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RESOURCES AND SUPPORT

Cover Note

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

1. Background

In March 2011, the Management Board discussed a Reflection Paper on Independence outlining outstanding issues and the respective policy options to address them in the context of a broader Policy on Independence.

In June 2011, after having consulted the Scientific Committee and the Advisory Forum, the Management Board endorsed a Draft Policy on Independence and Scientific Decision Making Processes. The draft policy was put out for consultation. The public consultation closed on 16 September 2011. EFSA received more than 100 comments from 25 organisations and individuals. On 12 October, a Stakeholder Consultative Workshop was organised successfully by EFSA in Brussels with more than 140 participants representing interested parties of the whole food chain and Union institutions. A report outlining the comments received during the public consultation and gathered at the Workshop and the way they are addressed in the forthcoming policy will be published on the occasion of the Board meeting. The report is also annexed as supporting document to the present note (Annex A).

The draft Policy, amended to take account of the comments and of the discussions, is submitted to the Board for discussion and possible adoption.

2. Overview of the changes incorporated in the draft Policy

Following the public consultation and the discussions held on 12 October 2011 at the Consultative Workshop on Independence, the following main changes to the draft Policy endorsed by the Board at the meeting in June 2011 are proposed:

- Clarification regarding competences of Member States in the food safety institutional framework;
- Recognition of importance of interaction between risk assessors and risk managers in the risk analysis process;
- Alignment with the recent changes introduced in the Rules of Procedure of the Board and with the adoption of the Code of conduct of Board members;
- Clarification regarding essential role of calls for data in the context of EFSA's data collection practices;
- Further details added on selection criteria for members of the Working Groups;
- Acknowledgment of relevance for Union policies of concept of public-private partnerships;

- Further details added on role and limitations of hearing experts;
- Reference to a new initiative in 2012 to test the feasibility of opening up the risk assessment process to observers from interested parties;
- Reference to newly established Application desk;
- Amendment to definition of Conflict of interest to better reflect OECD's guidelines;
- Explicit reference to breach of trust process;
- Clarification on the way EFSA prevents conflicts of interests of staff and former staff members;
- Commitment to annual reporting on independence as of 2012;
- Additional clerical changes enhancing the readability of the document.

3 Conclusion

The Management Board is kindly requested to consider the proposed Policy for possible adoption. After adoption, EFSA will develop the necessary implementing rules.

Enclosure: *Technical report of EFSA. Outcome of the public consultation on the draft Policy on Independence and Scientific Decision Making Processes.*



RESOURCES AND SUPPORT

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

Executive Summary

In 2002, the European Food Safety Authority 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. EFSA's Founding Regulation (Regulation (EC) No 178/2002¹) introduced the functional separation of risk assessment and risk management and enshrined the interrelated core values of independence, scientific excellence, transparency, and openness.

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. However, concerns in relation to objectivity of scientific advice are widespread in public opinions through the European Union, also for what concerns areas falling within EFSA's remit.

This policy describes all the steps that have been taken by EFSA to ensure the implementation of those values and produces a comprehensive, overarching 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.

In addition, this document identifies areas for improvement that will be implemented by EFSA as of early 2012. From that moment the Executive Director will regularly report on the status of implementation of the Policy. The main areas to be implemented are the following ones:

- The merging of the existing Guidance document and Procedure on identifying and handling potential conflicts of interest, which will simplify the applicable rules and clarify certain procedural aspects, enhance the level of detail provided on how conclusions regarding conflicts of interests are reached by outlining the admissible and incompatible interests in a transparent manner and, where appropriate and proportionate, extend the obligation to complete Dols to contractors and grant beneficiaries performing preparatory scientific work for EFSA. Finally, the implementing rules will clarify and strengthen the procedure to be applied to sanction experts found in patent breach of EFSA's rules on independence;
- Annual reporting on the implementation of the present Policy;
- A new initiative in 2012 to test the feasibility of opening up the Risk assessment process to observers; and
- Adjustments in the procedure for the selection of experts for EFSA's Working Groups and in other internal documents such as EFSA Science Strategy.

¹ Article 37 of 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, OJ L 31 1.2.2002, p. 1.

This Policy has been built through a process of extensive consultation. In addition to the consultation of the Scientific Committee, the Advisory Forum and EFSA staff, an on-line consultation and a workshop with over 140 participants were organised in 2011. The Policy takes as well account of more than three years of experience in the implementation of the 2007 Policy on Declarations of Interest, as well as the recommendations put forward by independent contractors and auditors delivering respectively a benchmarking report², an external review of the implementation³ and audit reports. All those inputs are reflected in this document. It will remain a “live document” to be regularly reviewed to adjust the strategic direction in line with changes in the working environment.

