the public interest (Article 25); the appointment of independent experts to the Scientific Committee and Panels (Article 26); and the recording of diverging scientific opinions (Article 30).

2.2 Milestones

While advice on DOIs has been available in the Rules of Procedures of the various EFSA units and bodies since inception, a *Code of Conduct*[7] and *Guidance*[8] on the implementation of Article 37 of the Founding Regulation were adopted by the Authority in 2004 which recognised that, as the Authority had become fully operational, guidance was required in declaring interests and avoiding any conflicts. It identified who should declare an interest, what needed to be declared and when. In addition, it laid down the operational procedures for staff to follow and the obligations of all individuals to disclose interests. In summary, it directed that all Members of the Management Board, Advisory Forum, Scientific Committee, Panels, external experts, Executive Director, and all AD grade staff

[4] *Eurobarometer Survey Report on Science and Technology (2010), see http://ec.europa.eu/public_opinion/archives/ebs/ebs_340_en.pdf.*

[5] F. Paeps, *Image of EFSA: Qualitative Research Report,* see http://www.efsa.europa.eu/en/mb100318/docs/mb100318-ax8a.pdf.

[6] European Commission, *Communication from the Commission on the collection and use of expertise by the commission: principles and guidelines. "Improving the knowledge base for better policies"*, COM(2002) 713 final, at 3.

[7] EFSA Code of Conduct on Declarations of Interest; 13th Meeting of Management Board, Dublin, March 10, 2004, see http://www.efsa.europa.eu/en/mb040310/docs/mb040310-ax5.pdf.

[8] EFSA Revised Guidance on Declarations of Interest; 17th Meeting of Management Board, The Hague, December 16, 2004, see http://www.efsa.europa.eu/en/events/event/mb041216.htm.

are obliged to declare financial, intellectual or other interests upon appointment, annually, orally at meetings, on appointment as rapporteur for an opinion, or whenever a change in interest occurred.

In September 2007, EFSA adopted a *Policy on Declarations of Interest (DOIs)*[9] which laid down specific provisions for identifying and handling conflicts of interest. To implement the policy, a set of comprehensive DOI forms were drawn up, supported by a detailed *Guidance Document on Declarations of Interest*[10] and a *Procedure for Identifying and Handling Potential Conflicts of Interest*[11]. The guidance document described a two-step approach: (i) an annual DOI (aDOI) and (ii) a specific DOI (sDOI) linked to a specific subject matter (e.g. a product) to be filled by experts before each meeting.

Over time, EFSA has put in place a multifaceted set of implementing rule concerning *inter alia* staff regulations, an enhancement of the rules for expert selection, consolidation of the rules of procedure Scientific Committee and Scientific Panels, and the harmonisation of EFSA's assessment methodologies and risk assessment practices[12]. However, these initiatives are not duly reflected in the *Policy on DOIs* which is exclusively focused on the prevention of conflicts of interests. This has focused attention on DoI-related matters, often overlooking the importance of the other pillars of EFSA's approach to independence.

3. Governance measures to safeguard independence

3.1 Organisational governance

The governance structures laid down in the Founding Regulation provide a strong basis for independence. In particular the functional separation of risk assessment from risk management ensures that EFSA's advice is free from undue political influence and the emphasis on openness and transparency means that its activities are easily accessible to public scrutiny. By giving EFSA a mandate in risk communication, the EU regulators ensured that EFSA would have an independent scientific voice on matters related to food safety. Like other agencies such as the UK's Food Standards Agency or the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), EFSA's independent Management Board plays a crucial role in ensuring that the Authority acts independently.

3.2 Scientific governance

(i) Selection of experts

With the exception of the scientific networks, representatives of which are nominated by the Member States, 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. During the selection process, interests declared by the applicants are reviewed. In addition, independent external evaluators and observers review the assessment of applications to ensure that the selection process is coherent[13].

[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: Guidance Document on Declarations of Interest, see http://www.efsa.europa.eu/en/keydocs/docs/doiguidance.pdf.

[11]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.

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

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

(ii) Rules of procedure of EFSA's Scientific Committee, Panels and Working Groups

The Rules of Procedure, revised by EFSA's Management Board in 2009[14], provide a procedural framework for the establishment and operation of the Scientific Committee and Panels, covering issues such as the number of members in a panel; renewal of membership; reimbursement of panel members; assigning tasks to the Scientific Committee or Panels; the creation of Working Groups; observers to meetings; and public hearings.

