European Food Safety Authority

EXECUTIVE DIRECTOR

Parma, 27 JUL 2012
Ref. DD/SG/rl (2012) - **out-6736781**

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

Re : Complaint 0622/2012/ANA (S2010-153873)

Dear Mr Diamandouros,

I hereby acknowledge your letter dated 19 April 2012 related to the above complaint filed by Testbiotech, in which they maintain that the European Food Safety Authority (hereinafter "EFSA") would have failed to guarantee the independence of the Chair of the EFSA Scientific Panel on Genetically Modified Foods, and where they demand EFSA to:

1. acknowledge it failed to address the conflict of interest concerning the Chair of the GMO Panel and
2. implement effective measures to prevent similar alleged conflicts of interest in the future.

In your letter, you specifically ask EFSA to provide an opinion on the above claims and on the allegation that it failed to address the conflict of interest concerning the Chair of the GMO Panel.

1. On the alleged failure to address the conflict of interest concerning the Chair of the Scientific Panel on Genetically Modified Foods

In relation to the allegation and claim that EFSA failed to address the conflict of interest concerning Mr Harry Kuiper in his quality as Chairman of the Scientific Panel on Genetically Modified Foods, I would like to clarify what follows:

1.1 About the Scientific Panel on Genetically Modified Organisms and the role of Chair

The Panel on Genetically Modified Organisms (GMO) provides independent scientific advice on the safety of:

- Genetically modified organisms (GMOs) such as plants, animals and micro-organisms, on the basis of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms
- Genetically modified food and feed, on the basis of Regulation (EC) No 1829/2003 on genetically modified food and feed

The Panel carries out risk assessments in order to produce scientific opinions and advice for risk managers. Its risk assessment work is based on reviewing scientific information and data in order to evaluate the safety of a given GMO. This helps to provide a sound foundation for European

policies and legislation and supports risk managers in taking effective and timely decisions. The Panel carries out much of its work in the context of authorisation applications, since all GM food and feed products must be evaluated by EFSA before they can be authorised in the EU.

The Panel works independently, openly and transparently to deliver timely scientific advice of the highest standards to support the policies and decisions of risk managers.

The Panel carries out its work either in response to requests for scientific advice from risk managers or on its own initiative. It frequently sets up Working Groups involving external scientists with relevant expertise to focus on specific matters and help produce scientific opinions. The Panel itself meets regularly in plenary sessions to discuss work in progress and to adopt finalised scientific opinions. Each opinion results from a collective decision-making process with every Panel member having an equal say.

Main areas of activity:

- Risk assessment of GM food and feed applications - For any genetically modified organism and derived food or feed to be authorised in the EU, a company must submit an application for authorisation on placing on the market in line with European legislation. In accordance with EU legislation, an independent scientific risk assessment is to be carried out by the GMO Panel to evaluate the safety of the GMO and derived food or feed. The Panel's independent scientific advice is then used by the Commission and Member States when taking a decision on market approval.
- Development of guidance documents - As part of its remit, the GMO Panel produces a number of Guidance Documents to clarify its approach to risk assessment and to ensure transparency in its work. The Guidance Documents also aim to provide the companies with guidance for the preparation and presentation of applications.
- Scientific advice in response to ad-hoc requests from risk managers - The GMO Panel responds to ad-hoc requests on issues where risk managers require scientific advice to support the risk management process. For instance, the Panel has provided scientific advice relating to the safety of unauthorised GMOs in the EU and to the "safeguard clauses" invoked by certain EU Member States to temporarily prohibit the placing on their national market of specific GMOs authorised at EU level.
- Self-tasking activities - On its own initiative, the Panel identifies scientific issues related to GMO risk assessment which requires further attention. For instance, the Panel has produced a scientific report on the use of animal feeding trials in GMO risk assessment.

The EFSA GMO Unit is composed of EFSA's staff, provides support to the work of the GMO Panel and may carry out other projects in EFSA's remit.

1.2 About EFSA's rules on declarations of interest applicable to the 2009-2012 mandate of the Chair of the GMO Panel

As indicated in your letter, in this complaint you investigate whether the claim and complaint of Testbiotech are well founded with reference to the last mandate of Mr Kuiper, *i.e.* from June 2009 to June 2012.

As you know already, EFSA is a regulatory agency of the European Union. This means that it has legal personality and that it enjoys considerable discretion for the drawing up and adoption of its internal rules, exactly as all the other regulatory agencies of the Union, such as the

European Medicines Agency, the European Chemicals Agency etc. The powers linked to the adoption of its internal rules were indeed delegated to the Authority by the Legislator of the European Union by means of Article 25 of Regulation (EC) No 178/2002, which prescribes that the Management Board be competent for the adoption of EFSA's rules.

Therefore, it follows that the rules applicable for the prevention of conflicts of interest were those in force at EFSA between mid-2009 and June 2012, when the Prof. Kuiper's third mandate ended. It should be duly noted that these rules, contrary to those adopted by EFSA in February 2012, did not yet make reference to the definition of conflict of interest endorsed by the OECD.

The legality of the decisions taken by EFSA to prevent the occurrence of conflicts of interests has therefore to be judged pursuant to those rules only[1], and not to documents of international organisations that are not directly applicable to the facts at issue or to Union institutions, bodies or agencies.[2] The same holds true for maladministration complaints, as these can be found only in cases of illegality or breaches of the European and EFSA Codes of Good Administrative Behaviour or of the principles deriving therefrom.

Therefore, EFSA's internal rules applicable to the instant case can be identified in EFSA's Policy on Declarations of Interest adopted in September 2007 (Annex I) and in its two implementing decisions: the Procedure for identifying and handling potential conflicts of interest (Annex II) and the Guidance document on Declarations of Interest (Annex III).

According to the rules in force from 2009 to 2012, the interests declared by the concerned expert had to be screened in accordance with the indicative table set out in Annex I to the Procedure for identifying and handling potential conflicts of interest and to the table at page 7 of the same document.

1.3 About the alleged existence of certain Conflicts of Interests

In the complaint filed by Testbiotech several allegations are made by the complainant about the existence of certain Conflicts of Interests (CoI) that Mr Kuiper allegedly had *vis-à-vis* his role as Chairman of the EFSA GMO Scientific Panel.

In that respect, please allow me to rebut one by one the allegations that EFSA did not comply with its own rules aimed at preventing the occurrence of those supposed CoIs:

a. First, Testbiotech assumes that the scientific contribution to a Task Force of ILSI in subjects overlapping with those dealt with by the GMO Panel resulted automatically in a CoI. According to the rules in force at the time at EFSA, this is not correct.

   According to the table pre-defining the indicative levels of CoIs, having contributed in the past to a scientific activity as the one described in the DoI of Mr Kuiper and overlapping with the mandate of the Panel was **not** considered a potential CoI.[3] In the case at issue here, Mr Kuiper's contribution to ILSI's scientific papers ended in June 2005, *i.e.* more than seven years ago and certainly well before the mandate 2009-2012 of the GMO Panel started. This was indeed precisely the conclusion applied by EFSA to the interest regarding Mr Kuiper's scientific contribution to a publication coordinated by ILSI.

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[1] Judgment of the General Court (Fifth Chamber) of 9 September 2010, *Now Pharm against Commission*, Case T-74/08, not yet published, para. 91 and ff.

[2] Such as one of the several definitions proposed by the OECD and referred to by the complainant.

[3] Annex I to the Implementing Act to the Policy on Declarations of interest, Procedure for identifying and handling potential conflicts of interest

Having addressed the main complaint filed by Testbiotech, I now turn to address other incidental statements that can be identified in the body of the complaint:

b. Testbiotech also claims that EFSA allowed Mr Kuiper to have permanent contacts with ILSI. This is a generic, unfounded and unmotivated allegation. As the allegation is so generic, it does not allow EFSA to defend itself or the reputation of its experts. More in general, also with respect to different allegations, EFSA respectfully maintains that the Ombudsman should not allow a complainant to refer to leaflets and "reports" addressed to the general public in a uncircumstanciated way. For what concerns the generic, unfounded and unmotivated assertions of the complainant concerning "other experts" of the GMO Panel, EFSA respectfully submits that these allegations are not part of the present complaint, as it results from the letter received from the Ombudsman and dated 19 April 2012. In other words, EFSA regards these generic statements as inadmissible in the present complaint as they are of such a generic nature that renders impossible a sound defense of the Authority, or of the reputation of the expert(s) involved. Therefore, the Authority hereby requests the Ombudsman to declare the statements and allegations above inadmissible as of too generic a nature. Furthermore, the present complaint has been lodged well after two years the facts in question came to the attention of the person who lodged the complaint, as the Declarations of Interests of Mr Kuiper have consistently been available online, in their different versions, since 2008. According to Article 2(4) of the Ombudsman's rules of procedure, complaints have to be made within two years from this date.

c. For what concerns the references made by the complainant at page 2 of his complaint to the *Implementing Act to the Policy on Declarations of interest, Procedure for identifying and handling potential conflicts of interest*, EFSA is of the view that they are misquoted. The first quote[4] simply states that the role of Chair requires separate assessment of that person's DoIs. EFSA does not contest this, although it does not see the relevance of this reference as EFSA did perform a separate assessment of Mr Kuiper's DoIs in accordance with the applicable rules. Therefore, there was no illegality or breach of good administration principles from this point of view. The second quote adds that any member who has a CoI should refrain from offering himself as a candidate for that role.[5] However, as we saw under point a. above, the interest discussed here was not considered a CoI. Therefore, the complainant does not indicate why or where EFSA ignored or breached its own rules.

d. Testbiotech also asserts that the OECD definition of conflict of interest of 2007 should be applied to this case. However, the complainant does not clarify why that should be the case, considering that EFSA had already put in place an internal regulatory framework aimed at preventing CoI. In this respect, EFSA submits that as already discussed above,[6] OECD documents are not directly applicable to Union agencies, whose administrative processes should be assessed exclusively with reference to their own rules and applicable framework.

e. The Complainant's allegations regarding Dr Renckens and her alleged interaction with Mr Kuiper should be ignored by the Ombudsman because by the complainant's own admission, they are based on mere assumptions and unfounded speculations.

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[4] At page 2 of its complaint, Testbiotech claims that "As stated in the "Implementing Act to the Policy on Declaration of Interests, Procedure for Identifying and Handling Potential Conflicts of Interest" (as attached, page 5) "the role of the Chair of the Scientific Committee and Panels" "require separate assessment".

[5] At page 2 of its complaint, Testbiotech asserts that "Furthermore, it explains that: "Any Members that have one or more potential conflicts of interests should refrain from being a candidate for this role."

[6] See § 1.3, above.

Furthermore, EFSA should not be obliged to remind the complainant that, under certain circumstances, unfounded accusations *vis-à-vis* individuals may lead to criminal charges for defamation.

f. Regarding the complainant's contention that there were unmotivated changes between Mr Kuiper's DoI of October 2010 and the one published in March 2012, I can indeed confirm the following. It was only in December 2010 that, in accordance with Article 37 of Regulation (EC) No 178/2002 which prescribes the responsibility of the concerned expert for submitting an annual DoI, Mr Kuiper updated his DoI regarding the time span of his scientific contribution to two publications drafted under the coordinating auspices of ILSI. In that respect, at EFSA there was never any doubt regarding the fact that the interest in question ended in 2005, as EFSA staff screening Mr Kuiper's DoI were familiar with the two scientific papers coordinated by ILSI that represented the outcome of those activities. Indeed, the two scientific papers in question were published by ILSI in 2004 and 2005 respectively. Finally, it should be underlined that the delayed update of Mr Kuiper's DoI does not undermine or invalidate in any way the assessment of the interest discussed in this complaint, as explained under point a., above.

2. About the 2012 Implementing rules on Declarations of interest and the request to implement effective measures to prevent similar alleged conflicts of interest in the future

EFSA submits that, based on the experience gained in the past, it has strengthened even further its rules and procedures regarding conflicts of interest, especially for what it concerns the screening of interests of the members of the Scientific Committee, Scientific Panels and their working groups.

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 Stakeholders 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 IV).[7] For the Ombudsman it may be relevant to know that the complainant contributed to the public consultation and gave a presentation on the draft policy at this event (Annex V). EFSA issued a public report explaining how each comment received was addressed in the revised version of the Policy (Annex VI).

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.

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 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

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

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 million 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.[8]

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 VII)[9].

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 (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 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.

Of particular relevance is the fact that the new Implementing Rules foresee certain overarching principles whereby no expert is allowed to review his or her own work or is allowed to work for an industry which is affected, directly or indirectly, by EFSA's work.

In accordance with EFSA's founding principles of openness and transparency, to explain how the Authority implements those rules in practice, EFSA organised a second interactive stakeholder event in Brussels on 5 March 2012. 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 consulting EFSA's website.

On the basis of the explanations provided above, with particular reference to the request that EFSA should implement effective measures to prevent the occurrence of similar alleged conflicts of interest in the future, EFSA considers that Testbiotech's second claim has already been addressed.

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

[9] The Implementing rules are available online at http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf.

3. Summary of the conclusions

From the above it follows that EFSA considers the claims and the complaint made by Testbiotech:

1. For what concerns their request that EFSA acknowledge that it failed to address the conflict of interest of the Chair of the Scientific Panel on GMO, EFSA maintains that the applicant was not able to prove that the Authority breached its own rules or that it committed maladministration and that no CoI was identified concerning Mr Kuiper's interests with ILSI during the mandate 2009-2012. The Authority therefore respectfully is of the opinion that the request should be rejected by the Ombudsman.
2. Regarding their request to develop a strict policy on conflicts of interest applying to experts taking part in its working groups and scientific panels, EFSA respectfully submits that this has already been achieved, as demonstrated under § 2 of this opinion.

On the basis of the above EFSA respectfully submits that in its view no grounds for maladministration can be identified in the present file.

I trust that the above may address your questions and request, nevertheless I remain of course at your disposal in case you should need further information on this matter.

Yours sincerely,

Catherine Geslain-Lanéelle

Enclosures:

Annex I	EFSA's Policy on Declarations of Interest;
Annex II	Implementing Document. Procedure for the identifying and handling of potential conflicts of interest;
Annex III	Implementing Document. Guidance document on Declarations of Interest;
Annex IV	Policy on Independence and scientific decision making processes of the European Food Safety Authority of December 2011;
Annex V	Agenda of the Consultative workshop on Independence and Scientific decision making of 12 October 2011;
Annex VI	Technical report of EFSA. Outcome of the public consultation on a Draft policy on independence and scientific decision making processes of EFSA;
Annex VII	Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests.

EFSA POLICY ON DECLARATIONS OF INTERESTS

I. INTRODUCTION

Regulation (EC) No 178/2002 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[a] states that members of the Management Board, the members of the Advisory Forum, the members of the Scientific Committee and Panels and the Executive Director shall undertake to act independently.

For this purpose Article 37 of Regulation 178/2002 imposes the obligation on them to make a) a declaration of commitment b) 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*"[b]. Failure to fulfil in a timely and complete manner any of the obligations detailed above will be considered as a *prima facie* breach of trust towards the EFSA.

EFSA's approach of ensuring its independence is set out in this document which is implemented in the Guidance on Declarations of Interests (MB – 11.09.2007 – 5.3) and the Procedure for identifying and handling potential conflict of interests. (MB – 11.09.2007 – 5.4)

These documents implement the concept of Article 37 which takes into account that high quality of scientific expertise is by nature based on prior experience. Having an interest does not necessarily mean having a conflict of interest. The policy is not to ban or sanction the holding of interests by individuals operating in the sphere of EFSA but to facilitate in a transparent and consistent manner the handling of situations where potential conflicts may arise.

Independence and high standards of professional conduct by all those involved in the activities of EFSA - members of the Management Board, Advisory Forum, Scientific Committee, Scientific Panels, Expert Working Groups, other EFSA experts, the Executive Director and other members of EFSA staff - are crucial for the independence and the reputation of EFSA.

One aspect that influences the external perception of EFSA's independence is proving that those involved in the work of EFSA act independently of any external influence related to the

[a] *Official Journal* L 31, 1.2.2002, p. 1 as last amended by Commission Regulation (EC) No 575/2006 of 7 April 2006.

[b] The Executive Director of EFSA has extended this to the Deputy Executive Director and AD Staff of EFSA (declarations of the latter are not made public though).

subject of the activity. Openness is essential to ensure public confidence. Therefore, professionals involved in the activities of EFSA must reveal the interests they may have in EFSA's tasks.

EFSA has decided to review its procedures and arrangements and to further strengthen the robustness and transparency of the system of handling declarations of interests, based on the experience gained in handling declarations of interests since its establishment.

II. EFSA's approach to declarations of interest

By nature, declarations of interest are of individual nature. In order to ensure a coherent level of detail in the declarations, a set of interests have been defined. These are ownership or other investments, including shares, membership of a managing body or equivalent structure, membership of a scientific advisory body, employment, consultancy, research funding, intellectual property rights, other memberships, and any other interests. Interests of close family members are also to be included.

