



P. Nikiforos Diamandouros
European Ombudsman

Mr Christoph Then
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Strasbourg, **11 -04- 2012**

Complaint 775/2010/ANA

Dear Mr Then,

Please find enclosed EFSA's detailed opinion on my draft recommendations concerning your above complaint.

EFSA requested that the documents contained in Annexes III and IV should be treated as confidential. This request does not comply with Article 4.4 of the Ombudsman's Implementing Provisions. I therefore decided not to forward you these documents and to return them to EFSA, in accordance with the Ombudsman's established practice in such cases.

Please be informed that this also applies to the information EFSA sent to the Ombudsman in its reply of 30 November 2010 to my request for further information (Annexes I (documents 2 and 3) and IV of that reply) which I also returned to EFSA.

Please note that the documents which have been returned to EFSA do not form part of the Ombudsman's file and will not be taken into account in the Ombudsman's handling of the case.



If you wish to make any observations on EFSA's detailed opinion, please send them to me before 31 May 2012. Please note that, if I do not receive any observations from you, I may close the case with a decision, based on the information you have already provided and EFSA's submissions.

Yours sincerely,

P. Nikiforos Diamandouros

Enclosure:

- Copy of EFSA's detailed opinion on the Ombudsman's draft recommendations, together with Annexes I, II, V, VI and VII



European Food Safety Authority

EXECUTIVE DIRECTOR



Parma, **22 MAR. 2012**
Ref. OR/DD/SG/nm (2012) out-6460928

Mr P. Nikiforos Diamandouros
The European Ombudsman
Avenue du President Robert Schuman, 1
CS 30403
F-67001 Strasbourg
France

Complaint 0775/2010/ANA - EFSA's final opinion on the draft recommendations submitted by the European Ombudsman pursuant to Article 3(6) of the Decision of the European Parliament on the regulations and general conditions governing the performance of the Ombudsman's duties¹ and Article 8(2) of the Decision of the European Ombudsman adopting implementing provisions

Dear Mr P. Nikiforos Diamandouros,

Further to my first, provisional response (ref. 6124906 dated 13 December 2011) to your draft recommendations regarding complaint 0775/2010/ANA (your ref. S2011-147021), I would like to complement the elements provided in that letter with the following information, which is to be considered as the final opinion of the European Food Safety Authority on the draft recommendations:

1. The draft recommendations

In the report, the Ombudsman outlines three draft recommendations addressed to EFSA:

- a. EFSA should strengthen its rules and procedures with regard to negotiations by serving staff members concerning future jobs of the "revolving doors" type. In this regard, *EFSA should make clear that such negotiations themselves may amount to a conflict of interest*. It follows that EFSA should require serving staff members to disclose them in a timely manner, in accordance with EFSA's Policy on Declarations of Interests;
- b. *EFSA should acknowledge that it failed to observe the relevant procedural rules and to carry out a sufficiently thorough assessment of the potential CoI arising from the move of a former staff member to a biotechnology company; and*
- c. If a similar case arises in the future, *EFSA should: i) obtain sufficient information including as a minimum a proper account of the tasks carried out*

¹ Adopted by the European Parliament on 9 March 1994, OJ L 113, 4.5.1994, p. 15, as last amended.

at EFSA, a precise description of the proposed new employment and possible links between the new and the previous employment; ii) carry out a thorough assessment; and iii) properly record the results of this assessment.

2. EFSA's opinion on the draft recommendations

Having taken due account of the draft recommendations and of the submissions provided by the complainant, EFSA's opinion *vis-à-vis* the report of the Ombudsman is the following:

2.a. On the first draft recommendation

EFSA takes note of the fact that the Ombudsman acknowledges that the first draft recommendation is not linked to the specific case at issue in complaint 0775/2010/ANA. Therefore, EFSA submits that it appears this draft recommendation falls outside the subject matter of the complaint at issue and should therefore be rejected.

Irrespective of the procedural argument above, as it will be described more in detail below, EFSA already *proactively* addressed this draft recommendation by making clear in its more recent set of internal rules that negotiations with prospective employers are to be disclosed in the staff member's declarations of interest and that when appropriate, negotiations may be considered potential conflicts of interest with regard to the staff member's tasks and assignments.

In more detail, EFSA submits that, based on the experience gained in the past, it has substantially strengthened its rules and procedures regarding conflicts of interest, also with respect to negotiations of its staff with prospective employers.

As anticipated in the initial submission of 13 December 2011, in 2010 EFSA started a thorough process aimed at assessing the performances in implementing its complex framework on declarations of interest dating back to 2007 and identifying possible improvements thereto. Following a public consultation undertaken from July to mid September 2011 and the organisation of a Stakeholder Consultative Workshop on Independence on 12 October 2011, which resulted in the submission of more than 110 comments of the public and the participation of more than 140 interested parties, on 21 December 2011 EFSA adopted a new, comprehensive and sophisticated Policy on Independence and Scientific Decision Making Processes (Annex I).²

The 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.

For what concerns specifically its staff, starting from 2007 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 a thorough implementation of the staff regulations, to the systematic organisation of training

² The Policy on Independence and Scientific Decision Making Processes is available online at <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>.

courses on ethics and integrity for staff members and scientific experts, the development of a sophisticated and stringent screening system of interests, 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.

The Authority has made and continues to make significant investments in tools to facilitate the implementation, monitoring and enforcement of the system screening declarations of interests of its staff and experts. From 2008 to 2012, EFSA has invested more than €1.7 mil in the development, maintenance and upgrade of an electronic DoI tool, and annually the Authority allocates an estimated three full time equivalents to the screening of DoIs and related administrative tasks. The effective implementation of EFSA's DoI procedures has been validated by a number of both independent and internal reviews performed from 2008 to 2011 by contractors and auditors.³

In addition, the Policy identified areas for further improvement that EFSA committed to implement by early 2012, including the development of new implementing rules.

As a follow up operational implementation measure to the Policy, on 21 February 2012, EFSA's Executive Director signed off her Decision implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (Annex II)⁴.

The new implementing rules *inter alia* increase the transparency and intelligibility of the preventive and remedial measures ensuing for scientific experts from each interest and activity (Articles 10 and 11 of the decision and Annexes IV and V thereto); provide a clear definition of conflict of interest compatible with the OECD guidelines on this matter⁵ (Article 1(3)litt. b of the decision); foresee a clearer set of definitions of relevant activities that have to be declared (Article 1(4) of the decision); provide a clear set of general principles (Articles 2 and 9 of the decision); set up a system checking on an annual basis the compliance of a sample of DoIs against the applicable rules (Article 14(1) of the decision); include the obligation for tenderers to submit institutional DoIs with their offer and, most importantly, clarify the framework applicable to DoIs of staff members, require staff members to declare any negotiation with prospective employer(s) having a vested interest in EFSA or in its activities and foresee the possibility for EFSA of considering those negotiations as a potential CoI under certain conditions.

Pursuant to Article 23 of those rules, declarations of staff members are screened by their line manager. When the line manager identifies a potential Conflict of Interest, he or she highlights the finding to his or her hierarchical superior. If the superior confirms that there is a potential CoI, he or she shall bring the matter to the attention of the Appointing Authority, who takes the final decision after having consulted the Joint Committee and having heard the member of staff concerned. In that context, it is

³ For more details on this aspect please refer to the Policy on Independence and Scientific Decision Making Processes, *supra*, at 11.

⁴ The Implementing rules are available online at <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

⁵ OECD, 2007, Bribery in Public Procurement: Methods, Actors and Counter-Measures, OECD, Paris, at 33, available online at <http://www.oecd.org/dataoecd/47/11/44956834.pdf>.

explicitly provided that negotiations with prospective employers may be considered as a conflict of interest in case the staff member has received an external job offer and the tasks assigned to the staff member have an impact on EFSA's decision making process. Preventive measures that may be taken include *e.g.* the decision to reassign a staff member to a different unit, or to exclude her or him from the dossiers where the potential conflict arises.

In accordance with EFSA's founding principles of openness and transparency, to explain how the Authority implements those rules in practice, I organised a second interactive stakeholder event in Brussels on 5 March. This event was attended by about 100 delegates from partner organisations and interested parties and it provided EFSA with the opportunity to explain the developments introduced in the new rules and to use practical examples to better illustrate the implementation of the Policy. Furthermore, EFSA regularly communicates on independence related matters with the general public and interested parties as it is apparent by surfing on EFSA's website.