² Comparison between the tools ensuring EFSA's independent scientific advice and the instruments in use by organizations similar to EFSA, final report, February 2011.

³ Independent report of factual findings in connection with the implementation of EFSA policy on Declarations of Interests in certain Scientific Panels.



RESOURCES AND SUPPORT

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

1. Introduction

In 2002, the European Food Safety Authority 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 Authority⁴ 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 178/2002⁵) 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 the scientific and technical quality of the outputs it issues, its independence, 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 EFSA 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 risks⁶. 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)⁷ 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).

⁴ European Commission: White Paper on Food Safety (2000), see http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf.

⁵ Article 37 of 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, OJ L 31 1.2.2002, p. 1.

⁶ Special Eurobarometer 354 on Food-related risks http://ec.europa.eu/public_opinion/archives/ebs/ebs_354_en.pdf.

⁷ Eurobarometer Survey Report on Science and Technology (2010), see http://ec.europa.eu/public_opinion/archives/ebs/ebs_340_en.pdf.

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”⁸ are able to check themselves that decisions are sound and therefore are in a position to 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 independence of EFSA’s scientific advice⁹.

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 governance¹⁰ as well as working procedures¹¹. 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

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. The latter should be meant both as independence from other Union Institutions, agencies and bodies and as independence from vested interests of the food and feed sector, including economic ones. EFSA has defined quality as the degree of adherence to these core values in addition to timeliness of delivery and clarity in communication. In this context delivery of high quality outputs is essential to building trust.

The Authority’s core values are implemented by EFSA through a number of rules and procedures put in place over time and collected in our Operating Framework. 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 ensuring our quality standards are met.

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 Union level of risk assessment, attributed to EFSA, from risk management¹², reserved to the European Commission, Council, European

⁸ 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.

⁹ F. Paeps, Image of EFSA: Qualitative Research Report, see <http://www.efsa.europa.eu/en/mb100318/docs/mb100318-ax8a.pdf>.

¹⁰ § 4 and 5, below.

¹¹ From § 6 to § 10.

¹² Article 6 of Regulation (EC) No 178/2002, which provides that risk managers shall take into account the results of the risk assessments, including the opinion of the Authority, other legitimate factors and the precautionary principle.

Parliament and Member States' risk management bodies¹³ ensures that EFSA's advice is free from any undue political 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. Interaction with risk managers is considered fundamental to guarantee the efficacy and completeness of the Authority's action, and is ensured via multiple arrangements designed exactly to prevent any undue political influence. 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 safety¹⁴.

EFSA's Management Board plays a crucial role in ensuring that the Authority acts in line with its core values. The 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 interest¹⁵. It should be noted that EFSA has no role in that procedure. 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 chain¹⁶. 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 public¹⁷. Pursuant to the Rules of Procedure of the Management Board, compliance with that obligation is ensured by the Board, who are required to screen and discuss the declarations of interest to be submitted annually in writing by each member. The Board acts according to a Code of Conduct¹⁸ that upholds core principles and values such as integrity, objectivity and serving in the public interest while providing guidance on standards expected by Union institutions and the general public. In September 2011, the Board has also clarified and strengthened its internal process to screen declarations of interest, indicating that the screening is a shared and collegial responsibility of the Board¹⁹.

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 Authority²⁰. The Advisory Forum advises the Executive Director regarding cooperation and networking with Member State authorities²¹. 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 opinions²².

¹³ In accordance with the principle of subsidiarity enshrined in Article 5(3) of the Treaty on European Union, Member States maintain untouched their competences and responsibilities for risk assessment performed at national level, which in some Member States are also functionally separated from those for risk management.

¹⁴ Article 40 of Regulation (EC) No 178/2002.

¹⁵ Article 25 of Regulation (EC) No 178/2002

¹⁶*Ibidem*.

¹⁷ Article 37 of Regulation (EC) No 178/2002.

¹⁸ MB 16 06 11 item 11 doc 9 - Code of Conduct of the Management Board of the European Food Safety Authority, available at <http://www.efsa.europa.eu/en/keydocs/docs/codeconductmb110616.pdf>.

¹⁹ Article 13 of MB 20 10 11 - Rules of procedure of the Management Board o the European Food Safety Authority, available at <http://www.efsa.europa.eu/en/keydocs/docs/mbrules.pdf>.