To ensure consistent reporting and evaluation the following documents have been created:

- A set of comprehensive declaration of interests forms which seek detailed information from different areas and activities that may be of relevance in the context of specific interests. By applying these forms in a consistent way a coherent declaration of the level of interests is promoted which would seek to establish a common awareness of what kind of interests are to be declared. To support that, the forms provide various explanatory notes.

- A Guidance document on Declarations of Interest. This document presents

    - the importance of providing declarations of interest;
    - the nature of interests that are to be declared, and
    - the different documents that have been created for this purpose

    It is to be made available to the experts prior to the completion of their declaration of interests.

- A Procedure for identifying and handling potential conflicts of interest formalising the approach on how and when to assess the information provided in the declarations regarding such potential conflicts. The document also sets out a procedure for screening of the declarations of interest and outlines possible consequences linked to the interests declared for experts and members of EFSA's Scientific Committee and Panels.

All the above-mentioned documents shall be made public on the EFSA webpage.

III. Handling of conflicts of interest of Scientific Committee members, Panel members and other EFSA experts

Based on the information provided by the expert, the Head of the Unit supporting the relevant Panel or Working Group, or the Scientific Committee, will evaluate whether a declared interest constitutes a conflict. In the case of an identified potential conflict of interest, the Head of the Unit supporting the relevant Panel or Working Group or the Scientific Committee, will, in collaboration with the Chair, assess whether the expert will be allowed to participate in the EFSA activities or not.

IV. Handling of conflicts of interest for Management Board members, members of the Advisory Forum, the Executive Director and other members of EFSA Staff

Taking into account the different nomination procedures and the different roles and responsibilities of the members of the Management Board, Advisory Forum, the Executive Director and other members of EFSA staff compared to the members of the Scientific Committee and Panels, the Procedure for identifying and handling potential conflicts of interest lays down a different, simplified procedure which takes these differences into account.

Whilst the EFSA's founding regulation places specific declaration obligations upon the Executive Director, EFSA has decided that the requirement to declare interests should also apply similarly to all AD-grade staff in the Authority. This is in line with the spirit of the founding regulation under which all the individuals in a position to influence EFSA's output, particularly in the core business areas of science and communications, should act with independence and integrity and should be subject to the same standards of professional conduct as members of EFSA bodies and other EFSA experts and therefore use a similar system for the verification thereof.

EFSA staff is subject to obligations laid down under the EU Staff Regulation for officials and Conditions of Employment of Other Servants. In essence, all EU officials and servants are required to act with independence and integrity, cannot deal with matters in which they have personal interests or hold interests likely to impair their independence, must seek prior permission for any outside activity and must declare whether their spouse are in gainful employment in order for the institution to assess the compatibility with the official's duties.

V. Review of the policy

The policy set out in this document shall be reviewed within 3 year of its adoption. The members of the Management Board are asked to adopt the EFSA Policy on Declarations of Interest.

Parma, 5th October 2007

Patrick G. Wall
Chair

European Food Safety Authority

IMPLEMENTING ACT TO THE POLICY ON DECLARATION OF INTERESTS PROCEDURE FOR IDENTIFYING AND HANDLING POTENTIAL CONFLICTS OF INTEREST

INTRODUCTION

1. Article 37 of Regulation (EC) No 178/2002 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[1] addresses specific obligations of the members of the Management Board, the members of the Advisory Forum, the members of the Scientific Committee, Panels, their Working Groups and the Executive Director with regard to their independence. In conjunction with EFSA's mandate to deliver independent scientific advice, Article 37 also carries indirectly the obligation for EFSA to set up an operational system so that precautions can be taken in order to ensure the impartiality of the output of EFSA.

2. EFSA's approach of ensuring its independence is set out in the Policy for declarations of interest (MB – 11.09.2007 – 5.2) which is implemented in the Guidance on Declarations of Interest (MB – 11.09.2007 – 5.3) and in this Procedure.

3. The Procedure is divided in four sections laying down the respective procedures for: A) members of the Management Board; B) members of the Advisory Forum; C) members of the Scientific Committee, Panels and other EFSA experts, D) the Executive Director, and other members of EFSA Staff.

4. The Procedure provides:

- A formal procedure for the screening of declarations of interest and
- Transparent consequences linked to the interests declared.

5. It should be noted that this procedure is based on the principle that interests declared in a transparent way are not *per se* considered to represent conflicts of interest; rather they are considered to reflect all relevant interests.

[1] *Official Journal* L 31, 1.2.2002, p. 1 as last amended by Commission Regulation (EC) No 575/2006 of 7 April 2006.

A) MEMBERS OF THE MANAGEMENT BOARD

1. The members of the Management Board shall make their best efforts to refrain from involving themselves in any activity that would result in a conflict of interest. The members shall inform the Management Board of any changes in their interests.

2. Members of the Management Board shall undertake to act independently in the public interest.

I. Annual Declaration of interests

1. Members of the Management Board shall indicate in an annual public declaration and in line with the Guidance on Declarations of Interest (MB – 11.09.2007 – 5.3) either the absence of any interests which might be considered prejudicial to their independence or any interests which might be considered prejudicial to their independence, including interests which are inherent to the professional background of the individual[2].

2. The chairperson will review the declarations of interests of Management Board members to identify if there are any interests that could present a conflict with regard to the work of the Management Board. In this exercise, the chairperson may ask for the support of the vice chairpersons.

II. Declaration at the beginning of each meeting

1. In accordance with Article 37 of Regulation 178/2002 and the Rules of Procedure of the Management Board and the Advisory Forum, the chair will ask members to declare any interests at the beginning of each meeting and any declared interests will be recorded in the minutes.

2. On the basis of the type and nature of the conflict identified, the chairperson will consider the appropriate level of participation. As a general principle, any conflict of interest shall be incompatible with the obligations deriving from the function of the chairperson and vice-chairpersons.

[2] In accordance with Article. 37 of EFSA Founding Regulation

B) MEMBERS OF THE ADVISORY FORUM

Members of Advisory Forum shall undertake to act independently in the public interest.

I. Annual Declaration of interests

1. Members of Advisory Forum shall indicate in a transparent way in line with the Guidance Document on Declarations of Interests (MB – 11.09.2007 – 5.3) either the absence of any interests or any interests that might be considered prejudicial to their independence in an annual public declaration, including interests that are inherent to the professional background of the individual.

2. The Executive Director, chair of the Advisory Forum, will review the declarations of interest of the Advisory Forum members to identify if there are any interests that could present a conflict with regard to the work of the Advisory Forum. In this exercise, the Executive Director may ask for the support of another member of the Advisory Forum.

II. Declaration at the beginning of each meeting

1. In accordance with Article 37 of Regulation (EC) No 178/2002 and the Rules of Procedure of the Management Board and the Advisory Forum, the Executive Director will ask members to declare any interests at the beginning of each meeting and any declared interests will be recorded in the minutes.

2. On the basis of the type and nature of the conflict identified, the Executive Director will consider the appropriate level of participation.

C) MEMBERS OF THE SCIENTIFIC COMMITTEE, PANELS AND OTHER EFSA EXPERTS

1. For the Members of the Scientific Committee, Panels and other EFSA experts, including hearing experts, EFSA applies a detailed Annual Declaration of Interests (ADoI) in combination with a Specific Declaration of Interests (SDoI). The latter is linked to any specific activity/work performed for EFSA.

2. Due to their nature, for *ad hoc* working groups the ADoI needs to be completed. For panels and for standing working groups, *i.e.* groups that are established on an ongoing basis, both an ADoI and an SDoI shall be used.

3. The Head of the Unit supporting the relevant Panel or Working Group, or the Scientific Committee, will be responsible for the handling of the ADoIs and SDoIs as specified in the paragraphs hereunder.

I. The Annual Declaration of Interests (ADoI)

1. The ADoI aims to invite the concerned persons to provide a detailed description of their interests.

2. The ADoI is completed on an annual basis. Upon their receipt, the Head of the Unit supporting the relevant Scientific Panel or Working Group, or the Scientific Committee, will screen the ADoIs in order to highlight interests. In the process, the Head of Unit may seek additional background information with regard to the information that was declared in the ADoI.

II. Specific Declarations of Interest (SDoI)

1. In view of the need to declare interests in relation to each meeting, the SDoI is applied. The SDoI is without prejudice to the oral request for declarations of interest at the beginning of any meeting of the Scientific Committee, Panels or Working Group as required in accordance with Article 37 of Regulation (EC) No 178/2002.

2. The SDoI is linked to a specific subject matter or set of subject matters (e.g. substances/ product) at a specific meeting or a specific mandate to be covered at one or several meetings.

3. It allows the concerned persons to declare either of the following:

   a. there are no additional interests to be declared with respect to his/her ADoI;

   b. there are no new interests to be declared with respect to a previous SDoI;

   c. there are additional interests. In this case, the SDoI takes up the format of the ADoI to allow for a detailed declaration.

4. The SDoI will be distributed together with the invitation to a respective meeting or mandate. It is to be completed and returned before or on the day of that meeting or by the first meeting for that mandate. This in turn will allow the screening to be performed in advance of this activity.

5. The screening of the SDoI will be performed by the Head of the Unit supporting the relevant Scientific Panel or Working Group, or the Scientific Committee. This will be done while also considering the interest previously

declared in the ADoI.

• On the occasion of specific meetings, the Head of the Unit supporting the relevant Scientific Panel or Working Group, or the Scientific Committee, will inform the Panel on the conclusion with regard to the nature of the participation. This conclusion will be recorded in the minutes of the meeting.

III. Assessment of the potential conflicts of interest and decision on the nature of the participation

1. Some declared interests could clearly be such that they cannot be expected to cause any conflict of interest. The rest of the declared interests pose a potential conflict of interest by default. Whether a potential conflict will result in a factual conflict depends on various factors. Since EFSA's credibility is at stake in addition to its independence it is unavoidable to consider perceived conflicts of interest as well.

2. Whether a potential conflict of interest will result in a factual or perceived conflict of interest depends on the nature of that particular potential conflict, the remit of the Scientific Panel[3] or Scientific Committee of which the individual is a member, his or her role in that body, and the subject at issue.

3. The following roles in the Scientific Committee and Panels require separate assessments:

• Chair of the Scientific Committee and Panels,

• Rapporteur or equivalent leading/coordinating role,

• Member involved in the evaluation/drafting of an opinion,

• Member involved in taking a decision about and/or adoption of an opinion.

4. If a declared interest poses a factual or perceived conflict of interest for a certain role or activity in the Scientific Committee and Panels, it is in the interest of EFSA as well as of the individual with that interest that there is no involvement in that particular activity. This non-involvement should be made explicit and noticeable from minutes, reports and opinions.

5. It is undesirable when the Chair is excluded from participating in any part of the work of the Scientific Committee or Panel. Therefore, any Members that have one or more potential conflicts of interest should refrain from being a candidate for this role. Once elected, and for the duration of the mandate, the Chair should endeavour not to engage in activities that may result in any potential conflict of interest. Any change of interest shall immediately be declared to EFSA. If, as a result of this, the new interest is not compatible with holding the Chair, then a new Chair should be appointed.

6. Conflicts of interest may be of a different nature. They may be of a financial nature when individuals have a financial stake because of their employment, investment in a company or intellectual property rights whose value may be influenced in either a negative or positive sense by an opinion or the assessment of the safety or a claim of an ingredient or a product. However, conflicts can also be of a scientific nature when the individual has been involved in research relating to the subject that is being scrutinised. Similarly earlier involvement in an opinion of a national authority that will be assessed by the Scientific Committee or Panel may cause a conflict of interest for the concerned person. Religion or

[3] Working Groups are considered as part of the evaluation/drafting phase.

attitudes to life may also be responsible for conflicts of interest such as meat products and their derivatives for vegetarians. Conflicts can also be of a political nature for individuals who are employed by government research institutes or civil servants depending on the lines of responsibility within the institute or the ministry.

III. a The assignment of indicative levels of potential conflicts of interest

1. There are three indicative levels of potential conflict of interest: "A"[4], "B"[5], or "C"[6] that can be assigned to the relevant activities (Reference Table - Annex 1). As a matter of principle, the EFSA considers the activities under I, II, IV and V of the Annex 1 as critical if they are current, and as important if they are not ongoing. Hence, these are assigned an indicative level "C" and an indicative level "B", respectively. "A" means that there is no conflict of interest.

2. It should be noted though that the indicative level could only be attributed with regard to a specific activity. As an example, a member of the Scientific Committee, Panels, or other EFSA expert who is currently working for a company that is active in the field of EFSA's mandate (activity IV - employment) will be attributed an initial "Yes" following the screening of the ADoI. This serves as an indication that there is an interest. With regard to a specific meeting/activity this interest may or may not be classified as a conflict of interest. For example, in case of a product on the agenda of that meeting which is manufactured by the company the concerned person is employed by, that activity will be considered as a "C" indicative level of potential conflict of interest. This is also the case if it concerns a product that is a potential competitor of a complementary product.

III. b Decision on participation

1. The indicative level of potential conflict of interest can be either adjusted or confirmed by the Head of the Unit assisting the relevant scientific Panel, Scientific Committee or Working Group. In the process, the Head of Unit may seek additional background information with regard to the information that was declared in the SDoI. Adjustments to the indicative levels of potential conflict of interest may vary due to the taking into account of the general context in which that specific activity is developed, the nature of the employer or of the entity with which the concerned person is developing that activity and all particularities of the specific activity at issue.

2. As a rule, EFSA aims to determine the nature of the participation of the concerned persons by the application of transparent criteria as set out in this chapter and the conflict of interest levels assigned in line with the procedure described above.

3. The decision on the nature of participation of a member of the Scientific Committee, Panels, or of another EFSA expert in a specific meeting shall be taken by the Head of the Unit assisting the relevant scientific Panel, Scientific Committee or Working Group in consultation with the Chair on the basis of the level of potential conflict of interest.

[4] An indicative level of potential conflict of interest defined as "A" should be interpreted as non-existent.
[5] An indicative level of potential conflict of interest defined as "B" should be interpreted as possible.
[6] An indicative level of potential conflict of interest defined as "C" should be interpreted as existent.

For the chairpersons of the Scientific Committee, the Panels or the working groups

Once elected, and for the duration of the mandate, the chairperson should endeavour not to engage in activities that may result in a change in his/her level, and in any case shall immediately declare to the EFSA any changes that may affect this level. If, as a result, the potential conflict of interest level has become higher than is permitted, then a new chairperson should be appointed or temporarily replaced for the topic of concern, as appropriate.

For other Scientific Committee, Panel and working group members and other EFSA experts

The following table summarizes the ***permitted*** involvement level for a specific agenda or mandate:

Role/phase	**Permitted involvement for a specific agenda or mandate**	
	Specific product-related matters	**General matters (such As guidelines/data collection)**
Chair	**A**	**A**
Rapporteur or equivalent leading/coordinating role	**A**	**A** and **B**
Evaluation/drafting phase[7]	**A** The **B-**level concerned person addresses orally or in writing questions raised during the evaluation of products, but cannot draft assessment reports or parts of them.	**A** The **B**-level concerned person may contribute to the drafting of general guidance documents. The individual can participate in working groups, or report on his/her professional experience.
Decision phase/adoption	**A** The **B**-level concerned person cannot actively participate in the final discussion. However, he/she can be present to answer questions addressed specifically to him/her.	**A** and **B**

[7] Working Groups are considered as part of the evaluation/drafting phase

Level A

Involvement in all activities is permitted.

Level B

The level of involvement of the concerned person will depend on:
• the type of matter to be addressed: general matters such as guidelines versus specific product-related matters,
• the nature of the input required, and
• the role of the individual or the phase during which the person's involvement is required.

Level C: exclusion of the concerned person from certain activities

1. As a general rule, and without prejudice to the principles laid down in the paragraphs above, the person is excluded from participating in EFSA activities concerned by the potential conflict in question. Another expert in the field may need to be found.

2. In exceptional cases in which the concerned person's involvement in a particular activity is considered to be essential and where no suitable alternative expert can be found, the Head of the Unit supporting the concerned Panel should consult the with the Director of the Directorate of Risk Assessment and the Director of the Directorate of Scientific Cooperation and Assistance for a decision on whether to grant a waiver.

3. In cases referred to in paragraph 2 above, the availability of alternative experts in the field has to be considered prior to any submission and the Directors of the Risk Assessment and the Scientific Cooperation and Assistance Directorates. Where a search is performed for alternative experts, it will be considered that no alternative expert is available if the outcome of the search is negative only:

• after having discussed alternative experts with the respective Panel or Scientific Committee; and

• after having discussed alternative experts with the two Directors of the Scientific Directorates.

4. Thus, the two Directors should only be consulted in relation to cases referred to in paragraph 2 above when a search for alternative experts has already been carried out and the outcome of that search was negative. Such a waiver may be granted where the need for the individual's services outweighs the potential for a conflict of interest. Key factors for this assessment will be the relevance of the interest and the nature of the input to be provided by the concerned person. The Director competent for the unit supporting the relevant Panel or Working Group shall inform the Executive Director on the conclusion reached by the two Directors of the Scientific Directorates. This shall include all relevant information on which the conclusion is based.

5. If a waiver is granted the conflict will then be considered to be at level "B" as regards the involvement in the EFSA activities for which involvement is sought.

