A Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority

1. Introduction

In 2002, EFSA was established as the European Union’s independent risk assessment body for food and feed safety 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. The 2000 Commission White Paper on Food Safety recognised the fundamental importance of having an independent Authority with a legal personality separate from the institutions of the European Union. The separation of science from policy was seen as critical in strengthening food safety and rebuilding public confidence in the European food chain after the BSE and dioxin crises in particular.

EFSA’s Founding Regulation (Regulation (EC) No 178/2002) introduced the functional separation of risk assessment and risk management and enshrined the interrelated core values of independence, scientific excellence, transparency, and openness. The legislator considered these core values as instrumental to the accomplishment of EFSA’s mission, most fundamentally the provision of high-quality scientific advice. Article 22(7) of EFSA’s Founding Regulation stipulates that the Authority has to be a point of reference of risk assessment in the food chain by virtue of its independence, the scientific and technical quality of the outputs it issues and the information it disseminates, the transparency of its procedures and processes, and its diligence in performing its tasks. In addition and for what concerns in particular independence, Article 37 foresees that members of EFSA’s bodies shall undertake to act independently in the public interest.

Since its creation, the European Food Safety Authority has put in place a range of initiatives to safeguard its core values and build trust in its work. According to the Eurobarometer report on perceptions of food-related risk (2010), EU citizens have a high level of trust of in both scientists (73%) and national and European food safety agencies (64%) as sources of information on food risks. Nonetheless, less than half of EU citizens (47%) think that scientific advice on food-related risks is independent of commercial or political interests. In fact, as shown in the Eurobarometer Survey Report on Science and Technology (2010) public concerns in relation to objectivity of scientific advice are widespread: 58% of Europeans have little confidence in scientists and scientific research because of the work they do with industry. Neither are regulators operating in the life sciences and food safety domains immune from criticism, most frequently in relation to genetically modified organisms (GMOs). Independence,

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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”\(^5\) and therefore trust the process that led to that advice. While the majority of respondents to a 2010 survey on attitudes towards EFSA among key partners and stakeholders 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”, the Authority is committed to further improve the way it implements its core values in order to continue to build trust in the quality of EFSA’s scientific advice\(^6\).

2. Why a policy on independence and scientific decision-making processes?

This policy describes all the steps that have been taken by EFSA to ensure the implementation of its core values in its scientific outputs and decision-making processes. These include structure and governance as well as working procedures. The goal of this document is to produce a comprehensive, overarching policy document that outlines the many, different facets of the measures that the Authority has progressively put in place to assure high-quality scientific outputs based on transparent, open and unbiased scientific decision-making processes.

3. EFSA’s core values

In order to deliver high-quality science, the Legislator of the European Union required EFSA to found its operations on the core values deriving from Article 22 (7) of Regulation (EC) 178/2002: notably scientific excellence, openness, transparency and independence. Any of these core values is to 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, and not as a standalone principle or as a goal in itself.

The Authority’s core values are implemented by EFSA through a number of rules and procedures put in place over time. These can be identified in several pillars, described in detail in the following paragraphs. They cover, on the one hand, organisational governance and, on the other, scientific governance. The latter includes the procedures regulating how mandates are negotiated and accepted, the development of scientific work, communication and consultation, and other elements aiming at quality assurance.

This integrated policy brings together all those elements, along with the input received from a wide consultation process and the experience gained since inception.

4. Organisational governance

The governance structures laid down in EFSA’s Founding Regulation provide a strong basis for the decision-making processes that implement EFSA’s core values. The functional separation at European level of risk assessment, attributed to EFSA, from risk management, reserved to the European Commission, Council, European Parliament and Member States ensures that EFSA’s advice is free from any undue influence and the emphasis on openness and transparency means that its activities are easily accessible to public scrutiny and provides opportunities for engagement and involvement in EFSA’s work. By also giving EFSA a mandate in risk communication, the Union legislators ensured that EFSA would have a trusted scientific voice on scientific matters related to food safety.


The 61 members of the Board are appointed in a personal capacity 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. A representative of the European Commission is also part of the Management Board. By law, four of the members shall have a background in organisations representing consumers and other interests in the food chain. Nonetheless, all members of the Board, including the Chair and Vice-Chairs, 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. Pursuant to the Rules of Procedure of the Management Board, 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. The Board acts according to a Code of Conduct that it committed to respect. For any matters linked to the independence of members of the Board, the Authority might consult the Commission.

The Management Board is entrusted with the task of providing strategic direction and the adoption of strategic documents including internal rules, budget, annual work programme, and statements of estimates of revenue and expenditure, and establishment plan. The Executive Director is EFSA's legal representative and implements the strategic documents adopted by the Board as well as managing the daily operations of the Authority. The Advisory Forum advises the Executive Director regarding cooperation and networking with Member State authorities. EFSA's scientific staff provides scientific and technical advice and secretarial support to the Scientific Committee and Scientific Panels. Finally, the Scientific Panels and Scientific Committee adopt scientific opinions.