On the basis of the explanations provided above, with particular reference to the obligation of its staff to declare negotiations with prospective employers, EFSA considers the first draft recommendation as already completely implemented.

2.b. On the second draft recommendation

As mentioned in our previous exchanges on this matter, EFSA staff are employed with temporary contracts of five years that may, or not, be renewed by the Appointing Authority pursuant to Articles 8 and 88 of the Conditions of employment of other agents of the Communities.

EFSA highlights that Ms Renckens' contract had not been renewed by the Authority, and that her administrative complaint against that step was dismissed by the agency, which confirmed the decision not to renew it. Before leaving EFSA, Ms Renckens did not provide substantial details about her new employment. Therefore, EFSA's administration did not have any ground to question the information she had provided, that is that she did not have a new employment coming up after quitting EFSA.

Regrettably, the Authority did not process in a traceable manner the screening of the information Ms Renckens shared with her former colleagues about the position at a biotechnology company taken up during May 2008. This was also due to the fact that EFSA was still unfamiliar with this kind of occurrences⁶ and no specific processes were in place at the time. As a matter of fact, Ms Renckens' case was the first one where a former staff member moved to industry in a sector of relevance for the Authority. However, EFSA maintains that it did perform such an assessment, and that it did conclude that no conflict of interest existed.

With respect to the second draft recommendation, the Authority acknowledges that the system in place in 2011 to implement Article 16 of the Staff Regulations is more robust than the one in force in 2008 and 2009. Indeed, as indicated in more detail under paragraphs 2.a and 2.c of this opinion, the framework currently in place lays down in a clear manner all procedural steps that should be followed when dealing with such cases

⁶ The firsts contracts engaging temporary agents were signed by EFSA in 2003 and expired in 2008.

and provides mitigating measures based on a sufficiently thorough assessment of the potential conflict of interest, it obliges staff members to declare all relevant negotiations with a prospective employer without delay and provides for a traceable process and forum where difficult cases are thoroughly discussed and assessed. The Authority also acknowledges that it failed to record the assessment of the move of Ms Renckens to a biotechnology company in a way as it would be done today and it assures the Ombudsman that it has put in place all measures to ensure that such an oversight, also due to the fact that the case in question was the first one where a former staff member was moving to industry, does not occur anymore in the future.

Therefore, EFSA considers the second draft recommendation as accepted and implemented.

However, the Authority notes that the table outlining the figures of former EFSA staff members having left the Authority (Table 1) shows that the statistical incidence of staff leaving EFSA for industry is at most marginal. From the moment EFSA started operating a register of activities undertaken, or to be undertaken, by its former staff within two years after leaving service with the Authority, the number of cases similar to the one at issue here amounts to only two out of a grand total of thirty-six former employees having left the agency. In addition to the above, the person involved in one of those two cases started working for an industrial sector unrelated to EFSA’s mission and tasks, where no conflict of interest is possible with respect to that person’s previous tasks. The other thirty-four persons started working with other Union Institutions, bodies or agencies, Member States’ authorities, universities or other public organisations. The only case where a former staff member moved to “industry” in a sector related to EFSA’s remit was dealt with in accordance with the applicable provisions, as I will explain more in detail in the next paragraph. It can therefore be noted that the risk to EFSA’s independence deriving from Staff leaving to related industry sectors is remote.

Categories of staff	2010	2011
Leavers who took up employment in other EU institutions/agencies, national public organisations or international bodies	17	19
Leavers who took up employment in industrial sector	0	2 (1 of whom to an organisation within EFSA’s remit)

Table 1

2.c. On the third draft recommendation

With the third draft recommendation, the Ombudsman asks EFSA, should a similar case arise in the future, to obtain sufficient information including as a minimum a proper account of the tasks carried out at EFSA, a precise description of the proposed

new employment and possible links between the new and the previous employment; carry out a thorough assessment; and properly record the results of this assessment.

In essence, EFSA submits that it put already in place the processes and checks to ensure that it deals with similar cases in the way recommended by the Ombudsman. In effect, in 2011 EFSA was already confronted with a case similar to the one at issue here, and it processed that file in accordance with the draft recommendation above. In that case, a detailed assessment was performed by the Legal and Regulatory Affairs Unit (Annex III) and addressed to the Joint Committee advising the Executive Director. The Executive Director took then an informed decision proportional to the tasks, seniority and function of that person, imposing certain limitations on the staff member's future activities in the private sector (Annex IV). The measures focused on forbidding for one year the concerned person to contact his former colleagues and experts with a view to gaining non public documents and information and to oblige him to respect conflicts of interest that may arise in case he approaches EFSA's scientific experts.

Furthermore, EFSA submits that the enhanced framework put in place between 2008 and 2012 ensures that EFSA complies with the process above in all similar instances that may occur in the future. Indeed, in 2012, EFSA further strengthened the decision implementing Articles 16, 17 and 19 of the Staff Regulations amending that already in force (shared with you as Annex to our letter ref. 5447316) with the insertion of an obligation for the Executive Director to seek the advice of the Joint Committee,⁷ which is required to submit its written recommendation after having sought the input of the Head of the Legal and Regulatory Affairs Unit (Annex V). The screening occurs on the basis of the detailed information provided by the concerned person in accordance with the enhanced Annex II of the decision, which guides the submitter in a step by step process aimed at helping him or her to discharge his or her obligations with respect to Article 16 of the Staff Regulations. Similarly, the same Annex provides EFSA staff involved in the screening with the appropriate template channelling the workflow in a predetermined procedure that requires the indication of grounds justifying the decisions and any remedial measure taken. This means that, as requested by the Ombudsman in the third draft recommendation, the screening of the cases of colleagues leaving the Authority is duly recorded and motivated in a traceable manner and the process put in place ensures that in future, similar cases the Authority will implement the applicable provisions in the way indicated by the Ombudsman.

Finally, also based on the experience gained in the instant case and taking account of the need of continuously fostering a corporate culture based on ethics and integrity principles, EFSA has strengthened its internal rules and practices aimed at improving the profile of those matters with its staff as follows:

As part of that endeavour, as of November 2010, the Authority has been organising on a regular basis training courses on ethics and integrity for its staff members and scientific experts. These courses, mandatory for all staff, are constantly made available in EFSA's annual training programme and complement the fundamental information on ethics and integrity provided on the first working day as part of EFSA's induction

⁷ The Joint Committee is regulated by Section 3 of Annex II to the Staff Regulations.

programme by discussing real life cases that raise the awareness of staff about rules governing their conduct and the prevention and reporting of fraud and irregularities. This is particularly relevant for EFSA staff, many of whom have a scientific background and remain in the Union institutional environment for a limited period of time.

In that perspective, in December 2010, EFSA has also adopted a Practical Guide to Staff Ethics and Conducts (Annex VI), which is distributed to all staff when they join the Authority and that can be downloaded from a dedicated section of EFSA's intranet. Currently, the Authority is working on a revamped version of that document reflecting the new obligations imposed on EFSA staff since it was first finalised. The Guide, built on a similar tool developed by DG HR of the European Commission, provides an explanation of the fundamental obligations and limitations related to ethics and integrity as laid down in the Staff Regulations. It provides guidance in layman's language on issues ranging from relations with the public, to behaviour at work, individual obligations, how to prevent problems etc. For this reason, the guide has been tailored to EFSA's needs, e.g. making reference to matters of particular relevance for its staff, such as invitations to conferences, speeches, publications and other form of scientific publications. Finally, there is a specific section on obligations after leaving the service.

On 29 July 2011, EFSA has also appointed an ethics advisor (Annex VII), who advises staff members and other actors of the Authority's bodies on substance and on the procedure regarding questions related to ethics, conduct and integrity, such as conflicts of interests, planned activities outside the job duties, behaviour and freedom of expression inside and outside the Authority, publication of articles, obligations after leaving the service, etc. In that context, EFSA has created a functional mailbox for ethics and integrity questions, in order to facilitate access to the ethics advisor.


On the basis of the above, EFSA respectfully submits that the rules and processes developed in the timeframe from 2010 until now already comply with the third draft recommendation. EFSA also underlines that the draft recommendation above has already been practically applied and implemented in the only case that occurred since the entry into force of the strengthened rules and procedures, and that is the case to which I made reference in paragraph 2.b above (Annexes III and IV).