²⁰ Article 26 of Regulation (EC) No 178/2002.

²¹ Article 27 of Regulation (EC) No 178/2002.

²² Article 28 of Regulation (EC) No 178/2002.

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 appropriate²³. 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 database²⁴, meeting minutes, reports outlining the contributions received via the 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 on matters falling within its remit. This possibility is used by EFSA on a regular basis in particular in relation with the development of risk assessment methodologies or approaches. Approximately, 5% of EFSA outputs are represented by self tasks.

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 database²⁵.

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 standards²⁶. This in itself represents an additional procedural guarantee of the excellence, objectivity and transparency of the scientific processes and standards followed by EFSA. Indeed, while maintaining a case-by-case assessment for each relevant substance or product, 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, research projects 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

²³ Article 29 of Regulation (EC) No 178/2002

²⁴ EFSA Register of Questions Database, see <http://www.efsa.europa.eu/en/request/requests.htm>

²⁵ The Register of Questions is available on the internet at <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf>.

²⁶ For more information on the on EFSA's good risk assessment practices and methodologies <http://www.efsa.europa.eu/en/efsahow/rapractice.htm>.

of data from Member States, interested parties, third countries and international organisations and increase the comparability of data. To achieve this goal, EFSA systematically publishes calls and requests for data, studies and information with respect to the matters it is required to assess. 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.

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 published on the Official Journal of the European Union, EFSA's website and selected scientific publications. In addition, in order to ensure the broadest participation to the call, EFSA disseminates the call via its professional and institutional networks and its interested parties²⁷. 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. The European Council identified these partnerships as a key element in the free circulation of researchers, knowledge and technology that should stimulate European competitiveness as outlined in the vision for the European Research Area.²⁸ 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 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 manner²⁹.

²⁷ Article 28 of Regulation (EC) No 178/2002.

²⁸ Point n. 7 of the Conclusions of the European Council, 13 and 14 March 2008.

²⁹ For more information on the selection of EFSA's scientific experts, see <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

6.2 Rules of procedure

The Rules of Procedure of EFSA's Scientific Committee, Scientific Panels and their Working Groups³⁰, provide a procedural framework for the establishment and operation of 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 Working groups

After a mandate has been accepted, EFSA assigns the task to the competent Scientific Panel(s) or Scientific Committee, which then establishes a working group of selected experts to develop a draft scientific opinion. The experts of the working group are selected on the basis of the same criteria applied for the selection of members of EFSA's Scientific Committee and Scientific Panels³¹. 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. In the course of 2012, EFSA will develop an enhanced selection system for the selection of experts for working groups.

6.4 Collegial decision making

EFSA's Scientific Committee, Scientific Panels and Working Groups are populated by experts with a wide range of complementary skills and experiences, drawn from diverse backgrounds ranging from chemists to veterinarians. 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.

7. Other elements

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 documents³². 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 used 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

³⁰ 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>.

³¹ See § 6.1.

³² For EFSA's approach to public consultations on science, see <http://www.efsa.europa.eu/en/keydocs/docs/consultationpolicy.pdf>.

consults both civil society, through public consultations, and its partners, via networks³³. Networks consist of nationally appointed EU Member State organisations with expertise in the fields covered by the network³⁴. 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. After each public consultation, EFSA publishes a report that outlines the comments received and how they were taken into account by EFSA. 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. However, EFSA creates a firewall that prevents hearing experts from exerting any undue influence over the discussions of the independent experts by excluding the former from the drafting of outputs and from the final exchanges and voting on those outputs. 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 website³⁵.

7.2 Transparency in the Decision Making Process

EFSA is committed to publishing all Standard Operating Procedures related to the development of its scientific outputs. 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)³⁶ deals with procedural aspects and the second (2010)³⁷ 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. In accordance with these principles, in its scientific opinions EFSA is committed to highlighting all relevant uncertainties, the level of those, and when necessary gaps in available data or knowledge and the need for future research. Finally, a new initiative will be undertaken by EFSA in 2012 to test the feasibility of opening up the risk assessment process to observers from interested parties.

7.3 Quality Management System

In line with all Quality Management systems and ISO 9001:2008, the EFSA Quality Management system is made up of 3 Components: Strategy, Process Management, and Measurement and improvement. A number of documents including the Founding Regulation, The Internal Control Standards of the Commission (ICS) and the EFSA Annual management plan are all used to set out the strategy and underline management's commitment to this important area. Execution of the strategy is accomplished through the implementation of the Policies, Decision and Standard Operating procedures which go to make up the EFSA Operating Framework. Measurement and improvement are currently embodied in The Internal and External Review Process (INEX) (19) and Internal Audits against the ICS.