(iii) Quality review programme

EFSA operates a programme of self review, internal review and external review (INEX[15]) for a proportion of its scientific outputs, both pre- and post-adoption. It ensures that best scientific and risk assessment practices are adhered to and that internal standard operating procedures are applied in the generation of EFSA's scientific advice.

(iv) Collegial decision making

EFSA's Panels and Working Groups are populated by scientists with a wide range of complementary skills and experiences, drawn from diverse backgrounds. This means that the risk of one viewpoint exerting an undue influence is limited and EFSA's advice does not represent the views of any single expert or school of thought. In addition, 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.

(v) Data collection and analysis

Data collection is one of the core tasks of EFSA and a fundamental requirement of the risk assessment process. Article 33 of the Founding Regulation stipulates that, in addition to collection, EFSA is tasked with collating, analysing, validating and summarising data as well as harmonising methodologies to facilitate transfer of data from Member States and increasing the comparability of data. Furthermore, EFSA provides guidance on data requirements to a range of stakeholders and partners. In relation to dossiers received from applicants seeking authorisation of products or claims, EFSA not only collects the data but also directs the data requirements. Moreover, the Authority has developed the internal capacity in fields such as statistics and risk assessment methodologies to analyse and validate data to ensure they are fit for purpose. As the concept of post-marketing monitoring of authorised products gains wide acceptance, EFSA will support risk managers in this task.

(vi) Consultations with partners and stakeholders

EFSA is committed to openness and transparency and frequently consults its stakeholders, partners and the public at large on key issues, both scientific and otherwise. This includes EFSA's core planning and strategy documents as well as key scientific and communication issues and all guidance documents[16]. In 2010, EFSA launched 93 public consultations and a similar number is planned for 2011. EFSA frequently uses its capacity to invite hearing experts to participate in discussions that require specialist knowledge, broadening the scientific expertise at its disposal without directly influencing the scientific decision-making process. In addition, technical meetings and workshops are organised with specific stakeholder groups and where appropriate are webcast live on EFSA's website[17].

[14] 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.

[15] *Scientific Advice by the Scientific Committee: Internal and External Review: Proposal for a Review System for EFSA's Scientific Activities,* see http://www.efsa.europa.eu/en/efsajournal/pub/526.htm.

[16] For EFSA's approach to public consultations on science, see http://www.efsa.europa.eu/en/keydocs/docs/consultationpolicy.pdf

[17] For example, the meeting on gut and immune function health claims, see http://www.efsa.europa.eu/en/press/news/nda101206.htm.

(vii) Transparency in the scientific workflow

EFSA receives its mandates from the EU's risk managers – predominantly the European Commission, but also the European Parliament and Member States – and also has the capacity to self-mandate on key scientific issues that are not addressed specifically elsewhere. The progress of a mandate from receipt through to the adoption of the scientific output can be freely accessed by all interested parties via the EFSA website via the Register of Questions database[18], meeting minutes, outcomes of public consultations etc. In addition, all documentation supporting the scientific decision-making process – draft assessment reports, Member State contributions etc. – are published alongside the final output. To guide transparency in risk assessment, EFSA's Scientific Committee, which includes the Chairs of all the Scientific Panels, issued two sets of guidance documents. The first (2006)[19] deals with procedural aspects and the second (2010)[20] with the general principles to be applied to the identification of data sources, criteria for inclusion/exclusion of data, confidentiality of data, assumptions and uncertainties.

4. Experience gained from implementing the Policy on DOIs

EFSA screens over 5000 DOIs annually (both annual and specific) and checks more than 35,000 agenda items for potential conflicts of interest. The Authority has made a significant investment in tools to facilitate the registration and monitoring of DOIs as these represent a considerable workload for both experts and staff. By way of example, EFSA has invested more than €0.6 m and three full-time staff equivalents in the development of an electronic DOI tool (an IT programme launched in 2009 to manage the DOI system), and annually the Authority allocates an estimated three FTEs and €180 k budget to the screening of DOIs and related administrative tasks. To assess the efficiency of its DOI implementation procedures, evidence is available from a number of both independent and internal reviews.