That notwithstanding, should cases similar to the one at issue here arise in the future, the Authority hereby explicitly and formally commits to: i) obtain sufficient information including as a minimum a proper account of the tasks carried out at EFSA, a precise description of the proposed new employment and possible links between the new and the previous employment; ii) carry out a thorough assessment; and iii) properly record the results of this assessment.

The above is without prejudice to the questions ensuing from giving effect to any limit imposed on former staff members in the context of a procedure under Article 16 of the Staff Regulations.

I trust that the above responds to your report dated 7 December 2011. In line with EFSA's policy on transparency this letter will be published on our website.

Yours sincerely,



Catherine Geslain-Lanéelle

Enclosures:

Annex I - The Policy on Independence and Scientific Decision Making Processes of the European Food Safety Authority;

Annex II - Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests;

Annex III - Note of the Legal and Regulatory Affairs Unit regarding a request pursuant to Article 16 of the Staff (CONFIDENTIAL document as including personal data protected under Regulation (EC) No 45/2001);

Annex IV - Decision of the Appointing Authority regarding a request pursuant to Article 16 of the Staff Regulations (CONFIDENTIAL document as including personal data protected under Regulation (EC) No 45/2001);

Annex V - Decision of the Executive Director concerning the implementation of Articles 16, 17(2) and 19 of the Staff Regulations and of Articles 11 and 81 of the Conditions of Employment of Other Servants of the Union;

Annex VI - Regulations EFSA's Practical Guide to Staff Ethics and Conduct;

Annex VII - Decision of the Executive Director appointing an ethics advisor.



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, enhances the level of detail provided on how conclusions regarding conflicts of interests are reached. This is ensured by outlining the admissible and incompatible interests in a transparent manner and, where appropriate and proportionate, by extending the obligation to complete DoIs 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 from interested persons; 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 L31 1.2.2002, p. 1.

This Policy has been built through a process of extensive consultation, internally with EFSA staff and externally with interested parties and the Authority's Scientific Committee and Advisory Forum, taking 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.

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 L31 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 of 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, EFSA's internal rules ensure the independence of the Authority's scientific outputs while taking due account of the inevitable complexity of funding of research activity. 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/qmo110331.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/doiguideance.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 Dols and related administrative tasks.

The DoI pillar of this Policy takes account of more than three years of experience in the implementation of the 2007 *Policy on DoIs*, 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 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. The DoI 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 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 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 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 DoIs* 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, 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 DoIs to contractors and grant beneficiaries performing preparatory scientific work for EFSA. With this approach, the Authority strives to ensure that the outsourcing of scientific work is assigned exclusively to legal or natural persons with the appropriate degree of independence, be they contractors or grant beneficiaries. 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.

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.

EFSA commits to subject every other year the DoI pillar of the Independence Policy to a comprehensive evaluation or audit, aimed at checking the compliance rate with the Authority’s internal rules. This activity may be taken up by the Court of Auditors, by EFSA’s Internal audit capability or by a contractor selected following an open and transparent procedure processed pursuant to EFSA’s financial regulation.

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.


As of 2012, EFSA commits to annual reporting on the implementation of this policy and in particular to cases where experts were found to be in patent breach of EFSA's rules on independence. The Executive Director will regularly report to the Board the status of implementation of the present policy, including results from the audit of the DoI pillar of this Policy.

12. Review of the Policy

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

Adopted in Warsaw, Poland
on 15 December 2011

For the EFSA Management Board



Prof. Diána Bánáti
Chair of the Management Board

Decision

EFSA – European Food Safety Authority	Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests	Decision No.: EFSA/2012/05/LRA
	Effective Dates: 21/02/2012 01/07/2012	Supersedes: N/A

Approvals	Signature	Name
Originator	RESU/LRA	OR/DD
Executive Director	+	CGL
Management Board	N/A	N/A

Introduction	See citations and recitals of the annexed Decision
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Description	Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests
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References	• Regulation (EC) No 178/2002
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Relevant Documents	Policy on Independence and Scientific Decision-Making Processes of EFSA, adopted by the Management Board on 15 December 2011
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Decision History

Date	Revision No.	Description of Change
N/A	N/A	N/A

Abbreviations	<i>Cf. Decision</i>

**DECISION OF THE EXECUTIVE DIRECTOR OF THE EUROPEAN FOOD
SAFETY AUTHORITY**

**implementing EFSA's Policy on Independence and Scientific Decision Making
Processes regarding Declarations of interests**

THE EXECUTIVE DIRECTOR OF THE EUROPEAN FOOD SAFETY
AUTHORITY,

Having regard to:

Regulation (EC) No 178/2002¹ laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety, and in particular Articles 22 and 37 thereof;

The Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority, adopted by EFSA's Management Board on 15 December 2011 (hereinafter also "the Policy");²

The Staff Regulations of Officials of the European Communities and conditions of employment of other servants of the European Communities,³

The Financial Regulation applicable to the General Budget of the European Communities⁴ as well as the detailed rules for the implementation of the Financial Regulation,⁵

Whereas:

- (1) Independence and high standards of professional conduct by all those involved in the activities of EFSA are crucial for EFSA's scientific excellence and reputation;
- (2) Transparency and openness are essential to ensure public confidence;

¹ OJ L 31, 1.2.2002, p. 1 as last amended.

² Mb 15 12 11 – Policy on independence and scientific decision making process – ADOPTED.

³ Staff Regulations and conditions of employment replaced the Staff Regulations of officials and the conditions of employment of other servants of the European Economic Community and the European Atomic Energy Community laid down by Council Regulations No 31 (EEC) and No 11 (EAEC) of 18.12.1961 (OJ 45, 14.6.1962 - Special Edition 1959-62, November 1972), as last amended.

⁴ Regulation (EC, Euratom) N° 1605/2002 on the Financial Regulation applicable to the General Budget of the European Communities, OJ L 248, 16/9/2002, p.1 as last amended.

⁵ Regulation (EC, Euratom) N° 2342/2002 laying down detailed rules for the implementation of the Financial Regulation, OJ L 357, 31/12/2002, p.1, as last amended.

- (3) According to Regulation (EC) No 178/2002, the responsibility for declaring any interest that might be considered prejudicial to their independence can only be placed on the individuals completing their declaration;
- (4) High quality of scientific expertise is by nature based on prior experience and knowledge acquired in the relevant domain. Interests are therefore a natural and inevitable consequence of attaining scientific recognition at international level in a given field. Some of those interests may however conflict with EFSA's aim to deliver scientific advice;
- (5) Any conflict of interests by experts and staff carrying out activities within the remit of EFSA should be promptly identified, handled and removed without delay. To this end, a system of declaration of interests and their subsequent screening and evaluation is required;
- (6) In order to ensure a coherent level of detail in the declarations of interests, a set of activities that might cause potential Conflicts of Interest should be defined;
- (7) To ensure consistent reporting and evaluation, a set of comprehensive declaration of interests forms should be used;
- (8) A transparent procedure should be followed by establishing *inter alia* the following aspects:
 - a. Guidelines to staff performing the screening of declarations of interest;
 - b. Transparent consequences linked to the interests declared; and
 - c. An enforcement procedure to deal with the most serious cases of breach of these rules.
- (9) For scientific experts the scheme put in place should consist of a three-pronged approach: the Annual Declaration of Interest (ADoI), the Specific Declaration of Interest (SDoI) and the Oral Declaration of Interest at the beginning of each meeting (ODoI);
- (10) The Policy should be implemented as far as it is feasible and cost effective through an IT tool that ensures the consistency and complete traceability of the process and minimises the burden for the actors involved;
- (11) With a view to ensuring a systematic and coherent implementation of Articles 11 and 11a of the Staff Regulations, the requirement to declare interests should apply to all managers and knowledge workers working for EFSA; that requirement should also be applied to seconded national experts;
- (12) Regulation (EC) No 178/2002 requires the Authority to establish and maintain an efficient and fruitful cooperation with bodies active in the Member States carrying out tasks similar to those entrusted to EFSA. Without prejudice to the responsibility of each Member State and of its authorities for the appointment of their representatives, including in relation to preventing conflicts of interest, it is therefore appropriate to establish a dedicated set of rules enabling EFSA to optimise the use of resources available and foster a real and effective network of organisations active within its remit.