III.c Review

At any time, the Executive Director may review, in consultation with the Chair of the Scientific Committee, the decisions taken in accordance with this procedure.

D) EXECUTIVE DIRECTOR AND OTHER EFSA STAFF

I. The Executive Director

1. The Executive Director shall make his/her best efforts to refrain from involving himself/herself in any activity that would result in a conflict of interest. The Executive Director shall inform the Management Board of EFSA of any changes in his/her interests.

2. The Executive Director shall undertake to act independently in the public interest.

Annual Declaration of interests

3. The Executive Director shall indicate in an annual public declaration and in line with the Guidance on Declarations of Interest (MB – 11.09.2007 – 5.3) either the absence of any interests that might be considered prejudicial to his/her independence or any interests that might be considered prejudicial to his/her independence.

4. The Chair of the Management Board will review the declaration of interests of the Executive Director to identify if there are any interests that could present a conflict with regard to the work of the Executive Director.

II. Other EFSA staff

1. Whilst EFSA's founding Regulation places specific declaration obligations upon the Executive Director, the EFSA has decided that the requirement to declare interests should also apply to all AD-grade staff in the Authority. This is in line with the spirit of the founding Regulation under which all the individuals in a position to influence EFSA's output, particularly in the core business areas of science and communications, should act with independence and integrity and should be subject to the same standards of professional conduct as members of EFSA bodies and other EFSA experts, using a similar system for the verification thereof.

2. EFSA staff is subject to obligations laid down under the EU Staff Regulation for officials and other servants. In essence, all EU officials and servants are required to act with independence and integrity, cannot deal with matters in which they have personal interests or hold interests likely to impair their independence, must seek prior permission for any outside activity and must declare whether their spouse are in gainful employment in order for the institution to assess the compatibility with the official's duties.

3. Declarations of member of staff will be screened by the respective line manager. When the line manager identifies a potential conflict of interest, he or she highlights the finding to his or her Director. If the Director confirms that there is indeed a potential conflict of interest, he or she brings the matter to the attention of the Executive Director. The Executive Director, after having consulted the Staff Committee and having heard the member of staff, might decide to exclude the person in question from any involvement in the relevant task. In the process the Executive Director may ask the view of a Review Committee for advice. The Review Committee shall be composed of the four Directors, of the Head of Human Resources and of the Head of Legal and Policy Affairs.

4. The procedure above is without prejudice to other measures that may be taken by the Executive Director in accordance with the Staff Regulationsfor officials and other servants. Article 90 of the Staff Regulations is applicable to the procedure laid down above.

Done at Parma, on 8/9/2009

Signed by

Catherine Geslain-Lanéelle

Executive Director of the European Food Safety Authority

ANNEX 1
REFERENCE TABLE

(high quality of scientific expertise is by nature based on prior experience and that therefore having an interest does not necessarily mean having a conflict of interest)

Nature of Activities and subject matter		Interest Level based on Annual Declaration of Interest[8]		Indicative conflict of Interest Level based on the Specific agenda or mandate		
		Current activity	Previous activity	current	past	none
I	Ownership of other investments, including shares	Y/N		C		A
II	Member of a Managing Body or equivalent structure	Y/N	Y/N	C	B	A
III	Member of a Scientific Advisory Body	Y/N	Y/N	B	A	A
IV	Employment	Y/N	Y/N	C	B	A
V	Consultancy/Advice	Y/N	Y/N	C	B	A
VI	Research funding	Y/N	Y/N	B	A	A
VII	Intellectual property rights	Y/N	Y/N	B	A	A
VIII	Other membership or affiliation	Y/N	Y/N			
IX	Other	Y/N	Y/N			
	Interests of close family members should be listed as appropriate under category I to IX					

[8] Y (Yes), N (No)

European Food Safety Authority

IMPLEMENTING ACT TO THE POLICY ON DECLARATION OF INTERESTS GUIDANCE DOCUMENT ON DECLARATIONS OF INTEREST

INTRODUCTION

1. This guidance is part of the scheme implementing Article 37 of Regulation (EC) No 178/2002. It implements the EFSA Policy on Declarations of Interests[1] in line with the Decision concerning the establishment and operations of the Scientific Committee and Panels[2]. This document outlines

- the importance of providing declarations of interests and
- the nature of interests that are to be declared.

2. This guidance document aims at giving clear indications on how to declare an interest and is to be cross-read with the Procedure for identifying and handling potential conflicts of interest[3].

3. It should be noted that according to Regulation (EC) No 178/2002, the responsibility for declaring any possible conflict of interest is placed on the individuals completing their declaration.

4. The Authority recognises that scientific expertise underpins the fulfilment of its mission and tasks and that the quality of such expertise is inherently based on prior experience. It is also to be highlighted that an "interest" declared is not automatically considered a conflict of interest. It is well understood that, in general, individuals who are involved in a particular process inherently have a professional interest in the subject and in being involved in the process as such. Therefore, members of EFSA constitutive bodies mentioned in Article 24 of Regulation (EC) No 178/2002, *i.e.* the Management Board, the Advisory Forum, the Scientific Committee, the Scientific Panels and EFSA staff members, Working Group as well as any other EFSA experts all have a professional interest in the work they are undertaking and in the outcome of these activities. In the work processes of EFSA interests of an intellectual nature are considered as indispensable to safeguard the quality and overall balanced objectivity of the scientific work.

5. The scheme put in place consists of a two-step approach: The Annual Declaration of Interests (ADoI) and the Specific Declaration of Interests (SDoI). The ADoI highlights various interests. These may give rise to a potential conflict of interest in the context of a specific activity. The SDoI is to be filled in at the beginning of each meeting/activity of the Scientific Committee, Scientific Panels and Working Groups. The SDoI is linked to a specific subject matter or set of subject matters (*e.g.* substance/product) and it allows EFSA to assess whether a conflict of interest exists in the context of the specific activity.

6. For scientific experts and members of staff the Policy is implemented through a dedicated IT tool that allows minimising the burden for most of the actors involved. Against that background, the concept of Specific Declaration of Interests shall be meant as an update of the Annual Declaration of Interests.

[1] MB 11.09.2007 - 5.2.
[2] MB – 17.10.2002.
[3] MB 11.09.2007 - 5.4.

WHO SHOULD DECLARE INTERESTS AND WHEN?

A. Annual Declaration of Interests

The members of the Management Board, the members of the Advisory Forum, the members of the Scientific Committee, the Scientific Panels, Working Groups thereof as well as other EFSA experts and the Executive Director shall undertake to act independently in the public interest. For this purpose, they shall make a Declaration of Commitment (Annex 1), an Annual Declaration of Interests (ADoI) (Annex 2) and a Declaration concerning confidentiality (Annex 4). Those declarations shall be made annually in writing and shall be made public according to Article 38(1)d) of Regulation (EC) No 178/2002.

The aim of the ADoI is to concisely address all possible interests that might be considered relevant to assess independence, including interests that are inherent to the professional background of the individual.

Experts who are working for more than one scientific entity can complete a single ADoI, provided that all the relevant entities with which they cooperate within EFSA are mentioned in the ADoI.

The Executive Director has decided that the requirement to declare interests should also apply to all members of staff in the Authority classified at AD-grade or equivalent (i.e. including also ENDs and Contract Agent F.G. IV).

Other EFSA experts who are not working in a Working Group of the Scientific Committee or Scientific Panel (e.g. persons participating in meetings of EFSA's Networks, ESCO Working groups, PRAPeR, the Communication working group and the stakeholder platform) are encouraged to fill in an ADoI.

B. Specific Declaration of Interests

In order to address interests of relevance which are linked to a specific activity**,** the legal framework foresees that interests are to be declared at the beginning of each meeting.

The members of the Management Board, the members of the Advisory Forum, the members of the Scientific Committee, the Scientific Panels, Working Groups as well as other EFSA experts, including hearing experts, are asked to declare any interests that might be considered prejudicial to their independence in relation to the items on the agenda at the beginning of each meeting. Any declared interests will be recorded in the minutes. Furthermore, the members of the Scientific Committee, Scientific Panels, Working Groups as well as other EFSA experts, shall declare for each meeting such interests, using the Specific Declaration of Interests (SDoI) provided in Annex 3.

When a working group is dealing with only one mandate leading to the adoption of a single output, an ADoI referring to the mandate covers all meetings of that Working Group and no SDoI will be required for that Working Group. If several mandates are to be dealt with by a specific Working Group, an ADoI and an SDoI for each meeting are needed.

Other EFSA experts who are not working in a Working Group of the Scientific Committee or Scientific Panel (e.g. persons participating and attending meetings of EFSA's Networks, ESCO Working groups, PRAPeR, the Communication working group and the stakeholder platform) are kindly invited at the beginning of each meeting to declare any interests which might be considered prejudicial to their independence in relation to the items on the agenda. Any declared interests will be recorded in the minutes.

Finally, observers attending the meetings identified above, staff of the European Commission or of other European Community agencies, observers sent on behalf of the European Parliament, the OIE, the WHO or other relevant international bodies, Pre-accession countries and third Countries are kindly

invited to declare any interests which might be considered prejudicial to their independence in relation to the items on the agenda. Any declared interests will be recorded in the minutes.

WHAT TO DECLARE?

A. Annual Declaration of Interests

It should be noted that when completing in the DoI form the appropriate response to each Yes/No question must be selected.

The nature of the activities listed below shall be declared in the ADoI. These activities can be current or past (see the "other definitions" below).

Nature of the activities

I. **Ownership or other investments, including shares** is to be interpreted as meaning any financial interests in a company/entity operating in the food or feed business[4], including holding of stocks and shares, equity, bonds, partnership interests[5] in the capital of a company, one of its subsidiaries or a company in which it has a holding. The holding of financial interests connected with a pension scheme or an equivalent financial instrument would not be considered a financial interest, provided that the individual has no influence on its financial management.

II. **Member of a Managing Body or equivalent structure** is to be interpreted as meaning any participation in the internal decision-making (*e.g.* board membership, directorship) of a company, trade association or equivalent entity operating in a domain falling within EFSA's remit.

III. **Member of a Scientific Advisory Body** is to be interpreted as meaning that the person concerned is participating or has participated in the works of a Scientific Advisory Body operating in a domain falling within EFSA's remit with a right to vote on the outputs of that entity (e.g. voting on scientific output adopted by that entity).

IV. **Employment** is to be interpreted as covering all forms of employment, part-time and full-time, either paid or unpaid, in any organisation whose activities fall within EFSA's remit.

V. **Consultancy/Advice** is to be interpreted as an activity in which the concerned person charges or does not charge a fee for providing advice or services in a particular field falling within EFSA's remit. Any contracts or collaborations with the EFSA falling outside the work of the Panel/Working Group/Scientific Committee as identified above should also be specified under this activity. The subject matter should only indicate the domain in which the consultancy is/has been active.

VI. **Research funding** is to be interpreted as meaning any funding for research in relation to matter or work financed by a private or public entity, including grants, rents, sponsorships and fellowships and received in a personal capacity and falling within EFSA's remit. Research projects may be grouped together without stating the title of each project, provided that a relationship between them exists.

VII. **Intellectual property rights** are to be interpreted as meaning rights granted to creators and owners of works that are the result of human intellectual creativity and that pertain to a domain falling within EFSA's remit. These can be publications or can be in the industrial, scientific and artistic domain. They

[4] By reference to the definitions set out in Article 3 of Regulation (EC) No 178/2002, food or feed business should be taken to mean any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food or feed.

[5] When declaring financial interests e.g. stock and shares, only the kind, company name need to be stated.

can be in the form of an invention, a manuscript, a suite of software, or a business name *(e.g.* copyrights, patents, trademarks *et cetera*).

VIII. **Other membership or affiliation** is to be interpreted as any membership or affiliation other than the above that can be perceived as an interest in the field of activity of the EFSA.

IX. **Interests of close family member** are to be interpreted as meaning that they include known interests held by family members and relatives belonging to the same household or under the care of the members of the household in a domain falling within EFSA's remit. In order to maintain privacy, their names do not need to be declared. The relationship (e.g. wife) should not be specified.

X. **Other** is to be interpreted as meaning any activities or interests other than the above that can be perceived as an interest in an activity falling within EFSA's remit.

Other definitions

- **Current** is to be interpreted as meaning activities that are currently ongoing.

- **Past period** is to be interpreted as meaning activities that are no longer ongoing and that have been completed in the five years preceding the filling in of the DoI.

- **Name of entity or organization** is to be interpreted as meaning name, location and nature of all organisations (private, public, etc.) that relate to EFSA's remit. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.

- **Subject matter** is to be interpreted as meaning the domain in which the activity was or is carried out (e.g. zoonoses, fish welfare, mycotoxins, food additives, novel foods). Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institutions should equally be declared.

B. Specific Declaration of Interests

For members of the Scientific Committee, Scientific Panels, Working Groups as well as other EFSA experts the activities defined below shall be declared in the Specific Declarations of Interests for the time period specified under "other definitions" below. The specific interests apply in relation to the procedure for which the participation of the expert is envisaged.

When a working group is dealing with only one mandate leading to the adoption of a single output, an ADoI referring to the mandate covers all meetings of that Working Group and no SDoI will be required for that Working Group. If several mandates are to be dealt with by a specific Working Group, an ADoI and an SDoI for each meeting are needed.

It should be noted that if the meeting or assignment involves a particular matter involving specific parties, with an interest in the meeting or assignment, the experts should identify them to the extent feasible. For a meeting or assignment related to a product being assessed, the entities with a financial interest may include the sponsor and firms who would manufacture or market (1) the product/substance being reviewed, (2) products/substances that would be used in conjunction with the one being reviewed, and (3) products/substances that would compete with the one being reviewed. Thus, a financial interest in a "competing product"/substance and/or a competitor company is relevant to the conflict of interest analysis. Such determinations need to be based on scientific and economic considerations taken on a case-by-case basis.

It should be noted that when completing the SDoI form the appropriate response to each Yes/No question must be clearly selected.

Nature of the activities

I. **Ownership or other investments, including shares** is to be interpreted as meaning any financial interests in a company/entity whose product or substance is being reviewed or a company that is a competitor in this area or a company that manufactures or markets products or substances used in an activity falling within EFSA's remit or in conjunction with the one being reviewed, including holding of stocks and shares, equity, bonds, partnership interests[6] in the capital of a company, one of its subsidiaries or a company of which it has a holding. The holding of financial interests connected with a pension scheme would not be considered as a financial interest provided that the individual has no influence on its financial management.

II. **Member of a Managing Body or equivalent structure** is to be interpreted as meaning any participation in the internal decision-making of a company, trade association or equivalent entity (e.g. board membership, directorship) whose product or substance is being reviewed or a company that is a competitor in this area or a company that manufactures or markets products or substances used in an activity included in EFSA's remit or in conjunction with the one being reviewed or the one from a competitor.

III. **Member of a Scientific Advisory Body** is to be interpreted as meaning that the person concerned is participating or has participated, with a right to vote on the outputs, in the works of a Scientific Advisory Body which has expressed an opinion, a statement or an advice about the product or substance at issue or about a competing product or about products or substances used in conjunction with the one in question or the one from a competitor.

IV. **Employment** is to be interpreted as covering all forms of employment, part-time and full-time, either paid or unpaid, in any organisation (private or public) whose product or substance is being reviewed or which has been involved in any way in the development or assessment of the product or substance or in a company that is a competitor in this area or a company that manufactures or markets products or substances used in conjunction with the one being reviewed or the one from a competitor.

V. **Consultancy/Advice** is to be interpreted as an activity where the concerned person charges or does not charge a fee for providing advice or services in a particular field such as 1) the development of the product or substance 2) a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or the one from a competitor. Any contracts or collaborations with the EFSA falling outside the work of the Panel/Working Group/Scientific Committee as identified above should be specified under this activity. The subject matter should only indicate the domain in which the consultancy is/has been active.

VI. **Research funding** is to be interpreted as meaning any funding for research on the development of the product or substance or a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or the one from a competitor if financed by a private or public entity, including grants, rents, sponsorships and fellowships and received in a personal capacity. Research projects can be grouped together without stating the title of each project provided that a relationship between them exists.

VII. **Intellectual property rights** are to be interpreted as meaning rights granted to creators and owners of works that are the result of human intellectual creativity. These can be publications or can be in the industrial, scientific and artistic domain. They can be in the form of an invention, a document, a suite of software, or a business name (e.g. copyrights, trademarks, patents on the product or substance or a competitor product or substance or a substance or product used in conjunction with the one being reviewed or the one from a competitor).

[6] When declaring financial interests e.g. stock and shares, only the kind and company name need to be stated.

VIII. Other membership or affiliation is to be interpreted as any membership or affiliation other than the above that can be perceived as an interest in the field of activity of EFSA.

IX. **Interests of close family members** are to be interpreted as meaning *inter alia* known interests held by family members and relatives belonging to the same household or under the care of the members of the household and that relate to the development of the product or substance or a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or the one from a competitor. In order to maintain privacy, their names do not need to be declared. The relationship (e.g. wife) should not be specified.