4.1 Internal analysis of statistics on conflicts of interest

EFSA has analysed its recent statistics on the recording of conflicts of interest and remedial actions taken. In 2010, the screening of annual DOIs resulted in experts being excluded from EFSA's activities on 24 occasions. In relation to specific DOIs, members of Panels or Working Groups were not allowed to draft or chair a meeting on 280 occasions, and on 53 occasions experts were excluded from participating in a specific agenda item. In relation to breaches of trust (failure to declare an interest), EFSA has over the past two years instigated dismissal procedures against experts on four occasions as laid down in the implementing rules of the *Policy on DOIs*. In the cases concluded to date, these have resulted in voluntary resignations; in all cases, the scientific outputs on which those experts worked were reviewed by EFSA to ensure that there was no undue influence on the outcome.

4.2 Benchmarking report[21]

In 2010, EFSA commissioned an independent report to review its systems and procedures for ensuring the independence of its scientific advice. After an open call, external consultants were engaged to compare EFSA's policies, structures and practices relating to independence by undertaking a comparative study. The study compared EFSA to ten other peer organisations[22], focusing in particular on governance, policies for the

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

[19] *Transparency in risk assessment carried out by EFSA: Guidance Document on procedural aspects*, see http://www.efsa.europa.eu/en/efsajournal/pub/353.htm.

[20] *Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessments carried out by EFSA. Part 2: General Principles*, see http://www.efsa.europa.eu/en/efsajournal/pub/1051.htm.

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

[22] European Chemicals Agency, European Medicines Agency, DG SANCO (European Commission), Codex Alimentarius Commission & the joint FAO/WHO committees, French Agency for Food, Environmental & Occupational Health Safety

development of scientific advice, the appointment of external scientific experts, declaration of interests and the management of potential conflicts of interest.

Compared with the peer organisations, the report finds that EFSA has one of the most advanced and robust systems in place for ensuring the independence of its scientific advice. It notes in particular EFSA's governance structures, the breadth of scientific views available via the Panel structure, and the well-documented policies for identifying and handling conflicts of interest. It makes a number of recommendations in the following areas:

i. More comprehensive definition of conflict of interest
ii. Reinforcement of the positive obligations of experts to inform of any matter that could undermine independence
iii. Emphasis on the application of ethical standards including declaring conflicts of interest
iv. Focus on scientific work carried out by EFSA's own staff members.
v. More input from the public on selection of experts and potential conflicts of interest.
vi. Consequences if a conflict of interest is identified
vii. Shortening of the retrospective period in which an interest has to be declared
viii. Increased opportunities for stakeholder involvement in processes associated with independence

4.3 Audit reports

With a view to ensuring the consistent implementation of the *Policy on DOIs*, EFSA's performance in this area has been the subject of several audits which are an important component of its accountability to the European institutions. The Internal Audit Service (IAS) of the European Commission has presented two reports of EFSA's independence procedures (annual DOIs and specific DOIs) in 2009 and EFSA's Internal Audit Capacity has presented two reports in 2009 and one in 2008. The outcomes of the audits have provided reassurance that, in general, EFSA's implementation of the policy is efficient and effective while recommending some procedural and strategic changes in emphasis that are regularly used to reinforce the implementation of the policy. The European Court of Auditors (ECA) will address independence in 2011 and its findings will be taken into consideration for the review of the *Policy on DOIs*.

4.4 External review of implementation

In another initiative aimed at objectively identifying weaknesses and possible improvements in the procedures for screening DOIs, EFSA commissioned an external consultant to analyse samples of previous screening results and their traceability up to the point of adoption of a scientific output. The report[23], which included an analysis of more than 180 screenings of experts, concludes that EFSA is generally effective in implementing the DOI screening policy with compliance issues noted in only a small minority of cases. It also makes a number of recommendations for EFSA including:

i. Increasing experts' contribution to and awareness of conflicts of interest
ii. Shifting the focus from individual measures to a more balanced, group-level approach
iii. Enhancing the level of detail provided on how conclusions regarding conflicts of interest are reached
iv. Reducing the retrospective period for declaring an interest from 5 years to 2 years.

4.5 Experience of experts and EFSA staff

To assess the efficiency and efficacy of the DOI procedures, the views of both EFSA staff and experts have been actively solicited on a number of occasions: through the regular survey of experts and other informal means. These

(ANSES), German Federal Institute for Risk Assessment (BfR), UK Food Standards Agency, Canadian Health Products and Food Branch , US Food and Drug Administration; US National Academy of Sciences.

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

have tended to focus on the more technical aspects of the implementation procedures and have been the source of ongoing improvements to the system. The recommendations of all the feedback will be fed into the review of the policy in 2011.