HAS ADOPTED THE FOLLOWING DECISION:

TITLE I - GENERAL PRINCIPLES AND INTERESTS TO BE DECLARED

SECTION I - GENERAL PRINCIPLES

Article 1- Scope and definitions

1. The present decision lays down detailed rules for the implementation of the Policy on Independence and Scientific Decision Making Processes of the European Food Safety Authority, adopted by EFSA's Management Board on 15 December 2011 (hereinafter "the Policy").
2. The present decision is applicable to members of its Scientific Committee, Scientific Panels, working groups, members of the Networks, peer review meetings and networking meetings pursuant to Article 36(1) of Regulation (EC) No 178/2002, hearing experts and observers⁶. It is also applicable to the members of the Management Board and the Advisory Forum, the Executive Director and other EFSA staff, staff of other European Union Institutions, bodies and agencies participating in EFSA's meetings, as well as contractors, grant beneficiaries and their respective employees.
3. For the purposes of this decision:
 - a. **Interest** meaning the relation of being objectively concerned in something, e.g. by having a right or title thereto, a claim thereupon, or a share therein. For the purposes of the present Decision, declarable interests shall be **all interests falling within fields of competence of the Authority**;
 - b. **Conflict of Interest (CoI)** meaning a 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;
 - c. **Annual Declaration of Interest**⁷ (ADoI) meaning the written declaration to be submitted annually pursuant to Articles 3 and 6 of this decision;
 - d. **Specific Declaration of Interest**⁸ (SDoI) meaning the written declaration to be submitted before each meeting pursuant to Articles 4 and 7 of this decision;
 - e. **Oral Declaration of Interest (ODOI)**⁹ meaning the verbal declaration to be made at the beginning of each meeting pursuant to Articles 5 and 8 of this decision;
 - f. **Food Safety Organisation (FSO)** meaning any organisation included in the list drawn up by the Authority's Management Board according to Article 2 of Commission Regulation (EC) 2230/2004 and any other legal entity, carrying out tasks within EFSA's mission, pursuing public interest objectives and whose

⁶ For the definitions of the categories of scientific experts please refer to the Decision of the Executive Director Concerning the Selection of Members of the Scientific Committee, Scientific Panels and External Experts to Assist EFSA with its scientific work.

⁷ Mb 15 12 11 – Policy on independence and scientific decision making process – ADOPTED, p. 11.

⁸ *Ibid.*

⁹ *Ibid.*

governance ensures the performance of its tasks with independence and integrity as set out in Article 2(1) of that Commission Regulation, such as universities or public research institutes. This shall apply to entities based both inside and outside the European Union.

- g. **Interests of close family member** meaning interests in the subject matter held by partners or persons dependent on the individual submitting the DoI.
4. For the purposes of this decision, concerned persons shall declare all interests corresponding to the following definitions:
- I. **Economic interest** meaning any economic stake or share in a body with an interest in the subject matter, including the stocks, equities or bonds thereof, or of one of its subsidiaries or of a company in which it has a holding;¹⁰
 - II. **Member of a managing body or equivalent structure** meaning any participation in the internal decision-making (e.g. board membership, directorship) of a public or private entity with an interest in the subject matter;
 - III. **Member of a scientific advisory body** meaning any participation in the works of a scientific advisory body, created permanent or created ad hoc, managed by a body with an interest in the subject matter, with a right to have an influence on its output(s). This includes also participation in scientific activities carried out with EFSA, such as membership of Scientific Panels, working groups and Networks. Any advice related to products, their development and/or assessment methods thereof shall be declared exclusively under “Ad hoc or occasional consultancy”;
 - IV. **Employment** meaning any form of regular occupation or business, part-time or full-time, paid or unpaid, including self-employment (e.g. consultancy), in any body with an interest in the subject matter. This also includes employment by EFSA. **Employment by industry** shall mean any form of employment by any legal or natural person carrying out any of the activities on which EFSA’s scientific outputs impact directly or indirectly, such as food production, processing and distribution, agriculture or animal husbandry;
 - V. **Ad hoc or occasional consultancy** meaning any *ad hoc* or occasional activity in which the concerned person provides advice or services to undertakings, trade associations or other bodies with an interest in the subject matter. This includes also services provided on an honorary basis (i.e. for free or without the payment of fees or emoluments) and any advice related to products, their development and/or assessment methods thereof;
 - VI. **Research funding** meaning any funding for research or developmental work on the subject matter received from any public or private body by the concerned person in his or her personal capacity or falling under the professional sphere of influence of that person. It includes grants, rents and reimbursement of expenses, sponsorships and fellowships, also received from EFSA. Grouping by funders and supporters or by subject matters shall be accepted. The expert shall also clarify whether the research (co-)funding received from the private sector during the year preceding the submission of the DoI exceeds 25% of the annual research budget that is managed by the expert for the area under concern or that is otherwise benefiting him or her, including research funding by the organisation employing the expert.

¹⁰ Financial instruments on which the individual has no influence are not to be considered relevant for the purposes of the present decision.

- VII. **Intellectual property rights** meaning rights on the subject matter granted to creators and owners of works that are the result of human intellectual creativity¹¹ and may lead to a financial gain. Plain authorship and publications shall not be declared;
- VIII. **Other memberships or affiliations** meaning any membership or affiliation not falling under the definitions provided above and relevant for the purposes of the present decision, to any body with an interest in the subject matter, including professional organisations;
- IX. **Other relevant interest** meaning any interest not falling under the definitions provided above and relevant for the purposes of the present decision.

Article 2- General principles of declarations and assessment of interests

- 1. The following general principles shall be applicable to all persons subject to the present Decision:
 - a. The identification and handling of conflict of interests as defined in Article 1 shall be based on the evaluation of ADOI, SDOI and ODOI submitted by the concerned persons and staff as specified in the present decision;
 - b. The responsibility for a complete and truthful declaration shall lie exclusively with the person completing the declaration;
 - c. Only activities having taken place in the five years preceding the submission of the declaration shall be declared;
 - d. Scientific experts having been granted a waiver pursuant to Article 16 shall not be allowed to be, or act as, chairman, vice-chairman or rapporteur of EFSA's scientific groups.

SECTION II - INTERESTS TO BE DECLARED

Article 3- Interests to be declared in the Annual Declaration of Interests

- 1. Individuals who are requested to submit an ADOI shall declare any interest belonging to the categories defined in Article 1(4) with respect to all activities in which they are involved or have been involved during the five years preceding the submission of the DoI and which fall within EFSA's remit.
- 2. Individuals shall indicate whether interests declared are **Current** (when activities are currently ongoing); or they refer to a **Past period** (when they are no longer ongoing but have been completed during the five years preceding the submission of the DoI).
- 3. Details on the **name of body or organization** of relevance for each declared interest shall be given. This is to be interpreted as meaning the full name, location of the seat (town and country) and nature (private or public).
- 4. Details on the **subject matter of each declared interest** shall be given, indicating the domain in which the activity is, or was, carried out and clarifying the interest and role of the concerned body or organisation in the matter and the role of the concerned person.
- 5. Individuals subject to the Policy shall update and resubmit to EFSA their ADOI without delay following any change in their interests.

¹¹ *E.g.* patents, trademarks *et cetera*.

Article 4- Interests to be declared in the Specific Declaration of Interests

1. Individuals who are requested to submit an SDoI shall consider the agenda of the specific meeting and their current ADoI and declare:
 - a. all additional interests to be declared with respect to the agenda; or
 - b. that there are no new interests to be declared with respect to a previous SDoI; or
 - c. that there are additional interests that do require an updating of the ADoI, specifying their particulars.
2. Declarable interests shall consist of any interest belonging to the categories defined in Article 1(4) **with reference to the items on the agenda of the meeting or specific output**, as appropriate.
3. By declaring interests, it shall be specified whether interests declared are **Current**; or they refer to a **Past period**.
4. Details on the name of the **body or organisation** as well as on the **subject matter** for each relevant interest shall be provided with reference to the items on the agenda of the meeting.
5. For a meeting or assignment concerning a **specific product or substance**, the bodies with an interest in the product may also include undertakings or bodies that develop, manufacture or market:
 - a. the product/substance being reviewed,
 - b. products/substances that would be used in conjunction with the one being reviewed, or
 - c. products/substances that would compete with the one being reviewed.

Insofar as persons subject to the Policy hold an interest in a "**competing product"/substance and/or a competing company, and they are aware of this, such interests** shall also be declared as these may be pertinent to the screening of interests. Such determinations shall be based on the specificities of each sector in which EFSA operates. In that respect, for instance, EFSA may take due account of the intended effect or claim and of the target population of a certain product or substance.