X. **Other** is to be interpreted as meaning that the person concerned has any activities or interests other than the above that can be perceived as an interest in the field of activity of EFSA.

Other definitions

• **Current** is to be interpreted as meaning the activities that are currently ongoing.

• **Past period** is to be interpreted as meaning activities that are no longer ongoing and which have been completed in the five years preceding the filling in of the DoI.

• **Name of entity or organization** is to be interpreted as meaning name, location and nature of all organisations (private, public, etc.) that relate to the item on the agenda or in the mandate. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.

• **Item on the agenda or in the mandate** is to be interpreted as meaning the item(s) in the agenda or the mandate that is of concern *e.g.* types of substances, products, guidance documents, processes or policies. Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should be equally declared.

CONSEQUENCES OF NOT DECLARING[7]

1. Only experts whose ADoI has already been submitted to EFSA may be invited to a Working Group, Panel or any other EFSA scientific meeting and only experts who have submitted an SDoI at the latest one EFSA working day before that meeting may attend a meeting they have been invited to.

2. Failure to submit a complete ADoI or SDoI in accordance with the requests received from the competent Secretariat will result in the expert's impossibility either to be invited to (ADoI), or to attend (SDoI), the relevant meeting, as appropriate.

3. Failure to fulfil in a timely and complete manner any of the obligations outlined in this act will be considered as a *prima facie* breach of trust towards EFSA. Because of that failure, appropriate actions, including the dismissal of the concerned persons, might be taken by EFSA.

I. Completing the information

1. In case EFSA has knowledge of information that is not consistent with the declaration of interest of an expert and an initial internal assessment of the information implies that the interest is a declarable interest, a letter to the expert shall be issued by the Executive Director seeking additional background information with regard to the information that was not declared. At the same time, the expert shall be asked to update the missing details of the relevant DoI.

[7] This paragraph shall apply exclusively to Members of the Scientific Committee, Scientific Panels and EFSA external experts.

2. Upon completion of the update, the relevant DoI shall be processed and screened in accordance with the Procedure for identifying and handling potential conflicts of interests.
3. On the basis of the outcome of that operation, EFSA may take a remedial action regarding the expert's participation to EFSA activity pursuant to the said Procedure.

II. The process regarding omissions and breaches to EFSA's Policy on DoI

1. On the basis of the assessment of the updated DoI, EFSA shall start an internal procedure in order to establish whether the omission of the expert needs to be considered as a breach of trust vis-à-vis the Authority if it is found that:
    a. The information missing from the relevant DoIs is a declarable interest according to EFSA's Guidance; and
    b. The expert did not declare the missing information intentionally or through gross negligence or he/she failed otherwise to meet his obligations under EFSA's Policy on DoI.
2. The expert shall be notified of the opening of the procedure and of the possible consequences of this procedure leading to a potential dismissal. Upon request, the expert shall have access to all documents related to the procedure.
3. The expert shall be invited to a hearing in order to gather his views on the facts in question. The hearing shall be organised before any decision be taken. During the hearing, he/she shall have the possibility of expressing his/her point of view. EFSA shall take account of any comments or documents submitted before and during the hearing.
4. The reasoned decision on the submission to the Management Board is notified to the expert within seven calendar days as of the day the decision is signed. Within fourteen calendar days, starting from the date of notification the expert may submit to EFSA a complaint against the above-mentioned decision.
5. When EFSA has concluded its position in favour of the dismissal, the decision on the submission to the Management Board and the complaint (if any) shall be submitted to the Management Board for the final decision.
6. The decision to dismiss a member of a Panel or the Scientific Committee shall be taken by the Management Board on a proposal of the Executive Director[8].
7. If EFSA finds an expert to be in breach of the present rules, the Executive Director shall ask the Internal Audit Capability to carry out a review of the scientific outputs adopted by the scientific entity(ies) to which that expert was providing his/her input. The IAC will clarify whether, and if appropriate the extent to which, that expert influenced the scientific outputs adopted by those scientific entities. The IAC will report his/her findings to the Executive Director and to the Audit Committee.

8 See Article 24 of EFSA's Management Board Decision on the establishment and operations of its Scientific Committee and Scientific Panels.

PUBLICATION

The **ADoIs** will be made public in accordance with Article 38 of Regulation (EC) No 178/2002.

COMPLIANCE WITH PROVISIONS ON PROTECTION OF PERSONAL DATA, INCLUDING INFORMATION ON THE CONSERVATION PERIOD OF DECLARATIONS OF INTEREST

Without prejudice to Regulation (EC) No 178/2002, EFSA shall process Annual Declarations of Interest and Specific Declarations of Interest pursuant to Regulation (EC) N° 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.

The purpose of the data processing is to safeguard the independency of EFSA and its constituent bodies.

The legal basis for Declaration of Interests processing is provided in:

- Article 37 and 38 of Regulation (EC) N° 178/2002 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;
- Article 13 of 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;
- As concerns Annual Declarations of Interest of EFSA staff, Article 11 and 11, litt. (a) of the Staff Regulations,

The EFSA Executive Director is identified as the controller of handling the declarations of interest.

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 DoI Guidance document, available on the EFSA website.

The recipients of the Declarations of Interest are the persons and bodies identified in the document "Procedure for Identifying and Handling Potential Conflicts of Interest", 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 Community Law, including the European Court of Auditors, the Internal Audit Service, OLAF, the European Ombudsman and the European Data Protection Supervisor.

The conservation period of Declarations of Interest per category of data subjects:

- Members of EFSA constituent bodies (Management Board, Advisory Forum, Scientific Committee and Scientific Panels) as well as external experts: DoIs are kept for 5 years after the discharge for the budgetary year to which the DoI relates;
- Executive Director: All DoIs since the start of the EFSA mandate of the Executive Director are kept until 5 years after the discharge for the budgetary year in which the Executive Director terminates the mandate at EFSA;
- EFSA staff: ADoIs of EFSA staff are kept for a maximum period of 5 years.

Data subjects with active EFSA involvements have a right to access their Declaration of Interest and to update or correct it at any time. The DoI electronic system, available upon username/password authentication, allows the permanent accessible tool to meet this right of 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 the purpose to update the Declaration on the missing information. In case an internal procedure is opened as referred to in the section “Consequences of not declaring” of the DoI Guidance document, the data subject will be notified.

Data subjects also are entitled to have recourse at any time to the European Data Protection Supervisor: http://www.edps.europa.eu

Done at Parma, on 8/9/2009

Signed by

Catherine Geslain-Lanéelle

Executive Director of the European Food Safety Authority

ANNEXES:
1. Declaration of commitment
2. Annual Declaration of interests
3. Specific Declaration of Interests
4. Declaration concerning confidentiality

ANNEX 1: DECLARATION OF COMMITMENT

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

First Name: _____

Surname: _____

Position:

[ ] Member of the Management Board
[ ] Member of the Advisory Forum
[ ] Member of the Scientific Committee
[ ] Member of Panel on _____
[ ] External expert of Working Group(s) on _____
[ ] Member of a Network on _____

Pursuant to Article 37 of Regulation (EC) No 178/2002 establishing the European Food Safety Authority, I hereby undertake to make all reasonable efforts to attend and participate in the meetings of the above body and to act independently of any external influence. In particular, I know that I am obliged to make and sign an **Annual written Declaration of Interests (ADoI)** and where required a **Specific Declaration of Interests (SDoI)** in accordance with the **Procedure for identifying and handling potential conflict of interests**.

DONE AT: _____ ON _____

SIGNATURE: _____

ANNEX 2: ANNUAL DECLARATION OF INTERESTS (ADoI)

(Please note that high quality of scientific expertise is by nature based on prior experience and that therefore having an interest does not necessarily mean having a conflict of interest)

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

First Name: _____

Surname: _____

EFSA involvement[9] _____

hereby declares to have the following interests

(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.)

Nature of Activities: I. Ownership or other investments, including shares[4]	**Current [1] From Month/year**	**Name of Entity [2] *Please indicate Private or Public***	**Subject matter [3]**

1. Please indicate activities that are currently ongoing. Indicate starting date (month/year).
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate to EFSA's remit. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please indicate the domain in which the activity was or is carried out (e.g. zoonoses, fish welfare, mycotoxins, food additives, novel foods). Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
4. Please indicate any financial interests in a company/entity operating in the food or feed business, including holding of stocks and shares, equity, bonds, partnership interests in the capital of a company, one of its subsidiaries or a company in which it has a holding. The holding of financial interests connected with a pension scheme would not be considered a financial interest provided that individual has no influence on its financial management. Only the kind of financial interests and the name of the entity need to be stated.

[9] Please specify all your current activities within EFSA *e.g.* Panel Member, ad hoc expert.

Nature of Activities: **II. Member of a Managing Body or equivalent structure[5]**	**Current [1]** ***Please answer Yes or No***	**Past Period [1]** ***From/To (Month/Year)***	**Name of Organisation [2]** ***Please indicate Private or Public***	**Subject matter [3]**

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). Please clearly select the appropriate Yes/No response.
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate to EFSA's remit. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well
3. Please indicate the domain in which the activity was or is carried out (e.g. zoonoses, fish welfare, mycotoxins, food additives, novel foods). Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
5. Please indicate any participation in the internal decision-making of a company, trade association or equivalent entity (*e.g.* board membership, directorship).

Nature of Activities: **III. Member of a Scientific Advisory Body[6]**	**Current [1]** ***Please answer Yes or No***	**Past Period [1]** ***From/To (Month/Year)***	**Name of Organisation [2]** ***Please indicate Private or Public***	**Subject matter [3]**

1. Please indicate activities that are currently ongoing. Indicate starting date (month/year). For activities that are no longer ongoing that have been completed in the preceding five years, please indicate starting and ending date (month/year). Please clearly select the appropriate Yes/No response.
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate to EFSA's remit Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please indicate the domain in which the activity was or is carried out (e.g. zoonoses, fish welfare, mycotoxins, food additives, novel foods). Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
6. Please indicate if you are participating or have participated in the works of a Scientific Advisory Body with voting rights on the outputs of that entity.

Nature of Activities: IV. Employment [7]	**Current [1]** ***Please answer Yes or No***	**Past Period [1]** ***From/To (Month/Year)***	**Name of Organisation [2]** ***Please indicate Private or Public***	**Subject matter [3]**

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). Please clearly select the appropriate Yes/No response.
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate to EFSA's remit. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well
3. Please indicate the domain in which the activity was or is carried out (e.g. zoonoses, fish welfare, mycotoxins, food additives, novel foods). Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
7. Please indicate if you are or have been employed part-time and full-time, either as a paid or unpaid worker either in private or public entities whose activities are linked to EFSA's remit.

Nature of Activities: V. Consultancy/Advisory [8]	**Current [1]** ***Please answer Yes or No***	**Past Period [1]** ***From/To (Month/Year)***	**Name of Organisation [2]** ***Please indicate Private or Public***	**Subject matter [3]**

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). Please clearly select the appropriate Yes/No response.
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate to EFSA's remit. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please indicate the domain in which the activity was or is carried out (e.g. zoonoses, fish welfare, mycotoxins, food additives, novel foods). Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
8. Please indicate any activity in which the concerned person charges or does not charge a fee for providing advice or services in a particular field. Any contracts or collaborations with the EFSA falling outside the work of the Panel/Working Group/Scientific Committee as identified above should also be specified under this activity.

Nature of Activities VI. Research funding [9]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2] *Please indicate Private or Public*	Subject matter [3]

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). Please clearly select the appropriate Yes/No response.
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate to EFSA's remit. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please indicate the domain in which the activity was or is carried out (e.g. zoonoses, fish welfare, mycotoxins, food additives, novel foods). Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
9. Please indicate any funding for research in relation to matter or work financed by a private or public entity, including grants, rents, sponsorships and fellowships and received in a personal capacity. Research projects may be grouped together without stating the title of each project provided that a relationship between them exists.

Nature of Activities VII. Intellectual property [10]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2] *Please indicate Private or Public*	Subject matter [3]

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). Please clearly select the appropriate Yes/No response.
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate to EFSA's remit. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please indicate the domain in which the activity was or is carried out (e.g. zoonoses, fish welfare, mycotoxins, food additives, novel foods). Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
10. Please indicate rights granted to creators and owners of works that are the result of human intellectual creativity. These can be publications or can be in the industrial, scientific and artistic domain. They can be in the form of an invention, a document, a suite of software, or a business name *(e.g.* copyrights, patents, trademarks *et cetera*).

Nature of Activities: VIII. Other membership or affiliation[11]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2] *Please indicate Private or Public*	Subject matter [3]

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). Please clearly select the appropriate Yes/No response.
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate to EFSA's remit. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please indicate the domain in which the activity was or is carried out (e.g. zoonoses, fish welfare, mycotoxins, food additives, novel foods).. Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
11. Please indicate any membership or affiliation other than the above that can be perceived as an interest in the field of activity of the EFSA.

Nature of Activities: IX. Interests of close family member[12]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2] *Please indicate Private or Public*	Subject matter [3]

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). Please clearly select the appropriate Yes/No response.
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate to EFSA's remit. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please indicate the domain in which the activity was or is carried out (e.g. zoonoses, fish welfare, mycotoxins, food additives, novel foods). Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
12. Please indicate known interests held by family members and relatives belonging to the same household or under the care of the members of the household.. In order to maintain privacy, their names do not need to be declared. The relationship (e.g. wife) should not be specified.

Nature of Activities: X. Other[13]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2] *Please indicate Private or Public*	Subject matter [3]

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). Please clearly select the appropriate Yes/No response.
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate to EFSA's remit. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please indicate the domain in which the activity was or is carried out (e.g. zoonoses, fish welfare, mycotoxins, food additives, novel foods).. Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
13. Please indicate any activities or interests other than the above which can be perceived as an interest in an activity included in EFSA's remit

I hereby declare that I have read both the Guidance Document on Declarations of Interests and the Procedure for identifying and handling potential conflict of interests and that the above Declaration of Interests is complete.

Date: _____ Signature: _____

If you need more sheets to declare your interests, do not hesitate to use blank ones or to ask for them, but please sign each one of them and attach them to this form.

ANNEX 3: SPECIFIC DECLARATION OF INTERESTS (SDoI)
ACTIVITIES IN EFSA[10]: _____

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

First Name: _____

Surname: _____

Profession: _____

Meeting of …….. Panel/Network
Meeting of the …….. Working Group
EFSA Mandate ……

Meeting dates:	
Venue:	

#	Items	Interest declared: (Please tick if YES)[11]

[10] Please specify the current activities within EFSA (*e.g.* Mandate or Meeting) and insert details (*e.g.* agenda).
[11] If a specific interest is declared, then please provide details in the table below using the explanatory notes.

#	Items	Interest declared: (Please tick if YES)[11]

I hereby declare that I have read both the Guidance Document on Declarations of Interests and the Procedure for identifying and handling potential conflict of interests and that:

1. **I have no interest in any of the above topic(s)**

Date: _____ Signature: _____

Or that

2. **I have already declared an interest to the above mentioned topics in the DoI of _____**

Date: _____ Signature: _____

SPECIFIC DECLARATION OF INTERESTS (SDoI)
hereby declare to have the following interests relating to the above[12] topics
(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)

Nature of Activities: I. Ownership or other investments, including shares[4]	**Current [1] From Month/year**	**Name of Entity [2] *Please indicate Private or Public***	**Item on the agenda or in the mandate [3]**

1. Please indicate activities that are currently ongoing. Indicate starting date (month/year).
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate directly to the specific area of expertise or field of potential activity of the individual within the EFSA. This includes but is not limited to, food and feed business as defined in Article 3 of Regulation (EC) No 178/2002: "a company, association (trade association) or any other entity with commercial interests" **and that is involved in the development of the product or substance or a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or the one from a competitor**. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please **indicate the item(s) in the agenda or the mandate that is of concern** *e.g.* types of substances, products, guidance documents, processes or policies. Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
4. Please indicate any financial interests in a company/entity **whose product or substance is being reviewed or a company that is a competitor in this area or a company that manufactures or markets products or substances used in the food chain in conjunction with the one being reviewed**, including holding of stocks and shares, equity, bonds, partnership interests[13] in the capital of a company, one of its subsidiaries or a company in the capital of which it has a holding.

Nature of Activities: II. Member of a Managing Body or equivalent structure[5]	**Current [2] *Please answer Yes or No***	**Past Period [2] *From/To (Month/Year)***	**Name of Organisation [3] *Please indicate Private or Public***	**Item on the agenda or in the mandate[4]**

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 all organisations (private, public, etc.) that relate directly to the specific area of expertise or field of potential activity of the individual within the EFSA. This includes but is not limited to, food and feed business as defined in Article 3 of Regulation (EC) No 178/2002: "a company, association (trade association) or any other entity with commercial interests" **and that is involved in the development of the product or substance or a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or the one from a competitor**. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please **indicate the item(s) in the agenda or the mandate that is of concern** *e.g.* types of substances, products, guidance documents, processes or policies. Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
5. Please indicate any participation in the internal decision-making of a company or equivalent entity (e.g. board membership, directorship) whose product or substance is being reviewed or a company that is a competitor in this area or a company that manufactures or markets products or substances used in **the food chain in** conjunction with the one being reviewed or the one from a competitor.