4.6 Ad hoc feedback from key partners and stakeholders

EFSA has an ongoing and regular dialogue with its key partner organisations, European institutions, and stakeholders, and has actively solicited their input on key issues such as the key audience research into perceptions of EFSA's described in the *Introduction*. In the ongoing process of dialogue, it has been suggested that, because Chairs and Vice-Chairs of Scientific Panels and the Scientific Committee have a more representative and visible role than ordinary members, more stringent criteria in relation to declarations of interest be applied to their election. The provisions for this already exist in the implementing rules of the *Policy on DOIs*[24]. This approach has been incorporated into the Rules of Procedure and will be applied to the renewal of the ANS and CEF Panels in 2011 and afterwards to the renewal of the remaining Scientific Panels and Scientific Committee in 2012. The criteria have also been applied to the election of Chair and Vice-Chairs of EFSA's Management Board in October 2010[25].

5. Key considerations and recommendations

5.1 Critical attention on EFSA's independence has tended to focus on just one aspect, albeit a crucial one – the DOIs of external experts – with little reference to the full spectrum of checks and balances that safeguard the independence of its scientific outputs. The various reviews have shown that EFSA's DOI system is valid but it should be both strengthened and simplified to improve implementation. Moreover, EFSA recognises that the independence of its scientific advice does not rely solely on the DOI system but equally on the other pillars described earlier: organisational governance; transparent selection of experts, scientific quality; rules of procedures for the Panels and Scientific Committee; collegial decision making; validation of data; broad consultation; and transparency in its workflows.

Furthermore, independence should be viewed in the broader context of the quality of EFSA's scientific decision-making processes which are critical in building trust in its scientific advice. The latter include considerations of, *inter alia*: the composition of working groups; the need for external consultation; data completeness checking; information sources; compliance with methodologies, guidance documents and operating procedures; uncertainties, assumptions and limitations, as well as the identification of any conflicts of interest.

EFSA is therefore proposing the creation of an integrated *Policy on Independence and Scientific Decision-Making Processes* that draws together the existing elements of its policies, implementing procedures and systems – along with the input received from a wide consultation process and the experience gained since inception – into a comprehensive and coherent document.

5.2 To aid the deliberations, the following questions are to be considered:

1. Does the Management Board support the proposal for the creation of an integrated *Policy on Independence and Scientific Decision-Making Processes* as described?

[24]Implementing Act to the Policy on Declaration of Interests: Procedure for Identifying and Handling Potential Conflicts of Interest, p. 7, see http://www.efsa.europa.eu/en/keydocs/docs/doiconflicts.pdf.

[25] 46th Meeting of EFSA Management Board, Brussels, 21 October, 2010, see http://www.efsa.europa.eu/en/events/event/mb101020.htm

2. Have the expectations of the Founding Regulation been met in relation to independence?
3. As the European research funding model increasingly involves links between the academic/public-sector and the private sector, how do we define "appropriate" independence for EFSA?
4. As many experts have links with industrial groups or other stakeholders, NGOs etc., how will EFSA foster and communicate the concept of "acceptable" independence?
5. What areas should EFSA focus on to guarantee independence – and the perception of independence – going forward?
6. As independence and scientific quality are intimately associated, how should independence be reflected in EFSA's forthcoming Science Strategy?
7. How can EFSA balance the need for access to the required expertise, particularly in highly specialised fields, with the sometimes competing demand for independence?
8. The emphasis of the *Policy on DOIs* is on EFSA checking to ensure the compliance of experts. Should a more balanced approach be adopted that reinforces the responsibility of scientists?
9. As the challenges to independence are shared by other risk assessment bodies, how can EFSA work more closely with Member States, other European agencies and partners to strengthen processes and develop a common approach?
10. As perception of independence is also closely related to the openness of an organisation, are there any additional measures/practices which EFSA could consider to strengthen its openness and transparency?
11. As the independence of science is a subject of broader societal debate, are there other activities which EFSA could consider, possibly in cooperation with organisations in other sectors?

6. Next steps

After the views of the Management Board on this Reflection Paper are heard, a guided public consultation (including the *Benchmarking Report* and the *External Review of Implementation*) will begin on EFSA's website for a 4-week period. The outcomes of the consultation along with the views of EFSA's Management Board, Scientific Committee, Advisory Forum and Stakeholder Consultative Platform, will be taken into full consideration in the drafting of the new policy. The draft policy and report of the consultation will be submitted to Management Board at its June meeting.