5. Scientific decision-making processes

As far as scientific governance is concerned, EFSA has put in place several procedures and workflows to ensure the implementation of its core values in its scientific processes, bodies and outputs.

5.1 Processing of requests and mandates

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 initiate its own scientific work (i.e. "self-mandate") when appropriate. The progress of a mandate from receipt through to the adoption of the scientific output can be checked at all times and freely accessed via the EFSA website, the Register of Questions database, meeting minutes, outcomes of public consultations, ongoing contacts with applicants, and EFSA's newly created Applications Desk.

The request outlines what is being asked of EFSA: the terms of reference, the timeframe, the context and the relevance of the matter for the European Union. Upon receipt of a request, EFSA considers its contents, discusses it with the requestor and addresses any issues that need clarifying, such as the feasibility of the deadline. Following these discussions, EFSA and the requestor agree on a mandate, which includes the final terms of reference and a mutually agreed deadline.

An important feature of EFSA's independence is represented by its ability to self task. This possibility is used by EFSA on a regular basis in particular in relation with the development of risk assessment methodologies or approaches.

9 A draft Code of Conduct has been submitted to the Management Board for discussion at the meeting taking place on 16 June 2011.
10 EFSA Register of Questions Database, see http://www.efsa.europa.eu/en/request/requests.htm
Information on each mandate, be it external (requested from the EU institutions or the Member States) or internal, including supporting documents and the current status, is available to the public in the Register of Questions database.\(^\text{11}\)

5.2 Development of methodologies

Over time, EFSA has invested significant resources to the development of a comprehensive body of good risk assessment practices and methodologies to guide the work of its Scientific Committee, Scientific Panels and its scientific staff to ensure their opinions respect the highest scientific standards.\(^\text{12}\) This in itself represents an additional procedural guarantee of the excellence, objectivity and transparency 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 or the coherence of the scientific output.

5.3 Information gathering: data from Member States, applicants and scientific literature

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 data collection methodologies to facilitate transfer of data from Member States and increase the comparability of data. In relation to dossiers received from applicants seeking authorisation of substances, products or claims, EFSA not only collects the data from Member States and stakeholders alike, but also directs the data requirements that applicants need to comply with when submitting a dossier and where appropriate that legal requirements are complied with. Moreover, the Authority has the internal capacity in fields such as statistics and risk assessment methodologies to analyse and validate data to ensure they are fit for purpose.

5.4 Working groups

After a mandate has been accepted, EFSA assigns the task to the competent Scientific Panel(s) or Scientific Committee, which then establish a working group of selected experts to develop a draft scientific opinion. EFSA’s secretariat publishes the minutes of each working group meeting. The initial draft position put forward by the rapporteur of the working group is thoroughly discussed, amended and endorsed by the working group. After being agreed at working group level, the draft assessment is then tabled before the competent Scientific Panel(s) or Scientific Committee.

6. EFSA’s Scientific Committee and Panels

After discussion and endorsement by a working group, a draft scientific output is transferred to the competent Scientific Panel or Scientific Committee where the debate becomes more focused as drafts are discussed, amended and finally adopted.

6.1 Selection of experts

The members of EFSA’s Scientific Committee and Scientific Panels are selected based on their scientific expertise and experience in risk assessment, and according to objective and transparent criteria predetermined in an open call.


for expression of interests. As regards the composition of the Scientific Committee and Scientific Panels, every effort is made to secure an appropriate geographical and gender balance, taking into consideration issues such as the diversity of scientific expertise and disciplines.

Unlike some other risk assessment bodies, EFSA relies heavily on external expertise from academia or research organisations (50% of the experts) and national risk assessment bodies to generate its scientific advice. Public-private partnerships are an established feature of research in the EU and worldwide and hence many of the scientific experts who contribute to EFSA will inevitably have links with the private sector. Therefore, during the selection process, all relevant interests declared by the applicants, such as financial ones, are screened with a view to preventing the appointment of candidates with evident and general conflicts of interest. In other words, a candidate is not considered anymore for membership of the Scientific Committee or Scientific Panels when EFSA identifies a potential conflict of interest of such a magnitude that would prevent his or her active participation in the majority of the meetings of that Committee or Panel. In addition, for the selection of members of the Scientific Committee and Scientific Panels, independent external evaluators and observers review the assessment of applications to ensure that the selection process is carried out in a consistent manner.