³³ For more information on networks of scientific organisations supporting EFSA, see <http://www.efsa.europa.eu/en/networks/supportingunits.htm>.

³⁴ MB 18 03 10 item 7 doc 6 – Decision concerning the establishment and operation of European Networks of scientific organisations operating in the fields with the Authority's mission, available at <http://www.efsa.europa.eu/en/scdocs/doc/panelnetworksrop.pdf>.

³⁵ 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>.

³⁶ Transparency in risk assessment carried out by EFSA: Guidance Document on procedural aspects, see <http://www.efsa.europa.eu/en/efsajournal/pub/353.htm>.

³⁷ 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>.

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. Furthermore, from November 2011, a newly launched Applications desk acts as a front office and support desk for applicants, Member States and other stakeholders who have questions regarding applications. It will also be responsible within EFSA for processing the initial administrative steps of all applications.

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 place³⁸.

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)*³⁹ 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 up⁴⁰, supported by a detailed *Guidance Document on Declarations of Interest*⁴¹.

The Authority has made and continues to make significant investments in tools to facilitate the implementation, monitoring and enforcement of the DOI screening system⁴². 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.

³⁸ For further details see below, § 5.VIII.

³⁹ EFSA Policy on Declarations of Interest, see <http://www.efsa.europa.eu/en/keydocs/docs/doipolicy.pdf>.

⁴⁰ 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>.

⁴¹ 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>.

⁴² 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 DOIs and related administrative tasks.

The Dol 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 respectively a benchmarking report⁴³, an external review of the implementation⁴⁴ and audit reports. The Dol 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. The Dol system also ensures that no expert may review his or her own work, unless it is an output of the Authority. Food and feed safety are no exception to these general principles, and the Dol 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 when an individual is in a position to exploit his or her own professional or official capacity in some way for personal or corporate benefit with regard to that person's function in the context of his or her cooperation with EFSA*".

The Dol 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 Dol 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 Dol (ADol); and/or (ii) a written specific Dol (SDol) linked to a specific subject matter (e.g. an application dossier); and/or (iii) an oral declaration of interests (ODol) at the beginning of each meeting. ADols are posted by EFSA on its website, whereas SDols and ODols 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 Col identified, and 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 rules will simplify the applicable rules and clarify certain procedural aspects such as the obligation of experts to take ownership of their declarations. It will also enhance the level of detail provided on how conclusions regarding conflicts of interests are reached by outlining the admissible and incompatible interests in a transparent manner and, where appropriate and proportionate, extend the obligation to complete Dols to contractors and grant beneficiaries performing preparatory scientific work for EFSA. Finally, the implementing rules will clarify and strengthen the procedure to be applied to sanction experts found in patent breach of EFSA's rules on independence.

Every other year, EFSA commits to systematically subject the Dol pillar of the Independence Policy to a comprehensive evaluation or audit, aimed at checking the compliance rate with the Authority's internal rules.

⁴³ Comparison between the tools ensuring EFSA's independent scientific advice and the instruments in use by organizations similar to EFSA, final report, February 2011.

⁴⁴ Independent report of factual findings in connection with the implementation of EFSA policy on Declarations of Interests in certain Scientific Panels.

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 adoption⁴⁵. 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 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 EFSA⁴⁶. 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 Authority⁴⁷ and used as a basis for preventing the occurrence of conflicts of interest, both during the assignment process and during his or her contract with EFSA. 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, and building on the experience gained in managing similar cases in the past, EFSA has adopted implementing rules of the Staff Regulations⁴⁸ 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. These rules better detail the process and the steps that are to be followed both by former staff and by 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 rules shall be adopted by the Executive Director. 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. As of 2012, EFSA commits to annual reporting on the implementation of this policy. The Executive Director will regularly report to the Board the status of implementation of the present policy.

12. Review of the Policy

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

Submitted for adoption in Warsaw, Poland
on 15 December 2011

For the EFSA Management Board

Prof. Diána Bánáti
Chair of the Management Board

⁴⁵ 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.

⁴⁶ Articles 11 and 11a of the Staff Regulations, above.

⁴⁷ In the case of EFSA, that corresponds to the Executive Director.

⁴⁸ Article 16 of the Staff Regulations, above.