[12] Please specify the current activities within EFSA *e.g.* mandate or meeting.
[13] When declaring financial interests (*e.g.* stock and shares) only the kind, number and company name need be stated.

Nature of Activities: III. Member of a Scientific Advisory Body[6]	**Current [1]** ***Please answer Yes or No***	**Past Period [1]** ***From/To (Month/Year)***	**Name of Organisation [2]** ***Please indicate Private or Public***	**Item on the agenda or in the mandate [3]**

1. Please indicate activities that are currently ongoing. Indicate starting date (month/year). For activities that are no longer ongoing and which have been completed in the preceding five years, please indicate starting and ending date (month/year).
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate directly to the specific area of expertise or field of potential activity of the individual within the EFSA. This includes but is not limited to, food and feed business as defined in Article 3 of Regulation (EC) No 178/2002: "a company, association (trade association) or any other entity with commercial interests" **and that is involved in the development of the product or substance or a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or the one from a competitor**. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please **indicate the item(s) in the agenda or the mandate that is of concern** *e.g.* types of substances, products, guidance documents, processes or policies. Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
5. Please indicate if you are participating or have participated, with voting rights on the outputs, in the works of a Scientific Advisory Body which has expressed an opinion, a statement or an advice about the product or substance at issue or about a competing product or about products or substances used in conjunction with the one **being reviewed** or the one from a competitor.

Nature of Activities: IV. Employment [7]	**Current [1]** ***Please answer Yes or No***	**Past Period [1]** ***From/To (Month/Year)***	**Name of Organisation [2]** ***Please indicate Private or Public***	**Item on the agenda or in the mandate [3]**

1. Please indicate activities that are currently ongoing. Indicate starting date (month/year). For activities that are no longer ongoing and which have been completed in the preceding five years, please indicate starting and ending date (month/year).
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate directly to the specific area of expertise or field of potential activity of the individual within the EFSA. This includes but is not limited to, food and feed business as defined in Article 3 of Regulation (EC) No 178/2002: "a company, association (trade association) or any other entity with commercial interests" **and that is involved in the development of the product or substance or a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or the one from a competitor**. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please **indicate the item(s) in the agenda or the mandate that is of concern** *e.g.* types of substances, products, guidance documents, processes or policies. Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
7. Please indicate if you are ort have been employed in a private company or in a public institution whose activities are linked to the food chain or **whose product or substance is being reviewed or a company that is a competitor in this area or a company that manufactures or markets products or substances used in the food chain in conjunction with the one being reviewed or the one from a competitor.**

Nature of Activities: V. Consultancy [8]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2] *Please indicate Private or Public*	Item on the agenda or in the mandate [3]

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 all organisations (private, public, etc.) that relate directly to the specific area of expertise or field of potential activity of the individual within the EFSA. This includes but is not limited to, food and feed business as defined in Article 3 of Regulation (EC) No 178/2002: "a company, association (trade association) or any other entity with commercial interests" **and that is involved in the development of the product or substance or** a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or the one from a competitor. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please **indicate the item(s) in the agenda or the mandate that is of concern** *e.g.* types of substances, products, guidance documents, processes or policies. Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
8. Please indicate any activities in which the concerned person charges or does not charge a fee for providing advice or services in a particular field such as the development of the product or substance or a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or the one from a competitor.

Nature of Activities VI. Research funding [9]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2] *Please indicate Private or Public*	Item on the agenda or in the mandate [3]

1. Please indicate activities that are currently ongoing. Indicate starting date (month/year). For activities that are no longer ongoing and which have been completed in the preceding five years, please indicate starting and ending date (month/year).
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate directly to the specific area of expertise or field of potential activity of the individual within the EFSA. This includes but is not limited to, food and feed business as defined in Article 3 of Regulation (EC) No 178/2002: "a company, association (trade association) or any other entity with commercial interests" **and that is involved in the development of the product or substance or a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or the one from a competitor**. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please **indicate the item(s) in the agenda or the mandate that is of concern** *e.g.* types of substances, products, guidance documents, processes or policies. Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
9. Please indicate any research **on the development of the product or substance or a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or with the one from a competitor** if financed by a private or public entity, including grants, rents, sponsorships and fellowships.

Nature of Activities VII. Intellectual property [10]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2] *Please indicate Private or Public*	Item on the agenda or in the mandate [3]

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 all organisations (private, public, etc.) that relate directly to the specific area of expertise or field of potential activity of the individual within the EFSA. This includes but is not limited to, food and feed business as defined in Article 3 of Regulation (EC) No 178/2002: "a company, association (trade association) or any other entity with commercial interests" **and that is involved in the development of the product or substance or a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or the one from a competitor**. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please **indicate the item(s) in the agenda or the mandate that is of concern** *e.g.* types of substances, products, guidance documents, processes or policies. Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
10. Please indicate any rights granted to creators and owners of works that are the result of human intellectual creativity. These can be publications or can be in the industrial, scientific and artistic domain. They can be in the form of an invention, a manuscript, a suite of software, or a business name *(e.g.* copyrights, trademarks, patents **on the product or substance or a competitor product or substance or a substance or product used in conjunction with the one being reviewed or the one from a competitor**).

Nature of Activities: VIII. Other membership or affiliation[11]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2] *Please indicate Private or Public*	Item on the agenda or in the mandate [3]

1. Please indicate if activities are currently ongoing. Indicate starting and ending date (month/year) within the preceding five years.
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate directly to the specific area of expertise or field of potential activity of the individual within the EFSA. This includes but is not limited to, food and feed business as defined in Article 3 of Regulation (EC) No 178/2002: "a company, association (trade association) or any other entity with commercial interests" **and that is involved in the development of the product or substance or a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or the one from a competitor**. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please **indicate the item(s) in the agenda or the mandate that is of concern** *e.g.* types of substances, products, guidance documents, processes or policies. Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
11. Please indicate any membership or affiliation other than the above that can be perceived as an interest in the field of activity of the EFSA.

Nature of Activities: IX. Interests of close family member[12]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2] *Please indicate Private or Public*	Item on the agenda or in the mandate [3]

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 all organisations (private, public, etc.) that relate directly to the specific area of expertise or field of potential activity of the individual within the EFSA. This includes but is not limited to, food and feed business as defined in Article 3 of Regulation (EC) No 178/2002: "a company, association (trade association) or any other entity with commercial interests" **and that is involved in the development of the product or substance or a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or the one from a competitor**. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please **indicate the item(s) in the agenda or the mandate that is of concern** *e.g.* types of substances, products, guidance documents, processes or policies. Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
12. Please indicate interests held by first-line members of his/her family *(i.e.* parents, spouse or partner and dependent children living in the same household) and that **relate to the development of the product or substance or a competitor product or substance or a substance or product used in conjunction either with the one being reviewed the one from a competitor**. **Please specify the item on the agenda or the mandate that is of concern.** In order to maintain privacy, the names of family/household members do not need to be declared.

Nature of Activities: X. Other[13]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2] *Please indicate Private or Public*	Item on the agenda or in the mandate [3]

1. Please indicate if activities are currently ongoing. Indicate starting and ending date (month/year) within the preceding five years.
2. Please indicate name, location and nature of all organisations (private, public, etc.) that relate directly to the specific area of expertise or field of potential activity of the individual within the EFSA. This includes but is not limited to, food and feed business as defined in Article 3 of Regulation (EC) No 178/2002: "a company, association (trade association) or any other entity with commercial interests" **and that is involved in the development of the product or substance or a competitor product or substance or a substance or product used in conjunction either with the one being reviewed or the one from a competitor**. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.
3. Please **indicate the item(s) in the agenda or the mandate that is of concern** *e.g.* types of substances, products, guidance documents, processes or policies. Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institution should equally be declared.
13. Please indicate any activities or interests other than the above that can be perceived as an interest in the field of activity of the EFSA.

Date: _____ **Signature:** _____

If you need more sheets to declare your interests, do not hesitate to use blank ones or to ask for them, but please sign each one of them and attach them to this form..

ANNEX 4: DECLARATION CONCERNING CONFIDENTIALITY

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

First Name: _____

Surname: _____

Position:

[ ] Member of the Management Board
[ ] Member of the Advisory Forum
[ ] Member of the
[ ] Member of a Panel on …….
[ ] External expert of Working Group(s) on…….
[ ] Member of a Network on _____
[ ] Hearing expert
[ ] Person employed by or anyway working for or on behalf of ……. in the context of the Contract/Grant entitled "…….."
[ ] Observer

Definitions:

For the purposes of this statement, the following definitions apply, in accordance with the criteria for the classification of EFSA documents laid down in the annex to the EFSA's Management Board decision concerning access to documents of 18/06/2004:

- "*Confidential Information*" means information transmitted to EFSA and classified as confidential according to vertical EU food legislation and/or declared as being 'confidential' by the applicant/owner of the document in compliance with applicable law; further, it means any information which is not made available or disclosed to unauthorized individuals or entities.
- "*Restricted Information*" includes all documents, notes, analyses, studies, reports, comments and any other materials produced during evaluation processes and to which authorized EFSA staff have access, directly or indirectly. Further, *"Restricted Information*" means any information whose unauthorized or uncontrolled external disclosure may harm the interests of EFSA or of any third party.

I hereby declare:

1. To be aware of my obligation to respect confidentiality. The obligation to respect confidentiality specifically pertains to [*as needed, please insert a reference to sensitive activity(ies), appropriate to be specifically mentioned in this declaration*] ;
2. Not to divulge or to make available outside the *Panel/Working Group*… information acquired as a result of my membership of the above-mentioned *Panel/Working Group* ;
3. To respect the confidential nature of any opinions expressed by members of the above-mentioned *Panel/Working Group* orally and in a written form as well as opinions of external experts (such as contractors) during discussions in meetings or provided in a written form;
4. I am aware this undertaking shall not be limited in time.

DONE AT: _____ ON _____

SIGNATURE: _____

European Food Safety Authority

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 178/2002[1]) 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 January2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L31 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 report[2], an external review of the implementation[3] 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.

European Food Safety Authority

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 Authority[4] with a legal personality separate from the institutions of the European Union. The separation of science from policy was seen as critical in strengthening food safety and rebuilding public confidence in the European food chain after the BSE and dioxin crises in particular.

EFSA's Founding Regulation (Regulation (EC) No 178/2002[5]) 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 risks[6]. 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 January2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L31 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 advice[9].

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

This policy describes all the steps that have been taken by EFSA to ensure the implementation of its core values in its scientific outputs and decision-making processes. These include structure and governance[10] as well as working procedures[11]. 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 management[12], 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 bodies[13] 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 safety[14].

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 interest[15]. 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 chain[16]. Nonetheless, all members of the Board, including the Chair and Vice-Chairs, are appointed in a personal capacity: they are required to act independently in the public interest and refrain from any activity that could result in a conflict of interest or is likely to be perceived as such by the public[17]. 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 Conduct[18] 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 Board[19].

The Management Board is entrusted with the task of providing strategic direction and the adoption of strategic documents including internal rules, budget, annual work programme, and statements of estimates of revenue and expenditure, and establishment plan. The Executive Director is EFSA's legal representative and implements the strategic documents adopted by the Board as well as managing the daily operations of the Authority[20]. The Advisory Forum advises the Executive Director regarding cooperation and networking with Member State authorities[21]. EFSA's scientific staff provides scientific and technical advice and secretarial support to the Scientific Committee and Scientific Panels. Finally, the Scientific Panels and Scientific Committee adopt scientific opinions[22].

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

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

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

[16] *Ibidem*.

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

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

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

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

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

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

5. Scientific decision-making processes

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

5.1 Processing of requests and mandates

EFSA receives its mandates from the EU's risk managers – predominantly the European Commission, but also the European Parliament and Member States – and also has the capacity to initiate its own scientific work (i.e. "self-mandate") when appropriate[23]. The progress of a mandate from receipt through to the adoption of the scientific output can be checked at all times and freely accessed via the EFSA website, the Register of Questions database[24], 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 database[25].

5.2 Development of methodologies

Over time, EFSA has invested significant resources to the development of a comprehensive body of good risk assessment practices and methodologies to guide the work of its Scientific Committee, Scientific Panels and its scientific staff to ensure their opinions respect the highest scientific standards[26]. 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 parties[27]. 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 manner[29].

[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 Groups[30], 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 Panels[31]. 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 documents[32]. 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 networks[33]. Networks consist of nationally appointed EU Member State organisations with expertise in the fields covered by the network[34]. 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 website[35].

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.

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

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

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

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

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

8. Enhanced contribution of scientific staff

EFSA staff members with a scientific background currently provide scientific support for the operation of its Scientific Committee, Scientific Panels, Working Groups and Networks. These staff members are engaged in background or preparatory work of a scientific nature, which in certain cases represents a fundamental step in the drafting and adoption of the final output. To meet EFSA's increasing workload and enable the Scientific Committee and Scientific Panels to focus on more fundamental scientific and overarching matters, EFSA is currently developing a science strategy that in the long term will enable the Authority to have at its disposal a range of internal expertise to address the important workload represented by the assessment of regulated claims, products and substances and react swiftly to unexpected needs and urgencies. Furthermore, from November 2011, a newly launched Applications desk acts as a front office and support desk for applicants, Member States and other stakeholders who have questions regarding applications. It will also be responsible within EFSA for processing the initial administrative steps of all applications.

9. Organisational culture

EFSA has gradually created, and continuously fosters, an organisational culture that does not tolerate conflicts of interest. This is ensured in a number of ways, ranging from the implementation of the staff regulations, to the systematic organisation of training courses on ethics and integrity for staff members and scientific experts, the implementation of a sophisticated and stringent screening system of interests declared by key people, the publication of all relevant documents regarding that system, the development of workflows, standard operating procedures and the provision of systematic legal advice to ensure a coherent interpretation of the comprehensive system put in place[38].

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 up[40], 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 system[42]. The effective implementation of DoI procedures has been validated by a number of both independent and internal reviews performed from 2008 to 2011 by contractors and auditors.

[38] For further details see below, § 5.VIII.
[39] EFSA Policy on Declarations of Interest, see http://www.efsa.europa.eu/en/keydocs/docs/doipolicy.pdf.
[40] Implementing Act to the Policy on Declaration of Interests: Procedure for Identifying and Handling Potential Conflicts of Interest, see http://www.efsa.europa.eu/en/keydocs/docs/doiconflicts.pdf.
[41] Implementing Act to the Policy on Declaration Of Interests: Guidance Document on Declarations of Interest, see http://www.efsa.europa.eu/en/keydocs/docs/doiguidance.pdf.
[42] EFSA has invested more than €0.6 mil in the development of an electronic DoI tool, and annually the Authority allocates an estimated three full time equivalents and €180 k budget to the screening of DoIs and related administrative tasks.

The 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 report[43], an external review of the implementation[44] 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 adoption[45]. 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 EFSA[46]. In order to implement the obligation foreseen in the Staff Regulations of avoiding conflicts of interest for the duration of their contract with EFSA, staff members of "administrator" level or equivalent are required to complete an annual DoI, which is then screened by the Appointing Authority[47] 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 Regulations[48] 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

SIGNED

Prof. Diána Bánáti
Chair of the Management Board

EFSA consultative workshop on Independence and Scientific Decision-Making Processes

Brussels, 12 October 2011

Moderator:	Vivienne Parry
Audience:	European Commission, European Parliament, Member States (EFSA's Advisory Forum), EU Presidency and national delegations, EFSA's Management Board, EFSA's Scientific Committee, Members of EFSA's Stakeholder Platform, Union agencies, international organisations and academia

Morning session

9.00	Welcome address by Catherine Geslain-Lanéelle, EFSA's Executive Director
9.15	Keynote address by MEP Kartika Tamara Liotard, Member of the European Parliament Committee on Environment, Pubic Health and Food Safety

Session I: Setting the scene

9.30 – 11.15 **Round Table - Trust in science: what are the basic ingredients?**

Speakers:

Science and society: public engagement and confidence in science - by Ortwin Renn, University of Stuttgart

Explaining the scientific process - by Andrew Wadge, Food Standards Agency, United Kingdom

Managing independence of scientific authorities: the case of EFSA - by Martijn Groenleer, University of Delft

Learnings from an international perspective – by Murray Lumpkin, Food and Drug Administration, United States of America

11.15 – 11.45 *Coffee/tea break*

Session II: **EFSA's draft Policy on Independence and Scientific Decision-Making Processes**

11.45 – 12.30 Introduction of EFSA's *draft Policy on Independence and Scientific Decision-Making Processes* and overview of comments received - by Dirk Detken, Head of Legal and Regulatory Affairs, EFSA.