Article 5- Interests to be declared in the Oral Declaration of Interests

1. At the beginning of each meeting subject to the Policy and considering the final agenda of the meeting, individuals who are required to submit ODoIs shall declare orally **any interest not already declared** through the ADoI or the SDoI that might be considered prejudicial to their independence in relation to the items on the agenda of that meeting.

SECTION III – DECLARATIONS

Article 6- Annual declaration of interests, declaration concerning confidentiality and declaration of commitment

1. Members of the Scientific Committee, the Scientific Panels, working groups as well as other external experts and hearing experts, shall declare any interest falling within EFSA's remit. The individuals above shall complete and submit the form provided in Annex I to the present decision for any EFSA scientific activity in which they are, or are to be, involved. They shall also confirm whether they

consider themselves to be in a potential CoI with respect to any EFSA activity in which they may be involved.

2. Only experts whose ADoI has been approved by EFSA may be appointed as member of a scientific group and be invited to a meeting subject to the Policy.
3. The individuals identified in paragraph 1 shall also make a declaration concerning confidentiality and commitment in accordance with the template provided in Annex II to the present decision.
4. The declarations referred to in this Article shall be made annually in writing and shall be made public in line with the transparency principle informing EFSA's activities.
5. Individuals who are working for more than one EFSA scientific group¹² shall complete a single ADoI where all the concerned bodies are indicated.

Article 7- Specific Declaration of Interest

1. Members of the Scientific Committee, the Scientific Panels, working groups as well as other external experts shall declare for each meeting subject to the Policy any relevant interest in relation to the items on the agenda or the absence of any such interest, using the SDoI provided in Annex III to this decision. Any further details of interests already declared in the ADoI shall be specified in the SDoI in light of the agenda of the meeting. Individuals submitting SDoIs shall confirm whether they consider themselves to be in a potential CoI with respect to any item on the agenda of the meeting.
2. EFSA shall request experts to complete their SDoIs when providing the invitation to the respective meeting or mandate. The experts shall complete and return their SDoIs before each meeting takes place, with reference to the points of the agenda. Only experts having an SDoI approved before the meeting may attend the meeting they have been invited to.
3. When a working group is dealing with only one mandate leading to a single output, a single SDoI referring to the mandate may cover all meetings of that working group (in addition to the ADoI).
4. If several mandates or questions leading to multiple outputs are to be dealt with by a specific working group, as evidenced through the mandate or the meeting agendas, or a working group is dealing with only one mandate addressing several questions, an SDoI shall be required for each meeting where new questions will be addressed (in addition to the ADoI). When a meeting of a Scientific Panel, Scientific Committee or a working group with multiple mandates is organized in the framework of the assessment of applications subject to a scientific assessment, the agenda and the SDoI shall make reference to individual substances or products discussed at the meeting.

Article 8- Oral declaration of interest at the beginning of the meeting

1. At the beginning of each meeting subject to the Policy, members of the Scientific Committee, the Scientific Panels, working groups as well as other external experts shall declare orally **any interest not already declared** that might be considered prejudicial to their independence in relation to any item on the agenda of that meeting, or the absence of any such interest.

¹² E.g. with a Scientific Panel or with a Working group.

2. Any interest declared orally shall be recorded in the minutes of the meeting.

TITLE II – PROCEDURE FOR IDENTIFYING AND HANDLING POTENTIAL CONFLICTS OF INTEREST OF SCIENTIFIC EXPERTS

SECTION I – SCREENING PROCESS FOR MEMBERS OF THE SCIENTIFIC COMMITTEE, SCIENTIFIC PANELS AND WORKING GROUPS

Article 9- Principles of assessment of interests declared by scientific experts

1. In addition to the general principles laid down in Article 2 above, the following principles shall be applied to declarations submitted by scientific experts:
 - a. The **ADoI** is used to decide on the **membership** of the Scientific Committee, Scientific Panels or working groups and for their respective **chairmanship**. The **SDoI** and **ODoI** are instrumental to identify whether the expert who is already a member of the concerned body, should nevertheless abstain, or be recused from, a specific item on the agenda.
 - b. Shall be subject to the present Decision any virtual or physical meeting:
 - i. organized by EFSA after receiving a mandate and before issuing the scientific or technical output, and
 - ii. involving members or external experts of EFSA’s Scientific Committee, Scientific Panels, working groups, Networks, peer review meetings and networking meetings, and
 - iii. regarding directly one or more scientific or technical outputs of EFSA.
 - c. Without prejudice to letter d. below, **interests** can only be assessed by considering whether the specific interests declared by a person are compatible with the **tasks** to be assigned by EFSA to him or her, having regard to the **mandate of the group** where the person participates and the **role and function** that he or she is required to take on or perform.
 - d. In any case, the concerned persons shall not be allowed to assess, rate or review their own work, and persons employed by industry shall not be allowed to become members of EFSA’s Scientific Committee, Scientific Panels and working groups.

Article 10- Screening of Annual Declarations of Interest

1. Upon receipt of the ADoI, the Head of the Unit supporting the Scientific Committee or the competent Scientific Panel, working group or other meeting subject to this Decision shall screen the declaration in order to assess potential CoI arising in any of the categories described in Article 1(4). The screening of ADoIs shall be performed according to the following criteria, reflected in the Reference Table of allowable interests – ADoIs provided in Annex IV to the present decision:
 - a. **Membership** of EFSA’s Scientific Committee, Scientific Panels or working group shall not be allowed when EFSA identifies a potential conflict of interest of a general nature when that would regularly lead to the exclusion of the expert’s from the meetings of that scientific group, such as employment with food or feed industry.

- i. A distinction is made between experts having interests related to FSOs and those having interests related to other organisations for categories II (Membership of management body), III (Membership of a scientific advisory body), IV (Employment) and V (Ad hoc or occasional consultancy). Activities carried out by associations or organizations where FSOs participate and that are performed on their behalf may be considered as de facto FSOs activities. For what concerns membership, the screening of interests falling under these categories shall lead to the following measures:
 - ii. An activity falling under category **II.B** (Member of a management body or equivalent other than a management body of a FSO) and category **V.B** (Ad hoc or occasional consultancy to bodies other than FSOs) that is ongoing at the moment of the screening shall be considered in CoI with membership of that group. This shall result in the impossibility for the concerned person to be considered for membership of that group.
 - iii. An activity falling under category **III.B** (Member of a scientific advisory body other than scientific groups of a FSO) that is ongoing at the moment of the screening shall be considered in CoI with membership of the expert of a One Mandate Working Group. This shall result in the impossibility for the concerned person to be considered for membership of that group.
 - iv. An activity falling under category **IV.B** (Employment with a body other than a FSO) that is ongoing at the moment of the screening shall be considered in CoI with membership of that group. This shall result in the impossibility for the concerned person to be considered for membership of the group. Membership shall also be prevented for activities that have been terminated in the two years preceding the submission of the ADol.
 - v. There is no distinction in the assessment between experts having interests related to FSOs and those having interests related to other organisations for categories **I** (Economic interests) and **VII** (Intellectual property rights). An activity falling under those categories that is ongoing at the moment of the screening shall be considered in CoI with the membership of the expert in that group. This shall result in the impossibility for the concerned person to be considered for membership of that group.
 - vi. For category **VI** (Research funding) the assessment is to be made on the basis of whether the (co-)funding for research or developmental work received from the private sector during the year preceding the submission of the DoI exceeds 25% of the annual budget that is managed by the expert for the area under concern or that is otherwise benefiting him or her, including projects funded by the organisation of the expert. If that threshold is exceeded, that interest shall be considered in conflict with the participation of the expert in the relevant group. This shall result in the impossibility for the concerned person to be considered for membership of that group.
- b. Furthermore, eligibility for **chairmanship** of an EFSA's Scientific Committee, Scientific Panels or working group requires compliance with specific criteria, as follows:
 - i. An activity falling under category **II.A** (Member of a management body or equivalent of a FSO) and category **III.B** (Member of a scientific advisory body other than scientific groups of a FSO) that is ongoing at the moment of the screening shall be considered in CoI with the chairmanship of the expert in that group. This shall result in the impossibility for the concerned person to be considered for chairmanship of that group.