6.2 Rules of procedure

The Rules of Procedure of EFSA’s Scientific Committee, Scientific Panels and their Working Groups, revised by EFSA’s Management Board in 2009, provide a procedural framework for the establishment and operation of the those scientific groups, covering issues such as the number of members in a panel; renewal of membership; reimbursement of panel members; the quorum for the adoption of outputs; the assignment of tasks to the Scientific Committee or Panels; the creation of Working Groups; the attendance of observers to meetings; and public hearings. This ensures coherence in EFSA’s scientific decision-making workflows, thereby granting impartiality and preventing any form of bias of its outputs.

6.3 Collegial decision making

EFSA’s Scientific Committee, Scientific Panels and Working Groups are populated by scientists with a wide range of complementary skills and experiences, drawn from diverse backgrounds. As outputs are adopted by consensus or by majority decision following a process that does provide room for contradictory debates at the working group level and the plenary sessions, the risk of one viewpoint exerting an undue influence over the other members of the group is limited and EFSA’s advice does not represent the views of any single expert or school of thought. As a last resort, experts who do not agree with the majority of their peers may adopt a duly reasoned minority opinion, where they explain the reasons for a divergent position. EFSA records all minority views and publishes them in its scientific outputs to ensure that the full plurality of views is transparently reflected in its advice. The quality of EFSA’s scientific outputs is therefore also enhanced by ensuring a shared responsibility of all members of a Panel and competent Working Group in relation to the preparatory work.

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7. **Other elements of quality assurance**

7.1 **Consultation: scientific experts from Member States, civil society, interested parties and partners**

EFSA is committed to openness and regularly consults and meets its partners, stakeholders 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 issues and all guidance documents. Consultations and scientific events contribute to enhancing the quality and completeness of EFSA’s scientific outputs. Guidance documents lay down the data requirements/methodologies that will be utilised by Panels in carrying out risk assessments. In other words, Panels do not determine their risk assessment methodologies in isolation – these are openly discussed and debated. EFSA consults both civil society, through public consultations, and its partners, via networks. Networks consist of nationally appointed EU Member State organisations with expertise in the fields covered by the network. Representatives of the Commission and other organisations, including those from outside the EU with specific expertise, may also be invited to participate in the work of the networks. In 2010, EFSA launched 91 public consultations and a similar number is planned for 2011. Furthermore, EFSA frequently uses its capacity to invite hearing experts to participate in discussions that require specialist knowledge, further broadening the scientific expertise at its disposal without directly influencing the scientific decision-making process. This allows the Authority to take stock of the data or expertise developed by industry, nongovernmental organisations and other interested parties on newly developed practices, processes, substances and products. In addition, technical meetings and workshops are regularly organised with specific stakeholder groups and where appropriate are webcast live on EFSA’s website.

7.2 **Process transparency**

All documentation supporting the scientific decision-making process, including all background documents, are published alongside the final output in the EFSA Journal. To guide transparency in risk assessment, EFSA’s Scientific Committee, which includes the Chairs of all the Scientific Panels, has issued two sets of guidance documents. The first one (2006) deals with procedural aspects and the second (2010) with the general principles to be applied to the identification of data sources, criteria for inclusion/exclusion of data, handling of confidential data, documentation and explanation of assumptions and uncertainties.

7.3 **Quality review programme**

To ensure the quality of its scientific outputs, a proportion of EFSA’s outputs are subject to thorough programme comprising several steps, both pre- and post-adoption. This ensures adherence with the best scientific and risk assessment practices and compliance with internal standard operating procedures in the generation of EFSA’s scientific advice. EFSA will further develop its quality programme with the objective of building a fully integrated quality management system.

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8. Enhanced contribution of scientific staff

EFSA staff members with a scientific background currently provide scientific support for the operation of its Scientific Committee, Scientific Panels, Working Groups and Networks. These staff members are engaged in background or preparatory work of a scientific nature which in certain cases represents a fundamental step in the drafting and adoption of the final output. To meet EFSA’s increasing workload and enable the Scientific Committee and Scientific Panels to focus on more fundamental scientific and overarching matters, EFSA is currently developing a science strategy that in the long term will enable the Authority to have at its disposal a range of internal expertise to address the important workload represented by the assessment of regulated claims, products and substances and react swiftly to unexpected needs and urgencies.

9. Organisational culture

EFSA has gradually created, and continuously fosters, an organisational culture that does not tolerate conflicts of interest. This is ensured in a number of ways, ranging from the implementation of the staff regulations, to the systematic organisation of training courses on ethics and integrity for staff members and scientific experts, the implementation of a sophisticated and stringent screening system of interests declared by key people, the publication of all relevant documents regarding that system, the development of workflows, standard operating procedures and the provision of systematic legal advice to ensure a coherent interpretation of the comprehensive system put in place.

In order to implement the more general provision stipulated under Article 22(7) of EFSA’s Founding Regulation, Article 37 of that Regulation requires 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”.

EFSA’s Management Board adopted a Policy on Declarations of Interests (DOIs) in 2007 which laid down specific provisions for preventing conflicts of interest. To implement the policy, a set of comprehensive rules and procedures were drawn up, supported by a detailed Guidance Document on Declarations of Interest.