12.45 – 14.00 *Lunch*

Afternoon session

14.00 – 15.00 **Interactive Session 1: Quality of science** chaired by Vittorio Silano, Chair of EFSA's Scientific Committee

D. Jans, FEFANA

C. Then, Testbiotech

J. Schlundt, Danish Technical University

15.00 – 16.00 **Interactive Session 2: Governance, Openness and Transparency** chaired by Anne-Laure Gassin, Director of Communications, EFSA

M. Frewen, FoodDrinkEurope

N. Holland, Corporate Europe Observatory

C. Tomalino, Euro Coop

16.00 – 16.30 *coffee/tea break*

16.30 – 17.30 **Interactive Session 3: Assessing interests** chaired by Hubert Deluyker, Director of Risk Assessment and Scientific Assistance, EFSA

R. Wittkowski, Bundesinstitut für Risikobewertung (BfR)

N. Van Belzen, International Life Sciences Institutes Europe

C. Udsen, The European Consumers' Organisation (BEUC)

17.30 **Closing address** by John Dalli, European Commissioner for Health and Consumer Policy

TECHNICAL REPORT OF EFSA

Outcome of the public consultation on the draft Policy on Independence and Scientific Decision-Making Processes

European Food Safety Authority[1]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

The European Food Safety Authority and its founding regulation attach a great importance to the independence of the Authority and of its scientific outputs and decision making processes.

On 17 June 2011, EFSA's Management Board endorsed a Draft Policy on Independence and Scientific Decision Making Processes.

Consequently, on 7 July 2011, the draft Policy was put out for consultation during summer. The public consultation closed on 16 September 2011. On 12 October, a Stakeholder Consultative Workshop was organised successfully by EFSA in Brussels with more than 140 participants. Overall, EFSA received more than 110 comments from 32 organisations and individuals.

This report outlines the comments received during the public consultation and at the Workshop and the way they are addressed in the forthcoming Policy.

KEY WORDS

(Independence, conflict of interest, bias, autonomy)

Suggested citation: European Food Safety Authority; Outcome of the public consultation on the draft Policy on Independence and Scientific Decision-Making Processes. Available online: http://www.efsa.europa.eu/en/publications/supporting.htm

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BACKGROUND

The European Food Safety Authority and its founding regulation attach a great importance to the independence of the Authority and of its scientific decision making processes.

EFSA implemented the legal obligations related to independence already in 2004. This was further refined several times, and a new and comprehensive system was adopted by EFSA's Management Board in September 2007.

As part of the review of the Policy on Declarations of Interest, in March 2011, EFSA's Management Board discussed a reflection paper outlining outstanding issues and the respective policy options to address them in the context of a broader Policy on Independence.

In June 2011, EFSA's Management Board endorsed a Draft Policy on Independence and Scientific Decision Making Processes. The draft Policy describes 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. This draft Policy has been built through a process of extensive internal consultation with 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 report[1], an external review of the implementation[2] and audit reports.

Furthermore, the draft policy was put out for public consultation during summer for a duration of ten weeks. The public consultation closed on 16 September 2011.

On 12 October, a Stakeholder Consultative Workshop was organised by EFSA in Brussels with more than 140 participants. At the event, Commissioner Dalli expressed full support to EFSA's efforts on independence. Combining the outcome of the public consultation with the discussions held at the 12 October Stakeholder Consultative Workshop, overall EFSA received more than 110 comments from 32 organisations and individuals in total.

This report outlines the comments received during the public consultation and at the Workshop and the way they are addressed in the draft Policy. The draft Policy, amended accordingly, is submitted for discussion and possible adoption at the December 2011 meeting of EFSA's Management Board.

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

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

1. Introduction

Combining the outcome of the public consultation held from 7 July to 16 September 2011 with the discussions held at the 12 October Stakeholder Consultative Workshop, where Commissioner Dalli expressed full support for EFSA's efforts, the Authority received in total more than 110 comments from 32 interested parties (individuals, nongovernmental organisations, industry sponsored organisations and trade associations, academia and national competent authorities) on its draft Policy on Independence and Scientific Decision Making Processes.

2. Screening and evaluation of the comments received

All submitted comments were compiled in a table with reference to the contributor and to the section of the draft Policy to which the comment referred (see Table 1 below). Comments submitted formally on behalf of an organisation appear with the name of the organisation. Comments submitted at the Consultative Worksop appear with the name of the person. All comments are addressed individually with a clear explanation of how they impacted on the revised text or of why they were rejected by EFSA.

Comments not related to the scope of the consultation are identified in the table as not relevant for this draft Policy. However, they were fed in the appropriate workflow and will be duly considered and addressed by the proper strategic document, such as EFSA's Science Strategy.

2.1. General comments

Several interested parties congratulated EFSA for its efforts in ensuring the independence of its scientific outputs, while some comments questioned the overall relevance and usefulness of the draft Policy albeit in rather general terms. When submitting specific criticism or suggestions, those comments were either incorporated in the revised text of the draft Policy or otherwise addressed.

There were also suggestions for editorial improvements and clarifications.

2.2. Specific comments

Although the full list of comments is only provided in Table 1 annexed hereto, a few of the most recurring themes deployed by several interested parties are summarised herein below.

- According to certain stakeholders, changes should be brought to the procedure of appointment and composition of members of EFSA's Management Board in order to involve interested parties in the process;
- Some interested parties recommended EFSA to implement mandatory cooling off periods, both for staff joining EFSA and for staff leaving the Authority;
- One contributor highlighted that EFSA should be more attentive in "outsourcing" scientific tasks to contractors, grant beneficiaries and external experts;
- Some stakeholders suggested that the rules and procedures regarding the selection of experts of Working Groups should be made more transparent and closer to those applicable to members of the Scientific Committee and Scientific Panels;
- Some contributors expressed their expectation that EFSA ensure the broadest base possible for documents and data supporting its scientific outputs;
- Some interested parties maintained that EFSA should perform constant and coherent reliability check of data gathered from Member States and interested parties;

- Some contributors argued that EFSA should ensure a closer involvement of nongovernmental organisations in its scientific activities, including their participation to plenaries of Panels and Scientific Committee or organisation of bilateral meetings between the Authority and applicants;

3. Incorporation of the relevant comments into the final text

EFSA's senior management with the specific support of its Legal and Regulatory Affairs Unit discussed the comments at several dedicated meetings. Many of the comments received were appropriate, of a high intellectual value and aimed at enhancing the quality and clarity of the document. These comments were taken into account and the draft Policy was revised where appropriate.

EFSA acknowledges the usefulness and quality of a large number of comments and would like to thank all interested parties for their efforts and contributions to its current and future work.

The way each comment has been addressed by EFSA is laid out in clear and concise terms in Table 1, below. The revised text of the draft Policy on Independence and Scientific Decision Making Processes is submitted to EFSA's Management Board for discussion and possible adoption at its December 2011 meeting.

Table 1: Table of public comments

1.CONTRIBUTOR	2. RELEVANT CHAPTER	3. CONTRIBUTION	4. EFSA's position
1. Introduction			
Corporate Europe Observatory	1. Introduction	Corporate Europe Observatory would like to submit some comments, without trying to be exhaustive, to the EFSA consultation on its draft "Policy on Independence and Scientific Decision Making Processes". As stressed in the introduction of this draft policy, "In fact, as shown in the Eurobarometer Survey Report on Science and Technology (2010)4 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)." [21-25]. CEO however thinks this draft policy is fully inadequate to address these strong concerns, that are based on widely published information regarding EFSA experts with industry links, or the basic fact that most EFSA opinions are based on industry testing. It should therefore be fully revised.	This is a generic comment that questions in general terms the validity of the draft policy. Detailed comments submitted by CEO on specific points of the document are addressed below.
Testbiotech	1. Introduction	Final comments - conclusions (if necessary referenced to line 277-284): We strongly recommend this paper not be adopted. It is not based on a proper problem-solution approach nor can it be regarded as a consistent policy paper in itself; it reads for the most part like a paper for defending particular persons and current EFSA's standards and processes that have been criticised by various stakeholders. In conclusion it is not sufficient for giving guidance on how to safeguard EFSA's independence in future. We think a much more radical approach will be necessary to rebuild trust in EFSA. EFSA will need a restart first at the management level and secondly with its expert panels. EFSA has to face the fact that from the beginning there has been a lack of sufficient criteria and mechanisms for assuring its independence (from vested economic interests) and safeguarding its scientific standards. During the last few years, the management has not been able to successfully address significant weaknesses like the severe conflicts of interest within its expert panels. "Business as usual" is therefore not an option.	This is a generic comment that questions in general terms the validity of the draft Policy. Detailed comments submitted by Testbiotech on specific points of the documents are addressed below.

Testbiotech	1. Introduction	In the introduction much emphasis is placed on the “separation of science from policy”. But this seems to be a misleading starting point for defining “a policy on independence” that aims at “rebuilding public confidence”. First of all, the risk manager and risk assessor both contribute to the overall process of risk analysis. EFSA has to be seen as part of the overall process; it is an independent institution but cannot be seen as an isolated body. The risk manager has to deliver regulations concerning overall risk assessment policies, such as general standards for risk assessment, criteria for assuring independence, election of the management board and staff regulations. A sufficiently high quality in risk analysis and implementation of independence and transparency can only be achieved by strong cooperation between those two actors. But this EFSA paper more or less sets aside the role of the risk manager. Instead EFSA should have sorted out what the risk manager should do to support EFSA´s independence by defining appropriate regulations, processes and mechanisms. The current crisis in the credibility of EFSA is caused not only by the management of EFSA but also by the EU Commission not acting appropriately according to its responsibilities. Secondly, by giving so much emphasis to independence at the political level, the main crucial challenge is neglected - independence from economic interests that might impact the work of EFSA directly or indirectly. Indeed the issue of vested economic interests that can heavily impact any scientific decision-making process is not even explicitly mentioned in this paper. This major deficiency is likely to be a consequence of the lack of an adequate analysis of the problems involved in EFSA´s current situation. In general this paper lacks an analysis of strengths and weaknesses in EFSA's current work and the whole paper is not based on a problem-solution approach but simply aims at defending EFSA's current practice.	The founding regulation exactly aims at the separation between risk assessment and risk management and achieves it with the creation of an independent EFSA. EFSA’s role is limited by law to providing scientific advice or scientific and technical assistance to EU Institutions or Member States. The draft policy does much more than defending current practices: it brings together in one comprehensive document all the policies already set in place and includes all the implementing rules concerning such issues as selection of experts, rules of procedure for the Scientific Committee and Scientific Panels staff procedures, the harmonisation of EFSA’s assessment methodologies and risk assessment practices. It improves the Declarations of Interest pillar of the draft policy and goes further by proposing a few clarifications and improvements.
POT & PAN FOODSERVICE SA	1. Introduction	As there is no specific ISO standard for ensuring independence, I think that such one would contribute to further improvement. I also still believe that wider participation would add more value to the system.	EFSA is not aware of any ISO standards applicable for ensuring independence. However, it did take into account the 2007 OECD guidelines for managing on conflicts of interest in the public service.
Eurogroup for Animals	1. Introduction	Line 28 - Interested parties and the public do not need to be ‘convinced’, they need to be ‘able to see for themselves’ that decisions are sound.	EFSA will review the text accordingly.
Confederazione Nazionale Coldiretti	1. Introduction	Coldiretti welcomes the EFSA’s initiative for a new policy on Independence and Scientific Decision Making Processes. In particular we appreciate the very honest and open starting point with reference made to the Eurobarometer survey and need to improve (perception of) independence and scientific decision making process. While agreeing with most parts of the documents, nonetheless we think a better focus could be required on: • the rationale, ie, exploring better what aspects could lead to 58% of EU citizens to mistrust the science-industry governance of food safety.	EFSA will insert the additional references suggested and in 2012 will test the feasibility of opening up the Risk assessment process to observers from interested persons.

		• the details of references made along the documents, which sometime seem left behind (quality system and procedures, measures to act independently, etc …) even if repealed. • additional EFSA's activities which could be covered by a new independence and transparency policy (including not only MB and Panels but also other critical moments of interplay with external factors, such as the SH fora etc.)	
7BEUC	1. Introduction	BEUC, the European consumer''s organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panellists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	In a 2010 benchmarking report commissioned by EFSA to assess the main features of other agencies' independence policies, EFSA's DoI Policy scores as the most comprehensive one. In an external audit commissioned in the same year, the contractor found a 1-2% of cases of inconsistent or wrong screening by EFSA staff. This does not mean that the screening of DoIs cannot be improved, but it shows that the scrutiny is already very strict. EFSA will clarify in the text the - so called - breach of trust procedure, which is triggered in case of omissions made by experts. EFSA commits to report annually on the implementation of its Policy on Independence as of 2012. EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. EFSA in 2012 will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will however be revised in order to clarify this aspect.

France Nature Environment	1. Introduction	All public consultations are in English. This exclude from the consultation many people who don't speak this language, which is only one of the official languages in EU. I will speak about the GMO panel of EFSA which is the one I know. Transparency is essential, but it is not the case with EFSA. EFSA does not respond to questions from NGO and even to written questions from members of European Parliament. When a response is finally provided by EFSA, it doesn't constitute a proper answer, but unrelated comments. About "high quality science", it is not enough to claim that. In fact, it is not the case, as all GMO files are not scientifically correct, but they are validated by EFSA. For instance, it is very well known that the statistical conditions do not allow to any conclusion, but the EFSA experts do conclude without scientific basis. Why? About immunogenicity, EFSA refers to "the weight of evidence", which is very "heavy" for an expression which means in fact that there is no scientific data from which infer a conclusion. This is not serious. Again: why? line 162: divergent positions: from my knowledge, this has happened only ONCE (about resistance genes to antibiotics). This meens that experts are chosen to be very homogeneous. In none other case in science there are so few divergences. Therefore, it is obvious that the panel is profoundly biased.	EFSA's language regime is regulated by a decision of the Executive Director which recognises English as the scientific working language of the Authority. Contrary to what the contributor maintains, pursuant to its Code of Good Administrative Behaviour, EFSA replies to all the requests it receives within a two months timeline from the receipt. Comments related to the assessments performed by the GMO Panel should be fed into the public consultations regularly performed by that Panel. line 162: For, what concerns the point on minority opinions, while it is true that minority opinions occur rarely, this has happened seven times in the past.
ILSI Europe aisbl	1. Introduction	We welcome the opportunity to comment on this document. Overall, we found the document of high quality. Line 12-13: "…the Authority has to be a point of reference of risk assessment in the food chain by virtue of its independence, the scientific and technical quality of the outputs it issues…" In line with what is said in the preceding line 11, and as we believe that independence is required for and subject to quality, we would like to suggest to change into "…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…" Line 27-28: "no matter what seems to be the right decision for those involved in the advisory process, it is essential that interested parties and the public at large are themselves convinced that decisions are sound" While recognising the importance of public perception, we would nevertheless like to argue that the primary function of government is to protect its citizens against real risks, not perceived risks. Consequently, risk assessment resources should be focused on real risk, whereas perceived risks should be addressed by education and communication. Line 68: "or is likely to be perceived as such by the public." While recognising the importance of public perception, we would nevertheless like to argue that the primary function of government is to protect its citizens against real conflicts of interest, not perceived conflicts of interest.	Line 12-13: EFSA will review the text accordingly. Line 27-28: perception is considered as fundamental by EFSA's founding regulation so EFSA cannot ignore this requirement in assessing interests. Line 68: see above.

M. Groenleer, Delft University of Technology	1. Introduction	On the assumed relationship between the separation of science from politics and rebuilding public confidence: Strengthening food safety through the separation of science from politics does not necessarily lead to increased public confidence. Instead of mutually reinforcing, they may sometimes even be conflicting or contradictory, which is also reflected in the continuing tension between risk assessment and risk management. The example of GMOs shows that, while on paper risk assessment and risk management may be clearly separated, in practice there is often no sharp distinction between science and politics. Science is not completely objective: when assessing risks scientists for instance take decisions on the use of particular methodologies and techniques, which potentially affect their conclusions. And even if science would be completely objective, politicians and the general public are not always willing to accept conclusions that only take into account purely scientific factors. So too much emphasis on the separation of science and politics might even be counterproductive from the agency's point of view, as it allows the Commission and the member states to distance themselves from EFSA and use it as a scapegoat. This, in turn, negatively affects the agency's reputation for independence and thus comes at the expense of public confidence in the agency in specific and the EU's food safety regime in general. Hence, the agency is now also answering, more broadly, concerns raised by national authorities and NGOs, if I have understood correctly. Rather than repeating the official rhetoric used upon the creation of EFSA, my suggestion would therefore be to acknowledge that science and politics cannot always be separated, and that this is often not desirable either, for the very reason that it sometimes comes at the expense of public confidence. Independent from whom? It would be useful to make a distinction in the draft policy between independence (or rather autonomy) from politics and from industry, or at least whenever referring to independence also make clear in respect of whom exactly. My point is that initiatives to safeguard the agency's independence from politics are likely to be different from those to safeguard the agency's independence from industry. The draft policy now primarily focuses on independence from one type of actor in the agency's environment, ie industry. What about the agency's independence from political actors, such as the Commission and the member states including the national authorities? See also my other comments.	The founding regulation aims at the separation between risk assessment and risk management and achieves it with the creation of an independent EFSA. EFSA's role is limited by law to providing scientific advice or scientific and technical assistance to EU Institutions or Member States. On the other hand, the concept of autonomy differs from that of independence, which has been identified by the Founding Regulation as one of the core values that the Authority should live up to.