- ii. An activity falling under category **II.B** (Member of a management body or equivalent other than a management body of a FSO), that is ongoing at the moment of the screening shall be considered in CoI with chairmanship of that group. This shall result in the impossibility for the concerned person to be considered for chairmanship of the group. Chairmanship shall also be prevented for activities that have been terminated in the two years preceding the submission of the ADoI.
 - iii. An activity falling under category **III.A** (Member of a scientific advisory body managed by a FSO), category **IV.A** (Employment with a FSO) and category **V.A** (Ad hoc or occasional consultancy to a FSO) that is ongoing at the moment of the screening shall be considered in CoI with the chairmanship of the expert in a One Mandate Working Group. This shall result in the impossibility for the concerned person to be considered for chairmanship of that group.
 - iv. An activity falling under category **IV.B** (Employment with a body other than a FSO) and category **V.B** (Ad hoc or occasional consultancy to bodies other than FSOs) that is ongoing at the moment of the screening shall be considered in CoI with chairmanship of that group. This shall result in the impossibility for the concerned person to be considered for chairmanship of the group. Chairmanship shall also be prevented for activities that have been terminated in the five years preceding the submission of the ADoI.
 - v. For categories **I** (Economic interests), **VI** (Research funding) and **VII** (Intellectual property rights) letters v. and vi. above apply. This shall result in the impossibility for the concerned person to be considered for chairmanship of that group.
 - vi. For the duration of the mandate, the Chairperson shall endeavour not to engage in activities that may result in potential conflicts of interest of that nature or intensity. If, as a result of changes in the declared interest, the new information renders the DoI of the Chairperson not compatible with his or her role, a new Chairperson shall be appointed.
- c. For **both membership and chairmanship**, interests falling under categories **VIII** (Other memberships or affiliations) and **IX** (Other interests) shall be assessed in light of the mission, scope, funding and nature of the activities of the concerned organisation.
2. In the process, the responsible Head of Unit may seek clarifications from the expert with regard to the information that was declared in the ADoI.
 3. The responsible Head of Unit shall report any potential conflicts of interest to the competent Director along with the preventive measures proposed in that respect. The decision on the outcome of the screening of the ADoI rests with the competent Director taking this proposal into account.
 4. Preventive measures taken to address potential conflicts of interests shall be recorded in the minutes of the concerned meeting.

Article 11- Screening of Specific Declarations of Interest

1. The screening of SDoIs shall be made according to the following criteria, reflected in the Reference Table of allowable interests – SDoI provided in Annex V:
 - a. **Interests** can only be assessed by considering whether the specific interests declared by a person are compatible with the **tasks** to be assigned by EFSA to him or her, having regard to the **items on the agenda of that meeting of**

the **group** where the person participates and the **role and function** that he or she is required to take on or perform in that meeting. As a rule, this shall not allow the concerned persons to assess, rate or review their own work.

- b. An activity falling under categories **I** (Economic interests), **II** (Membership of management body), **III** (Membership of a scientific advisory body), **IV** (Employment), **V** (*Ad hoc* or occasional consultancy) and **VII** (Intellectual property rights) that is overlapping with an item on the agenda and that is ongoing at the moment of the screening shall be considered in CoI with any participation of the expert in the item at issue. This shall result in the impossibility for the concerned person to be present when that item is discussed, voted or anyway processed by that scientific group.
 - c. For category **VI** (Research funding) the assessment is to be made on the basis of whether the (co-)funding for research or developmental work received from the private sector during the year preceding the submission of the DoI exceeds 25% of the annual budget that is managed by the expert for the area under concern or that is otherwise benefiting him or her, including projects funded by the organisation of the expert. If that occurs for one or more research projects that overlap with an item on the agenda and that are ongoing at the moment of the screening, this shall be considered in CoI with any participation of the expert in the item at issue. This shall result in the impossibility for the concerned person to be present when that item is discussed, voted or anyway processed by that scientific group.
 - d. Interests falling under categories **VIII** (Other memberships or affiliations) and **IX** (Other interests) are assessed in light of the mission, scope, funding and nature of the activities of the concerned organisation.
2. The Head of the unit supporting the Scientific Committee, Scientific Panel, working group or other meeting subject to the Policy shall perform the screening of the SDoI in advance of the meeting. Without prejudice to the principles set out in Articles 2 and 9, this shall be done taking in due account the information previously submitted in the ADoI and referring to the Reference Table of allowable interests provided in Annex V to the present decision.
 3. The responsible Head of Unit shall report any potential conflicts of interest along with the preventive measures taken in that respect. The decision on the outcome of the screening of the SDoI rests with the competent Head of Unit.
 4. Any preventive measure taken to address potential conflicts of interests shall be recorded in the minutes of the meeting and in the final scientific output.

Article 12- Screening of Oral Declarations of Interest

1. The Head of the unit supporting the Scientific Committee, Scientific Panel, working group or other meeting subject to the Policy shall perform the screening of the ODoI before starting the discussion of any of the items on the agenda. This shall be done taking in due account the information previously submitted in the ADoI and, where appropriate, in the SDoIs, and applying the criteria laid down in Article 11.
2. Any preventive measure taken to address potential conflicts of interests shall be recorded in the minutes of the meeting and in the final scientific output.

SECTION II - DECISION ON THE ASSESSMENT OF MEMBERS OF THE SCIENTIFIC COMMITTEE, SCIENTIFIC PANELS AND WORKING GROUPS

Article 13- Review of the decisions

1. In case a specific complaint is filed by the concerned person or should a reconsideration of a decision be considered appropriate to address a potential factual mistake, the Executive Director may seek the review of any decision taken in the context of this procedure. In the context of the review, the Executive Director shall submit the dossier to the Committee on Conflict of interests (CCI) consisting of the three science directors and of the Head of Legal and Regulatory Affairs for an initial advice for this review.¹³
2. On the basis of the advice provided by the CCI, the Executive Director may review the decision in question taking all measures necessary to rectify the deficiencies identified therein.
3. Should the review by the Executive Director identify a conflict of interest regarding a scientific output that has already been adopted, Article 15(4) shall apply by analogy.

Article 14- Process regarding omissions for members of the Scientific Committee, Scientific Panels, working groups and other external experts

1. EFSA shall systematically and regularly check the compliance of a sample of the DoIs submitted in the context of the present decision.
2. In case EFSA is, or is made, aware of some information that is not consistent with, or that is missing from, the declaration of an expert and a preliminary assessment suggests that it concerns a declarable interest, EFSA shall seek additional information from the expert with regard to the omission. At the same time, the expert shall be requested to update the missing details of the DoI.
3. Upon completion of the update, the DoI shall be processed and screened in accordance with the present Decision.
4. EFSA may take any appropriate preventive action regarding the expert's participation in EFSA's activities in accordance with Articles 10, 11 and 12, respectively.

Article 15- Process regarding breaches of EFSA's rules on declarations of interest

1. In case the assessment of the DoI updated following the process described in the previous article results in the identification of a CoI, the omission shall be considered a breach of the rules laid down in this decision.
2. In case the seriousness is such that it needs to be considered as a breach of trust, EFSA shall propose to the Management Board the dismissal of the concerned member from membership of EFSA's Scientific Committee and/or Scientific Panels.
3. In all other instances involving members of EFSA's Scientific Committee and/or Scientific Panels and working groups, the Executive Director shall take the appropriate decisions.

¹³ Decision of the Executive Director of the European Food Safety Authority establishing the Committee on Conflict of interests (CCI).

4. If EFSA finds an expert to be in breach of the present rules, the Executive Director may ask the Internal Audit Capability (IAC) to perform a review of the scientific outputs adopted by the scientific body(ies) to which that expert contributed. Upon receipt of such a request, the IAC shall clarify whether, and if appropriate the extent to which, that expert influenced the outputs adopted by those scientific bodies. The IAC shall report his or her findings to the Executive Director and to the Audit Committee of the Management Board. The Executive Director shall take all the appropriate measures to address these findings.

Article 16- Granting of waivers

1. When an external expert is assigned a potential CoI excluding him or her from participation in a working group and his or her expertise is considered essential for the completeness of certain outputs, the availability of alternative experts in the field shall be considered.
2. Where a search for alternative experts is performed the availability of alternative experts shall be discussed with the other participants in that meeting.
3. In exceptional cases, when the concerned external expert's involvement in a particular working group is considered essential and where no suitable alternative expert is found, the Head of the Unit supporting the concerned working group may request a waiver to the competent Director.
4. Such a waiver may be granted by the competent Director when the contribution of the concerned expert is found to be essential for the completeness of the draft output, when no suitable alternate could be identified and the expert's contribution could not be handled through participation as hearing expert. The Director competent for the unit supporting the scientific group shall inform the Executive Director on the conclusion reached. This shall include all pertinent information on which the conclusion is based.
5. Waivers shall be recorded in the minutes of the meeting(s) and in the ensuing scientific output.
6. Should a waiver be granted, the concerned expert shall be allowed to take part in the discussions and in the drafting phase of the scientific output. Scientific experts having been granted a waiver shall not be allowed to be, or act as, chairman, vice-chairman or rapporteur of EFSA's scientific groups.
7. No waivers shall be granted to experts involved in activities related to the assessment of dossiers submitted by applicants for the evaluation of regulated products, claims or substances.