The Authority has made and continues to make significant investments in tools to facilitate the implementation, monitoring and enforcement of the DoI screening system. 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 and auditors.

The DoI pillar of this Policy takes account of more than three years of experience in the implementation of the 2007 Policy on Dols, as well as the recommendations put forward by independent contractors and auditors delivering

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20 For further details see below, § 5.VIII.
24 EFSA has invested more than €0.6 mil 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 Dols and related administrative tasks.
respectively a benchmarking report\textsuperscript{25}, an external review of the implementation\textsuperscript{26} and audit reports. The DoI system 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. Food and feed safety are no exception to these general principles, and the DoI pillar must strive to ensure the broadest multidisciplinary participation possible in order to warrant the highest scientific quality of its outputs while guaranteeing that those responsible for the adoption of the relevant outputs look at the scientific matter in an objective and unbiased way. In doing so, the implementing decision lays down proportionate and implementable rules and procedures.

While it is recognised that conflicts can only be assessed by considering whether the specific affiliations/interests declared by a person are compatible with the tasks to be assigned to him/her by EFSA, it is appropriate to apply as a guideline the following definition of conflicts of interest which shall be considered as any “situation whereby one or more of the interests held by, or entrusted to, a single person are considered incompatible with that person’s role in the context of his or her cooperation with EFSA”.

The DoI pillar of this policy is implemented by a single decision of the Executive Director outlining the main principles, definitions and procedures applicable to the screening of declarations of interest. The single implementing decision will build on the two implementing documents of the 2007 Policy on Dols from which it will retain the scope, procedural workflow, list of declarable interests, main features of the relevant definitions, and other basic principles.

The three-step DoI screening process is maintained: depending on the roles, functions and relevant groups of the persons concerned, they are required to complete and submit (i) an annual written DoI (ADoI); and/or (ii) a written specific DoI (SDoI) linked to a specific subject matter (e.g. an application dossier); and/or (iii) an oral declaration of interests (ODoI) at the beginning of each meeting. ADoIs are posted by EFSA on its website, whereas SDoIs and ODoIs resulting in a potential conflict of interest are recorded in the minutes of the relevant meeting. The measures that EFSA may adopt will depend on the severity of the potential CoI identified, will range from the obligation for the concerned person to abstain from voting on a certain matter to his or her exclusion from all activities impacting on that interest and will foresee stricter measures for Chairs, Vice-Chairs of groups and rapporteurs of scientific documents. The implementing decision will simplify the applicable rules and clarify certain procedural aspects such as the obligation of experts to take ownership of their declarations. The implementing document will also enhance the level of detail provided on how conclusions regarding conflicts of interests are reached and, where appropriate and proportionate, extend the obligation to complete Dols to contractors and grant beneficiaries performing preparatory scientific work for EFSA.

10. Staff operating in the public interest

For what concerns the rules applicable to EFSA staff, the Authority 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\textsuperscript{27}. EFSA staff is hired on fixed-term contracts following calls for expression of interest that follow transparent procedures foreseeing 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 is fully subject to the

\textsuperscript{25} Comparison between the tools ensuring EFSA’s independent scientific advice and the instruments in use by organizations similar to EFSA, final report, February 2011.

\textsuperscript{26} Independent report of factual findings in connection with the implementation of EFSA policy on Declarations of Interests in certain Scientific Panels.

\textsuperscript{27} 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.
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 EFSA. In order to implement the obligation foreseen in the Staff Regulations of avoiding conflicts of interest for the duration of their contract with EFSA, staff members of “administrator” level or equivalent are required to complete an annual DoI, which is then screened by the Appointing Authority\(^2\) and used as a basis for preventing the occurrence of conflicts of interest. Declarations of Interest of senior managers and executive staff are available on the Authority’s website.

In order to foster even further the general obligation that EFSA staff operate in the public interest, EFSA has adopted implementing rules of the Staff Regulations that bind all EFSA staff leaving the Authority to get a prior authorisation for any occupational activity that they intend to engage in over a period of two years after the termination of service with the Authority.

11. Implementation and entry into force

The present policy enters into force on the day of its signature and replaces EFSA’s Policy on Declarations of Interests adopted by the Management Board in 2007. The appropriate implementing measures shall be adopted by the Executive Director not later than 31 December 2011. As a transitional measure, the implementing documents to the Policy on Declarations of Interests (2007) remain in force until the implementing measures of the present policy are adopted.

12. Review of the Policy

The policy set out in this document shall be reviewed within four years of its adoption.

[Place], [DD] [Month] 2011

For the EFSA Management Board

Diána Bánáti
Chair of the Management Board

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\(^2\) In the case of EFSA, that corresponds to the Executive Director.