M Groenleer, Delft University of Technology	1. Introduction	I very much support EFSA's efforts to come up with a policy on independence and am generally satisfied with what is already in the draft. My comments – which tend to be more general and thus often relate to more than one section of the draft policy - therefore focus on what in my perspective, which is an academic one, is missing. Of course, the proof of the policy is in its implementation and I am curious to learn more about how exactly implementation is going to be ensured. On the difference between independence and autonomy: A general remark to start off with. I prefer to use the term 'autonomy' instead of 'independence'. The terms 'autonomy' and 'independence' are often used interchangeably, as synonyms for the same concept. The term independence stresses the condition of being (politically) free. In contrast, the term autonomy emphasizes the capacity to manage one's own affairs. An agency is said to be fully autonomous when it is able to act independently of some or all of the groups that may constrain it. Fully autonomous (or independent) agencies can decide for themselves what to do instead of doing what others tell them to do. In reality, fully autonomous agencies of course do not exist. Agencies can never do exactly what they want. An autonomous agency is granted a level of autonomy by other actors or will attempt to ascertain a degree of control over its own affairs, but this does not mean that it is enjoying complete freedom, not subject to any external control, without constraints and restrictions, that it is, in fact, independent. Instead of referring to agencies as being fully autonomous or not at all, it is therefore more useful to describe them as more or less autonomous. Autonomy, in other words, is a matter of degree, varying across agencies and over time. Furthermore, whether agencies are considered autonomous highly depends on the environment in which they operate. Autonomy has different meanings within different socio-cultural settings and historical contexts; no objective criteria exist to qualify an agency as autonomous. Moreover, agencies are not autonomous by themselves. They are autonomous in relation to other actors in their environments. Agencies can be autonomous from a wide range of groups, both governmental and private or non-governmental. Autonomy thus is not only a continuous and a situational concept, it is also a relational concept. In that sense, the concept is highly suitable to apply to the case of (EU regulatory) agencies.	EFSA is bound by the legal framework applicable to it and to the concepts foreseen therein.

2. Why a policy on independence and scientific decision making processes?			
Corporate Europe Observatory	2. Why a policy on independence and scientific decision-making processes?	It should be noted that while EFSA says to be an independent body delivering scientific excellence, it is the EU institutions that give EFSA its mandates and finance their work. The EU institutions also deliver regulations concerning the overall risk assessment policies, general standards for risk assessment, criteria for assuring independence, election of the management board and staff regulations. New members of the Management Board are even selected from a short list drawn up by the European Commission; the EC itself is also represented on the Management Board. Therefore, it is also to an important extent the responsibility of the EU institutions to ensure radical change in EFSA's ways of working in order to guarantee food safety. The main goal of this policy should have been to make sure EFSA is independent from economical interests that might impact the work of EFSA directly or indirectly. This is what is at the root of much public concern as well. This is not at all addressed by this draft policy which we therefore find fully inadequate and should not be adopted.	EFSA's role is limited by law to providing scientific advice or scientific and technical assistance to EU Institutions or Member States. EFSA does not have the power to review its founding regulation.
Testbiotech	2. Why a policy on independence and scientific decision-making processes?	What is mostly missing under the heading of "Why a policy on independence and scientific decision-making processes? " is a proper "swot analysis" explicitly discussing the risks of vested economic interests" impact on EFSA's scientific decision-making process. In lacking a proper analysis of the recent crisis in EFSA´s credibility, the purpose of this paper becomes evident as being simply a tool to defend EFSA's position (and very likely also Mrs Banati herself and her close affiliations with the International Life Sciences Institute, ILSI, closely cooperating with industry). Without a proper analysis of the problems involved, the whole process of initiating the dialogue with stakeholders about EFSA's independence is in danger of becoming irrelevant. Issues that should be considered in this analysis are, for example, the several reports recently published clearly showing deficiencies in the independence of EFSA and its scientific decision-making process. Some examples: The move of Suzy Renckens from being head of EFSA´s GMO unit to biotech industry (http://www.testbiotech.org/en/node/316), the affiliation of the head of Management board Mrs Banati with ILSI (http://www.gmwatch.org/latest-listing/1-news-items/12527-efsa-chair-in-conflict-of-interest-scandal), and the affiliation of the chair of the GMO panel with ILSI (http://www.testbiotech.org/en/node/431). Further criticism was voiced concerning further conflict of interests within other EFSA units and panels. These publications lead to several discussions within the European Parliament, were picked up by media and are still an unsettled issue, contributing to the current crisis of EFSA´s credibility. So EFSA would indeed need a new policy to safeguard its independence, but this necessary process is counteracted by EFSA's attempt to defend its position and neglect the real problems and challenges within this draft policy paper.	EFSA's independence is not just about economic interests. Re. the proposal to have a SWOT analysis, the draft policy is the result of a large body of critical assessment, which has included a number of reviews undertaken by EFSA, internal and external audits, together with the experience gained in the implementation of our rules and procedures. The Comment regarding individual cases was addressed over the last two years in bilateral correspondence with Testbiotech. However, for what concerns comments submitted with reference to the Management Board, in accordance with a procedure foreseen in EFSA's Founding regulation Management Board members are appointed by the Council after consultation with the Parliament on the basis of a short list drawn up by the European Commission. EFSA plays no role. Management Board members act in the public interest and in accordance with EFSA's rules on DoIs, declarations of members of the Management Board are screened. In addition, members have voluntarily committed to a Code of conduct, which upholds core principles and values such as integrity, objectivity and serving in the public

			interest while providing guidance on standards expected by EU institutions and the general public. In September 2011, the Board adopted a revised version of its rules of procedure, which clarifies and strengthens even further the process for the screening of its members' DoIs. For what concerns criticism related to former EFSA staff, EFSA is implementing the rules of the Staff Regulations. Further, after having learnt some lessons from past cases, EFSA has adopted a strengthened framework decision for staff who leave EFSA, which better details the process and the steps that are to be followed. This has already been successfully implemented in one case, where EFSA imposed certain limitations to a staff member leaving EFSA. In addition, the DoI screening system similar to that adopted for experts has been extended also to staff members (ADs, CA FG IV and SNEs). This allows the Appointing authority to have at any time a complete picture of the interests of its staff, with a view to preventing the occurrence of a CoI.
Eurogroup for Animals	2. Why a policy on independence and scientific decision-making processes?	Line 39 - An 'unbiased' scientific decision is not possible if gaps in the scientific data are identified. This happened with food products from cloned animals and their offspring, when a scientific decision was made based upon available and therefore potentially 'biased' data. When this happens it needs to be acknowledged so the audience is clear if enough data is available for an unbiased decision to be made based upon scientific data or if assumptions have been made, and/or a decision is based upon available data. If a decision relies on available data then a process needs to be established for managing/reviewing decisions made on this basis.	Following good risk assessment practices, EFSA ensures it includes a statement about uncertainties in its opinions. Each of its opinions includes information about the data included and when necessary highlights limitations and the possible need for future research. This will be better reflected in the document and is thoroughly addressed in the EFSA draft Science Strategy.

Confederazione Nazionale Coldiretti	2. Why a policy on independence and scientific decision-making processes?	With regard to the scope (Paragraph 2, ll. 34-39, Par. 3), even if EFSA's foundations inside the Reg. 178 seems useful, it should be stated clearly if the present Policy (Guidance Document) stems from an initiative of the Management Board or from the Executive Directors. It could help to address the kind of reflections and thinking behind and the rationale. Also recovering a broader (time)frame of the discussion on the policy of independence and transparency may be helpful, including past sessions of the MB inside which dialogue on EFSA's policy took place and the main issues at stake; or particularly meaningful events which have been informative for organizational learning, including -allegations and conflicts with third parties media resonance of episodes interpreted as "lack of independence". A step by step analysis of the most salient of them could help supporting the major changes proposed inside the documents, and assess the relevance and pertinence of them with an eye on the "problem solving"capability of the action proposed via a virtual simulation "what if" ("what would have happened if this kind of policy/measures had been in place?"). Also a framework of EFSA step-wise improvements could be useful. Inside the SH platform was produced a Guidance for Public Consultation, which now allows for public scrutiny and motivation from EFSA in case of acceptance/rejection of the comments submitted from third parties.	Comment is unclear.
BEUC	2. Why a policy on independence and scientific decision-making processes?	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panellists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	In a 2010 benchmarking report commissioned by EFSA to assess the main features of other agencies' independence policies, EFSA's DoI Policy scores as the most comprehensive one. In an external audit commissioned in the same year, the contractor found a 1-2% of cases of inconsistent or wrong screening by EFSA staff. This does not mean that the screening of DoIs cannot be improved, but it shows that the scrutiny is already very strict. EFSA will clarify in the text the - so called - breach of trust procedure, which is triggered in case of omissions made by experts. EFSA commits to report annually on the implementation of its Policy on Independence as of 2012. EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will be revised in order to clarify this aspect.

Food Standards Agency	2. Why a policy on independence and scientific decision-making processes?	Please note that our response to this consultation is a coordinated response and brings together comments from colleagues in the FSA and other UK government departments who work in areas of EFSA's remit, and from scientific advisory committees which advise the FSA. Overall we welcome this policy document which brings together current practice and operating procedures of EFSA in one document. In general, we feel the document sets out a sensible framework for independent scientific advice and emphasises the importance of science-based decision making, which we fully support. It would at the outset be useful to describe the breadth of science input to EFSA's work - in particular to refer to the importance of the social, as well as the natural and physical sciences, to informing EFSA's role in undertaking effective risk assessment and risk communication and ultimate aim of engendering consumer trust.	EFSA thanks the FSA and the other UK government departments who work in areas of EFSA's remit for their support to the policy.
one of the societies	2. Why a policy on independence and scientific decision-making processes?	Madam,Mister, I just heard about your plans on the Draft Policy measures, and read them. My studies were on cellular biology, and the affect of them on each type of cells. I understand in your project that European Union will allow the Food Industry to create some new chemistry and add them to our food without a single scientific opinion of an independent laboratory. I just want to remind what happened bout lot of chemical additives that used to be on the food market several years ago: 1:the growth hormon was such a dangerous product million of people had diseases with that! 2:DEHP is used for plastics, but it is forbidden to contamine food with it: we just had an example in China few days ago. There is much of this kind of examples, you should know them much as anybody. 3:aspartam seems to be the most enormous mistake governments made. This product is dangerous and no one turned back on its resolution [Does] anyone want to make this mistake go on and on? Your purpose is just the open gate to this kind of tragedy. Do you consider that Food industrialists are such trustworthy we can allow them to manage our health with their develop[ment]s? Which kind of public scandal haven't be[en] retained from all those diseases discovered and "accidentally" created in the XXth century? It seems like European people were some people with a good health, a large life expectancy. I consider that this kind of decision is dangerous for our children, for our parents, and even for the all society that made millenars to create. "Man is a wolf for man", your authority is here to protect man from himself. Be strong and represent the power people gave to you. Please reconsider your plans and help [E]uropean people to keep a good health, say no to plural food addi[t]tives, to "cocktail effects", to new products non available for eating. Thanks to take a real care about those words	These comments do not relate to the draft policy, which is the only subject to the public consultation.

3. EFSA's core values			
Corporate Europe Observatory	3. EFSA's core values	EFSA's core values are said to include "scientific excellence, openness, transparency and independence" [43]. We find it hard to see how scientific excellence and independence can be guaranteed in the current situation, where EFSA opinions are based on industry testing and are formed by panels that comprise many experts with ties to the same industry. Food safety should be guaranteed by independent testing (the burden of which should be borne by the company) and research, and by assessments done by independent experts.	The pillar of Declarations of interests of EFSA's draft policy on independence aims exactly at avoiding conflicts of interests. EFSA's Policy on Declarations of Interests which is in force since 2007, which will form the backbone of the future Implementing act on declarations of interest of the forthcoming policy, has been recognised as an effective tool to prevent CoI. In a 2010 benchmarking report commissioned by EFSA to assess the main features of other agencies' independence policies, EFSA's DoI Policy scores as the most comprehensive one. In an external audit commissioned in the same year, the contractor found a 1-2% of cases of inconsistent or wrong screening by EFSA staff. This does not mean that the screening of DoIs cannot be improved, but it shows that the scrutiny is already very strict. Regarding the suggestion of having industry paying for "independent" testing, it should be borne in mind that EFSA's role is limited by law to providing scientific advice or scientific and technical assistance to EU Institutions or Member States.
Testbiotech	3. EFSA's core values	Again, safeguarding EFSA´s independence from vested economic interests is not even mentioned as a crucial challenge or core value.	Safeguarding EFSA from vested economic interests is already part of the broader and multifaceted concept of independence. However, the text will be reviewed to make this even clearer.

Confederazione Nazionale Coldiretti	3. EFSA's core values	ll.46 With regard to the details of the document, we think that there are often very promising parts left undeveloped and somehow black boxed with respect to the possibility to reassure external publics on the kind of quality procedures in place to achieve independence and transparency. For example, at line 46 we know that "The Authority' core values are implemented by EFSA through a number of rules and procedures put in place over time". To have examples here could help (if not an exhaustive list of them). EFSA's activities related to independence and transparency can also be better detailed. EFSA activities do not end up in Panels and Management Board. In fact the most critical aspects of independence, transparency and quality of the process may arise from events that even if peripheral to EFSA' core assessment, allow for a wider interplay with stakeholders and selected publics (ie, applicants). No mention in the document is made about those. It could be useful to include them.	The rules of procedure referred to in general terms as a matter of fact are developed in much more detail in the following paragraph of the text. We therefore believe it is not necessary to elaborate further on that point. The same holds true for transparency and openness, which are addressed in § 7 of the Policy. EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will however be revised in order to clarify this aspect.
BEUC	3. EFSA's core values	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panellists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	In a 2010 benchmarking report commissioned by EFSA to assess the main features of other agencies' independence policies, EFSA's DoI Policy scores as the most comprehensive one. In an external audit commissioned in the same year, the contractor found a 1-2% of cases of inconsistent or wrong screening by EFSA staff. This does not mean that the screening of DoIs cannot be improved, but it shows that the scrutiny is already very strict. EFSA will clarify in the text the so called breach of trust procedure, which is triggered in case of omissions made by experts. EFSA commits to report annually on the implementation of its Policy on Independence as of 2012. EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will however be revised in order to clarify this aspect.

FoodDrinkEurope	3. EFSA's core values	[After line 52] This principle of independence implies the independence from any external economic or political interests, but also from bias related to political, economic, social, philosophical, ethical, or any other non-scientific considerations. That being said, there is agreement that EFSA needs to have access to top quality science. Active top class scientists should not be automatically excluded from working with EFSA on the sole basis that they may have contacts with top scientific leaders in industry.	While this is true, as the aspects mentioned in the comment in question are subjective ones, it is impossible for EFSA from a practical point of view to consider these dimensions, unless they are reflected in an objective, traceable activity of the concerned person. The latter is part of the EFSA approach/DoI policy. This is why EFSA tries to have a balanced composition of its panels and working groups and frequently consults stakeholders. As regards the comment re. top class scientists, EFSA's draft policy recognises the principle that expertise comes with interests. Furthermore, as clarified in § 7,1, EFSA frequently uses its capacity to invite hearing experts to participate in discussions that require specialist knowledge, further broadening the scientific expertise at its disposal without directly influencing the scientific decision-making process. This allows the Authority to take stock of the data or expertise developed by industry, non-governmental organisations and other interested parties on newly developed practices, processes, substances and products.
University College Dublin	3. EFSA's core values	The Authority's core values are sometimes challenged when mandates are under negotiation because there is a perception that food safety is a food quality parameter and not a stand alone criterion that is a sine qua non for trade in food. This misclassification has to be guarded against both within and outwith the Authority. As an example see the EC's SCVMPH Opinion on Meat Inspection adopted 20-21 June 2001, a document that currently has been offered for consideration by EFSA Panels when addressing a number of mandates.	EFSA acknowledges the importance of differentiating food safety from food quality, which indeed is not related to EFSA's mission.
University College Dublin	3. EFSA's core values	EFSA's core values are sometimes challenged in the course of negotiation of mandates. There is a perception by those posing the question that food safety is one of a number of food quality parameters. This tendency has to be guarded against both within and outwith the Authority; otherwise the objectivity and primary function of the Authority is open to compromise. Food safety is a sine qua non for trade in food at every level and is not to be regarded or classified as another food quality "aspect" e.g. see Opinion of SCVMPH on meat inspection adopted 20-21 June 2001.	EFSA acknowledges the importance of differentiating food safety from food quality, which indeed is not related to EFSA's mission.