SECTION III - OTHER CASES

Article 17- Members of Networks, peer review meetings and of networking meetings

1. Members of networks, peer review meetings, networking meetings pursuant to Article 36(1) of Regulation (EC) No 178/2002 and their alternates shall be invited to complete and submit an ADoI pursuant to Article 6 (Annual declaration of interests) and to make an oral declaration pursuant to Article 8 (Oral declaration of interest), insofar as those provisions are compatible with the specificities of Networks, peer review meetings and networking meetings. No SDoI shall be requested.

2. Articles 10 (Screening of Annual Declarations of Interest) and 12 (Screening of Oral declarations of Interests) shall also be applicable by analogy, insofar as compatible, to ADoIs and ODoIs submitted by members of networks, peer review meetings and networking meetings and their alternates.
3. In case a potential CoI of a general nature is identified for one of the persons identified in paragraph 1, such as employment with food or feed processing industry, the competent Head of unit shall inform his or her Director. A CoI of a general nature is understood to be one for which the network member is in conflict as a result of the activities he is involved in. On the basis of the level assigned to each interest, the Director may liaise with the competent authority or Member State with a view to avoiding the occurrence of the conflict. The responsibility for the appointment or nomination of representatives of the Member State(s) or of its authorities in the meetings rests at all times exclusively with the Member State(s) or the bodies that are represented.

Article 18- Hearing experts

1. Pursuant to Article 28 of Regulation (EC) No 178/2002, and without prejudice to the Decision of the Executive Director concerning the selection of members of the Scientific Committee, Scientific Panels and external experts to assist EFSA with its scientific work,¹⁴ EFSA may organise hearings. It is in that context that hearing experts, as defined in Article 21 of the mentioned Decision of the Executive Director, may be invited to present their views irrespective of whether they hold potential conflicts of interest.
2. Without prejudice to paragraph 1 above, hearing experts shall be required to complete and submit an ADoI pursuant to Article 6 (Annual declaration of interests) of the present Decision. No SDoI or ODoIs shall be requested to hearing experts. No additional remedial measure is requested to prevent the potential CoI identified in the ADoIs of hearing experts as their participation is limited to providing testimony, without the possibility of taking part in the drafting, deliberation of the scientific output at issue or any other activity carried out in that meeting. Hearing experts shall not be allowed to take on any role undertaken by members of scientific groups.
3. The responsible Director or Head of Unit may reject the request of inviting hearing experts on various grounds, including the interests declared in the ADoI. Hearing experts shall be allowed in the meeting only for the relevant point(s) in the agenda.
4. Acceptance of hearing experts shall be recorded in the minutes of the meeting(s) and in the ensuing scientific output.

Article 19- Observers

1. Upon acceptance by EFSA, observers may be invited to attend meetings and events organised by the Authority, or parts thereof, only in order to observe them. Observers shall not in any way take part in the discussion, drafting, deliberation of the scientific output at issue or in other activities carried out there. Observers shall not be allowed to take on any role undertaken by members of scientific groups. The EFSA Guidelines for Observers apply.

¹⁴ Decision of the Executive Director concerning the selection of members of the Scientific Committee, Scientific Panels and external experts to assist EFSA with its scientific work signed on 14 March 2011.

2. Without prejudice to the possibility for the European Commission's representatives to attend EFSA's meetings pursuant to Article 28(8) of Regulation (EC) No 178/2002, accreditation to observe any of the above-mentioned meetings shall be submitted in writing.
3. Staff of FSOs and staff of European Union Institutions, bodies and agencies may attend EFSA's scientific meetings as observers.
4. When staff of FSOs and staff of European Union Institutions, bodies and agencies take part in EFSA's scientific meetings in their quality as members of the competent scientific group, they shall be subject to the relevant provisions of the present Decision. As a consequence, their DoIs shall be screened as those of any other member or expert.

TITLE III - MEMBERS OF EFSA'S GOVERNANCE BODIES, EXECUTIVE DIRECTOR AND STAFF

Article 20- Declarations of interest of members of the Management Board

1. Members of the Management Board shall undertake to act independently in the public interest. For this purpose, they shall make a declaration of commitment (Annex II) and an ADoI (Annex I) indicating any direct or indirect interests which might be considered prejudicial to their independence in accordance with Article 37(1) of Regulation (EC) No 178/2002 and Article 8 of the Code of conduct of the Management Board of the European Food Safety Authority. They shall also make their best efforts to refrain from involving themselves in any activity that would result in a CoI. Those declarations are made annually in writing and are made available on EFSA's website.
2. The members shall inform the Board of any change in their interests by updating their ADoI. When EFSA receives an updated DoI of a Management Board Member, the Executive Director provides an assessment thereof to the Board. The Board shall discuss each case on the basis of the assessment submitted by the Executive Director. The Board shall reach a conclusion with regard to the DoI assessment and shall recommend a follow-up. If an identified conflict that is substantially affecting the work of the Board or EFSA's reputation is not resolved, the Board, acting on a two-thirds majority, may ask for the replacement of the concerned person.

Article 21- Declarations of interests of members of the Advisory Forum

1. Members of Advisory Forum shall undertake to act independently in the public interest, make a declaration of commitment (Annex II) and an ADoI (Annex I) indicating any direct or indirect interest which might be considered prejudicial to their independence. They shall also make their best efforts to refrain from involving themselves in any activity that would result in a CoI. Those declarations shall be made available on EFSA's website. The members shall inform the Advisory Forum of any change in their interests by updating their ADoI.
2. Articles 10 (Screening of Annual Declarations of Interest) and 12 (Screening of Oral Declarations of Interest) shall be applicable to ADoIs submitted by members of the Advisory Forum insofar as those provisions are compatible with the specificities of the AF. No SDoI shall be requested. The Executive Director, in his or her quality as Chairperson of the Advisory Forum, shall screen the ADoIs and

ODOIs of the members to identify if there is any interest that could present a potential conflict with regard to the work of the Advisory Forum.

3. In case a potential CoI of a generic nature is identified for one of the persons identified in paragraph 1, the Executive Director may liaise with the competent authority or Member State with a view to avoiding the occurrence of conflicts of interests. A CoI of a generic nature is understood to be one for which the member is in conflict as a result of the activities he is involved in.

Article 22- Declarations of interest of the Executive Director

1. The Executive Director shall undertake to act independently in the public interest, make a declaration of commitment and an ADoI (Annex I) indicating any direct or indirect interests which might be considered prejudicial to his or her independence. Those declarations shall be made annually in writing and shall be made available on EFSA's website.
2. The Executive Director shall make his or her best effort to refrain from involving himself or herself in any activity that would result in a CoI. The Executive Director shall inform the Management Board of any change in his or her interests.
3. The Management Board shall screen the declaration of interests of the Executive Director in order to identify if an interest could present a potential conflict with regard to the work of the Executive Director.
4. In accordance with Article 11a of the Staff Regulations, the Executive Director shall not, in the performance of his or her duties, deal with a matter in which, directly or indirectly, he or she has any personal interest such as to impair his or her independence.

Article 23- Declarations of interest of other EFSA staff

1. The requirement to declare annually their interests shall also apply to all managers and knowledge workers working with EFSA. Save as hereinafter provided, Articles 3 (Interests to be declared in the Annual Declaration of Interests), 6 (ADoIs) and 10 (Screening of Annual Declarations of Interest) shall be applicable by analogy to those individuals.
2. Declarations of Interest of EFSA's Management Team shall be made available on the Authority's website.
3. The requirement to declare annually their interests shall apply to all persons identified under paragraph 1, irrespective of whether they are on duty or on leave. In addition to the interests defined under Article 1 of the present decision, EFSA staff shall declare also any negotiation with prospective employer(s) having a vested interest in EFSA or in its activities.
4. Declarations of members of staff shall be screened by the responsible line manager. When the line manager identifies a potential CoI, he or she shall highlight the finding to his or her hierarchical superior. If the superior confirms that there is a potential CoI, he or she shall bring the matter to the attention of the Executive Director in his or her quality as Appointing Authority.
5. Employment by EFSA shall be considered in conflict with membership of an EFSA's Scientific Committee, Scientific Panel or working groups.

6. Negotiations with a prospective employer may be considered by the Appointing Authority as a CoI when the staff member has received an offer and the tasks assigned to the staff member have an impact on EFSA's decision making process.
7. The Executive Director, after having consulted the Joint Committee and having heard the member of staff concerned, may decide to reassign the person in question or take any measure considered appropriate to ensure the potential conflict of interest in question does not occur, or to remedy a CoI.
8. When, as a result of the procedure above, a staff member is transferred to another Unit or Directorate, his or her ADoI shall be updated and submitted to his or her new line manager for screening. The procedure laid down above applies to updated DoIs.
9. Any change regarding interests already declared shall result in a swift update of the ADoI, which shall be submitted to the responsible line manager without delay. The procedure laid down above applies to updated DoIs.
10. The procedure laid down in this Article is without prejudice to disciplinary measures that may be taken by the Executive Director in accordance with the Staff Regulations for officials and other servants.
11. Article 90 of the Staff Regulations is applicable to the procedures laid down in this Article.

TITLE IV - PROCUREMENT AND GRANTS AWARDING PROCEDURES

Article 24– Declaration by tenderers to EFSA's procurement procedures

1. EFSA shall demand legal or natural persons applying to EFSA's public procurement procedures concerning a scientific or technical project to submit a true, accurate and up to date declaration of interest using the template provided by EFSA and laid down in Annex VI of the present Decision.
2. In the context of paragraph 1, legal or natural persons shall declare any interest that may be considered prejudicial to their independence with reference to the subject matter of the concerned procedure and to the operational body that will carry out the project or provide the requested services. The declaration shall be submitted together with the offer.
3. Tenderers shall update their declarations without delay in case of any change in those interests.
4. To interpret the concepts and definitions contained in the template declaration, tenderers referred to in paragraph 1 shall make reference to the definitions laid down in Article 1(4). Article 10 (Screening of Annual Declarations of Interest) shall be applicable to DoIs submitted in the context of paragraph 1 insofar as those provisions are compatible. No SDoI shall be requested.

Article 25– Declaration by employees and consultants in the context of procurement and grants procedures of EFSA

1. Upon reasoned proposal of the competent EFSA unit and following the decision of the EFSA's Mandate Review Committee, EFSA may demand legal or natural persons applying to its public procurement or grant procedures to submit as part of their offer/grant application a true, complete and updated individual declaration of

interest also for each of the members of the team they propose in the context of that contract or grant agreement.

2. The proposal by the competent EFSA unit referred to in paragraph 1 may be based, *inter alia*, on the degree of urgency of a certain call, the level of sensitivity of the subject matter, reasons linked to the programme of work of EFSA or on other elements such as the type of contract to be signed.
3. In case the applicant is awarded the grant or contract, the individual declarations referred to in paragraph 1 shall be provided by the concerned legal or natural person to the Authorising Officer together with the offer/application for grant and shall comply with the template laid down in Annex III of the present Decision. Tenderers and applicants, even during the implementation of the contract / grant agreement, shall update their declarations without delay in case of any change in the activities at issue. Specific calls or procedures may specify a different timeline for the submission of the individual declarations.
4. To interpret the concepts and definitions contained in the template declaration, tenderers or applicants referred to in paragraph 1 shall make reference to the definitions laid down in Article 1(4). Article 11 (Screening of Specific Declarations of Interest) shall be applicable to individual DoIs submitted pursuant to paragraph 3.
5. In case of amendments submitted during the period of implementation of the contract or grant project to the declaration, EFSA reserves the right to ask for individual declarations for project team members involved or proposed for involvement in activities under the respective contract or grant project.

Article 26– Screening of the declarations

1. The screening of the declarations of interest submitted under Articles 24 (Declaration by tenderers) or 25 (Declaration by employees and consultants in the context of procurement and grants procedures of EFSA) shall be performed by the EFSA Evaluation Committee designated for each procurement or grant call, with the participation, or under the supervision, of the competent line manager in an advisory capacity, if he or she is not already part of the committee. The screening of declarations may also involve the Authorizing Officer for the contract or grant in question.
2. Should a potential CoI be identified, the Evaluation Committee shall request the tenderer/grant applicant to put in place within a set time period measures appropriate to prevent the occurrence of that conflict, such as the replacement of the individual(s) with the identified conflict.
3. The evaluation committee shall assess the measures taken by the tenderer/grant applicant and the above sequence shall be repeated until no potential CoI is identified, or until the tenderer/grant applicant is excluded from the procedure for his or her inability to adopt the appropriate measures. In that case, the tenderer/grant applicant shall be excluded and his or her offer/application shall not be retained for contract/grant award.

TITLE V - COMMON PROVISIONS

Article 27- Publication and protection of personal data

1. Without prejudice to Regulation (EC) No 178/2002, EFSA shall process all Declarations of Interest pursuant to Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.
2. The purpose of the data processing is to safeguard the independence of EFSA and its constituent bodies.
3. The legal basis for Declaration of Interests processing is provided in:
 - a. Articles 22, 37 and 38 of Regulation (EC) No 178/2002;
 - b. As concerns Annual Declarations of Interest of EFSA staff, Article 11 and 11(a) of the Staff Regulations;
 - c. Article 94 of the Financial Regulation applicable to the General Budget of the European Communities as well as Article 133a of Regulation (EC, Euratom) No 2342/2002 laying down detailed rules for the implementation of the Financial Regulation.
4. The EFSA Executive Director is the controller of handling the declarations of interest.
5. The nature of interests to declare, the obligation to do so, as well as possible consequences of not declaring and the publication of Declarations, are explained in the present decision, also available on EFSA's website.
6. The recipients of the Declarations of Interest are the persons and bodies identified in the present document, without prejudice to the publicity requirement regarding specifically Annual Declarations of Interest laid down in Article 38(1) litt. (d) of Regulation (EC) No 178/2002. Furthermore, Declarations of Interest may be transferred to bodies in charge of a monitoring or inspection task in conformity with Union Law, including the European Court of Auditors, the Internal Audit Service, OLAF, the European Ombudsman and the European Data Protection Supervisor.
7. The conservation period of Declarations of Interest per category of data subjects shall be:
 - a. For Members of EFSA constituent bodies (Management Board, Advisory Forum, Scientific Committee and Scientific Panels) as well as external experts, 5 years after the discharge for the budgetary year to which the DoI relates;
 - b. For the Executive Director, 5 years after the discharge for the budgetary year in which the Executive Director terminates the mandate at EFSA;
 - c. For EFSA staff, 5 years after the discharge for the last budgetary year in which they worked for EFSA;
 - d. For DoIs submitted in the context of grants and procurement, 5 years after the discharge for the budgetary year in which the contract or grant was terminated.
8. Data subjects with active EFSA involvements have a right to access their Declaration of Interest and to update or correct it at any time. To meet this requirement, the DoI IT tool, available upon username/password authentication, is permanently accessible to data subjects. In case EFSA has knowledge of information that is not consistent with the declared interest, or in case of failure to submit a Declaration of Interest, the data subject concerned will be contacted with

ANNEX I: ANNUAL DECLARATION OF INTERESTS (ADoI)

Title (Ms., Mr., Dr., Prof.): _____

First Name: _____

Surname: _____

Profession: _____

EFSA involvement _____

hereby declares to have the following interests relating to his or her EFSA activities
(Please specify the interest that you or your close family members currently have or have had last year and/or in the past 5 years.)

I. Economic interest⁴	Current¹ <i>Please answer Yes or No</i>	Past Period¹ <i>From/To (Month/Year)</i>	Name of Organisation²	Subject matter³

1. Please indicate activities that are currently ongoing. Indicate starting date (month/year). For activities that are no longer ongoing and that have been completed in the preceding five years, please indicate starting and ending date (month/year).
2. Please indicate name, location and nature of the organization.
3. Please indicate the activity of the entity, e.g. types of substances, products, guidance documents, processes or policies and how it relates to remit of the scientific group.
4. Please indicate any economic stake or share in a body with an interest in the subject matter, including the stocks, equities or bonds thereof, or of one of its subsidiaries or of a company in which it has a holding. Financial instruments on which the individual has no influence are not to be considered relevant for the purposes of the present decision.