PAN Europe	3. EFSA's core values	• Realising high scientific standards? EFSA has a long way to go. EFSA is completely denying science produced by academic and independent scientists. So you could claim EFSA disregards science at large. Work is based entirely on industry-sponsored testing and it is questionable if you can call this science. As long as EFSA keeps on denying the entire scientific world, we think the EFSA claim of being a high ranking scientific institute is false. This basic mistake needs to be repaired urgently. Secondly looking at the panels, we see half of them being national civil servants, having published hardly anything in their life. The scientific level of panel opinions cannot be high if the panel is composed of people never seeing a laboratory from the inside, probably not following scientific progress in international journals, not visiting scientific meetings (beyond ILSI/SETAC-meetings) and not being used to deliver articles to peer-reviewed journals. This is a major handicap to the panels and probably also explains the reluctance to take 'real' science on board because they might not understand it. Assessing industry testing can be done in a more 'book-keeping' way by following the standard schemes of OECD and GLP administration. The second half of the panels is a mix of retired scientists, institute people who are probably looking for a profile to get contracts in the markets and hidden industry lobbyists. So generally the scientific output of EFSA cannot be but low, and might even be biased. If EFSA is serious in getting scientific top institute a radical change is needed. First of all scientists in the panels need to be paid because a 'real' scientist simply has no time because he/she is working in the laboratory, meet on symposia or working on fundraising. In the highly competitive world of science, you cannot spend time travelling to Parma without any revenues. Secondly, only real independent scientists should be allowed to the panels. It is not true that every scientist has links with companies. Enough scientists are available which do not have links to commercial parties, but they cannot work for free for EFSA. A quality criterion like a minimum of two peer-reviewed articles per year published (only original articles, no opinions, no reviews and no proposals/critics on risk assessment) should also be used to exclude non-publishing people. • Defend independent science and consider independent science to be of the highest level of reliability and quality. Independency of universities and institutes is threatened more and more by privatisation and market mechanisms. This makes it harder to find independent scientists and should make the scrutiny on interests stricter. At the same time EFSA is treating GLP-industry studies as those with the highest reliability (Klimisch ranking, see guidance on use of independent science). In this way EFSA is undermining independent science itself and self-destructing the aim of realising independence and high scientific levels. A big contradiction.	EFSA is not a research organisation, but rather an Union agency tasked with the provision of scientific advice and scientific and technical support to Union institutions and Member States. To accomplish its mission, EFSA relies on its scientific staff, national scientific organisations and institutes and independent experts. EFSA considers all scientific studies in its risk assessment processes. Study reliability must be judged solely on the basis of the study design and of the reproducibility of the findings reported. For example, EFSA's new guidance document for applicants seeking approval of active substances in pesticides makes clear that studies found in peer-reviewed open scientific literature should be considered. The composition of the Scientific Panels and Scientific Committee of EFSA derives from an open call for expression of interest aimed at selecting the best available scientific experts in the Panel's domains. In that context, 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.

4. Organisational governance			
Corporate Europe Observatory	4. Organisational governance	The management board should play a key role in guaranteeing the independence and soundness of EFSA opinions. Therefore, no industry influence should be allowed on the Management Board. [62-68] In March 2011, CEO wrote to EFSA and to Commissioner John Dalli to point out that four industry representatives were on the board. But according to EFSA's Founding Regulation, four of the 15 Management Board members "shall have their background in organisations representing consumers and other interests in the food chain". This means that there is at least one too many industry representatives (lobbyists) on the Management Board. EFSA has so far not taken action. Environmental organisations are also not represented on the board. In our letter, we highlight the fact that on its website, EFSA states that its board members "do not, in any way, represent a government, organisation or sector". Board members are appointed "intuitu personae" ("personal capacity") and "shall act in the public interest". It is not credible to claim that people employed by or otherwise directly linked with organisations with vested commercial interests, do not represent their employers or organisations, or to claim that they can be trusted to act in the public interest (rather than that of these organisations).	In accordance with a procedure foreseen in EFSA's Founding regulation Management Board members are appointed by the Council after consultation with the Parliament on the basis of a short list drawn up by the European Commission. EFSA plays no role. Management Board members act in the public interest and in accordance with EFSA's rules on DoIs, declarations of members of the Management Board are screened. In addition, members have voluntarily committed to a Code of conduct, which upholds core principles and values such as integrity, objectivity and serving in the public interest while providing guidance on standards expected by EU institutions and the general public. In September 2011, the Board adopted a revised version of its rules of procedure, which clarifies and strengthens even further the process for the screening of its members' DoIs. Furthermore, by law four members of the Board are from organisations "representing consumers and other interests in the food chain". Therefore it is by design that members of the Management Board have links with the food chain. They are selected for that very experience and expertise.

Euro Coop	4. Organisational governance	Lines 55 to 57: The separation of roles between risk management and risk assessment does not per se ensure that EFSA is free of any undue influence. Lines 65 to 72: Euro Coop strongly believes that it is of high importance to involve consumer representatives to an extensive degree in EFSA's Management Board. This would also help to reinforce European consumers' confidence in the European food safety policy. Euro Coop deems it is a key element to increase consumers' trust in EFSA's scientific opinions. Euro Coop would thus advice EFSA to support further involvement of civil society organisations in EFSA's Management Board such as in all stages of EFSA's activities. We appreciate EFSA's efforts in avoid any conflict of interest, but we still call for an accurate control of candidates to be appointed as part of EFSA's Management Board, as conflicts of interests happened even in the very recent past.	Lines 55 to 57: the draft policy does not claim that separation of risk assessment from risk management alone ensures that EFSA is independent. The draft policy ensures that other aspects such as social and economic ones are adequately handled by risk managers. Lines 65 to 72: in accordance with a procedure foreseen in EFSA's Founding regulation Management Board members are appointed by the Council after consultation with the Parliament on the basis of a short list drawn up by the European Commission. EFSA plays no role. Management Board members act in the public interest and in accordance with EFSA's rules on DoIs, declarations of members of the Management Board are screened. In addition, members have voluntarily committed to a Code of conduct, which upholds core principles and values such as integrity, objectivity and serving in the public interest while providing guidance on standards expected by EU institutions and the general public. In September 2011, the Board adopted a revised version of its rules of procedure, which clarifies and strengthens even further the process for the screening of its members' DoIs.

National Food Institute	4. Organisational governance	As the independent national risk assessment body of Denmark the National Food Institute has the following comments/questions to above mentioned document: A. Under the section 4 'Organizational governance' the texts seems to suggest that the functional separation of risk assessment and risk management is only effectuated at European level, i.e. not at national level. As we are aware that this functional separation also governs deliberations in a number of Member States, including Denmark, it would make sense if the text is revised to reflect this important state of affairs. Likewise the text in this section would seem to suggest that European risk assessment is performed only in EFSA. It would again be important if the text could reflect present reality, which is that basic scientific risk assessment work in Europe is performed primarily in Member States, while EFSA performs the important task of integrating and jointly evaluating such risk assessment data, permitting joint European scientific agreement in key areas. B. In section 9 'Organisational culture' the paper refers to the set of comprehensive EFSA rules and procedures for identifying and handling potential conflicts of interest. This procedure specifically states that earlier involvement in an opinion of a national authority may constitute a conflict of interest. The background for this principle is not clear. It should be noted that if the reciprocal situation was implemented a national panel member having been involved in risk assessment work for EFSA would not be entitled subsequently to engage in risk assessment work at national level, because of CoI. This outcome would presumably hinder the members states' experts participation in EFSA panels. Conflict of interest rules are typically implemented so that managers, stakeholders and society at large can be sure that undue influence is avoided when scientific risk assessment is developed. It would not seem clear – and would thus most likely be impossible to communicate – how the participation in previous scientific work regarding the question at hand would in itself constitute a conflict of interest? More specifically the implementation of these procedures would seem to result in a situation where Panel Members who participate in drafting opinions under EFSA contracts can potentially have a conflict of interest. The consequence of this will in some cases lead to situations where another expert in the Panel, who has not been involved in the assessment, would have to present the opinion at the Panel meeting, resulting in a sub-optimal use of resources, and in some cases a poor scientific outcome. Finally it would be interesting to have a clarification if earlier involvement in an opinion of an international authority may also constitute a conflict of interest? It is suggested to change this practice and have clear, concise and communicable procedures for implementation of these policies, avoiding listing previous scientific work per se as a potential for conflict of interest.	The text can be reviewed to better reflect the separation of Risk assessment from risk management at national level. It is not true that EFSA simply collates RA performed at national level. To the contrary, in addition to its networking tasks, EFSA regularly performs a high number of autonomous risk assessments, without any involvement of national competent authorities. For what concerns the comment on the assessment of previous involvement in a national authority, it should be borne in mind that in some specific instances it may be considered appropriate to consider that interest as a CoI, for instance when an expert from a national competent authority is called upon in EFSA to assess an opinion to whose development he or she has actively contributed.

Testbiotech	4. Organisational governance	With regard to the role and the composition of the management board, some major deficiencies are evident that should be analysed and discussed properly. If “rebuilding public confidence" in EFSA is to be enabled, the reorganisation and new constitution of the management board is of a high priority. Since the risk manager is involved in the election of the members of the management board this is an issue that needs close cooperation with the EU Commission and the Council. First of all, the management board should strictly be protected against direct and indirect influence by the food and agricultural industry. Further, the rules concerning the management board should be revised to make sure that this body can become a reliable element in the control of EFSA's independence. The board should be reorganised to represent a truly broad spectrum of relevant stakeholders and especially those institutions dealing with the interests of consumers and the protection of the environment (since EFSA is also dealing with issues of environmental risk assessment). It should be possible for relevant stakeholders such as consumer and environmental organisations to participate in the process of electing the board members by naming their own candidates and commenting on the others. The members of the management board selected by such a process would be much more likely to function as an "internal watch dog" responsible for selecting staff members and panel experts and other relevant decision-making.	In accordance with a procedure foreseen in EFSA’s Founding regulation Management Board members are appointed by the Council after consultation with the Parliament on the basis of a short list drawn up by the European Commission. EFSA plays no role. Management Board members act in the public interest and in accordance with EFSA’s rules on DoIs, declarations of members of the Management Board are screened. In addition, members have voluntarily committed to a Code of conduct, which upholds core principles and values such as integrity, objectivity and serving in the public interest while providing guidance on standards expected by EU institutions and the general public. In September 2011, the Board adopted a revised version of its rules of procedure, which clarifies and strengthens even further the process for the screening of its members' DoIs. Furthermore, by law four members of the Board are from organisations “representing consumers and other interests in the food chain”. Therefore it is by design that members of the Management Board have links with a particular food sector. They are selected for that very experience and expertise.
Anses	4. Organisational governance	We suggest to precise that there can have a separation between risk assessment and risk management at national level.	The text can be reviewed to better reflect the separation of risk assessment from risk management in some Member States.
Eurogroup for Animals	4. Organisational governance	line 57 - The word ‘political’ needs to be inserted between ‘undue influence’ lines 57-58 - Openness and transparency would be increased if some selected stakeholders would be allowed to attend all meetings as observers (see additional points below). If confidentiality is an issue then observers can be authorised in advance and sign agreements.	Line 57: the text can be revised accordingly.

		line 65 - Surely more that 4 out of 15 members should have a background in representing consumers and other interests in the food chain? To be fully open and transparent ideally the management board would have individuals with a broader range of backgrounds including animal welfare, veterinary and human medicine, environment.	Lines 57-58: EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will however be revised in order to clarify this aspect. Line 65: In accordance with a procedure foreseen in EFSA's Founding regulation Management Board members are appointed by the Council after consultation with the Parliament on the basis of a short list drawn up by the European Commission. EFSA plays no role. In addition, members have voluntarily committed to a Code of conduct, which upholds core principles and values such as integrity, objectivity and serving in the public interest while providing guidance on standards expected by EU institutions and the general public. In September 2011, the Board adopted a revised version of its rules of procedure, which clarifies and strengthens even further the process for the screening of its members' DoIs.
Confederazione Nazionale Coldiretti	4. Organisational governance	Coldiretti believes it could be really helpful to spend some lines to explain the new EFSA's organizational chart, and the rationale behind. Furthermore, how it complies with the policy on Independence and Scientific Decision Making. A detailed analysis on how panels have been displaced and transformed in their scope once assumed under new Directorates could improve clarity.	EFSA's organisational structure aims at the proper and efficient functioning of the organisation including the implementation of the core value of Independence.

BEUC	4. Organisational governance	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panelists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	In a 2010 benchmarking report commissioned by EFSA to assess the main features of other agencies' independence policies, EFSA's DoI Policy scores as the most comprehensive one. In an external audit commissioned in the same year, the contractor found a 1-2% of cases of inconsistent or wrong screening by EFSA staff. This does not mean that the screening of DoIs cannot be improved, but it shows that the scrutiny is already very strict. EFSA will clarify in the text the so called breach of trust procedure, which is triggered in case of omissions made by experts. EFSA commits to report annually on the implementation of its Policy on Independence as of 2012. EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons.. The text will however be revised in order to clarify this aspect.
Food Standards Agency	4. Organisational governance	Lines 54-60. This section asserts that functional separation of risk assessment and risk management and a responsibility for risk communication, in themselves, will engender trust in EFSA and its messages, as well as operating in an open and transparent manner. We would agree these are key foundation stones for this outcome, but it is felt that these assertions would be more compelling if it was possible to refer to independent research which would support this eg about how the communication has impacted on consumer/stakeholder behaviours/opinions. It is also important to recognise the value of combining information on risk assessment and risk management when communicating with the public. This section should also perhaps refer to the rigorous implementation of the various elements in this policy being a key part of aiming to ensure EFSA's advice is demonstrably free of undue influence. The overall impact of ensuring that food safety policy appropriately takes into account relevant science requires frequent and good communication between risk assessors and risk managers, which can be challenging, particularly in a European context where these functions are not in close proximity. It may be useful to include some text (perhaps in a separate section) describing how EFSA meets this challenge in the context of application of this policy, especially in situations where speed is of the essence. Lines 68-71: With regard to declaration of interest, it states that the Chair of the Management Board checks the Annual Declarations of Interest (ADoIs) of Board members. The policy could usefully make clear how the checking of the Chair's ADoI is undertaken.	Lines 54-60: While respecting EFSA's independence from Union risk managers, EFSA is fully committed to ongoing and systematic interaction with these, including DG SANCO. EFSA has put in place a series of mechanisms that ensure effective interaction with the Commission (bilateral meetings, systematic presence of Commission officials at EFSA meetings, presence of SANCO representative on EFSA's MB etc). Lines 68-71: The text will be revised to clarify the collegial responsibility of the Board in the screening of DoIs. In that respect in September 2011, the Board adopted a revised version of its rules of procedure, which clarifies and strengthens even further the process for the screening of its members' DoIs.

FoodDrinkEurope	4. Organisational governance	After line 59: To enhance the quality of a scientific opinion, EFSA may require additional information from individuals, petitioners or other stakeholders for the completion of a scientific opinion. In such cases, in particular, for example, invited face-to-face meetings, consultations, or hearings might be necessary and should apply in compliance with the fundamental requirements of ensuring full independence and autonomy of EFSA's panels. It should not be assumed that the independence of EFSA need be compromised by such bilateral meetings and guidelines should be drawn up by EFSA so as to allow such engagement with stakeholders, including industry, to take place at the stakeholders request. In cases where an opinion is prepared in light of information submitted by a stakeholder in response to specific regulatory requirements EFSA should, when appropriate, seek comments from the applicant on a draft of the opinion, and submit those comments to the Panel before the adoption of the opinion.	After line 59: The suggested text is already foreseen in the following paragraphs, such as § 5.3. the paragraph on organisational governance discusses the internal structures of EFSA.
Federal Institute for Risk	4. Organisational governance	Line 55-59: This sentence explains that at European level risk assessment and risk management is separated, and risk assessment is task of EFSA, while risk management is task of the European Commission, Council, European Parliament and the Member States. This sentence might be misunderstood since it might suggest that Member States only conduct risk management. In a similar way as at the European supranational level, risk assessment and risk management is institutionally separated in many MS. Thus we kindly request clarification of this important issue in the EFSA policy document.	Lines 55-59: the text can be revised to clarify that the separation of risk assessment from risk management applies also in some Member States and that Member States also carry out risk assessments.

Delft University of Technology	4. Organisational governance	On the independence of the management board: Even though the absence of member state representation might have led to a lower level of politicisation compared to other agencies' management boards, posts in the board have rotated among members from different countries and, as far as I know, the large member states have always been part of the board through a board member. How does the agency avoid the impression that the nationality of board members, in spite of the fact that they are appointed in a personal capacity, may thus nonetheless to some extent affect board decisions? Board members have 'to act independently in the public interest'. What does this mean exactly? Clearly, "the" public interest does not exist. Has the agency operationalized this in more concrete detail? The absence of member state representation in the board seems to have increased the Commission's role. It appears that members often follow the Commission representative. The dominant position of the Commission within the board is of course not surprising, in view of its information lead, particularly on staffing and budgetary matters, and its technical know-how and given the board's obligation to ensure that the work programme is consistent with the Commission's priorities. Yet, one may ask how the agency avoids that one particular board member, be it the Commission representative or another board member, dominates the discussions in the board. Particularly in light of the above, it appears strange that '[f]or any matters linked to the independence of members of the Board, the Authority might consult the Commission'. This sentence requires some clarification. On the independence of the director: The draft policy remains silent on how the independence of EFSA's director is ensured, notably when it comes to staffing and budgeting. As the draft policy is very much focused on independence in terms of scientific activities, it underplays independence in terms of administrative and procedural activities. Although perhaps more indirectly than in the case of the agency's scientific activities, such independence is of crucial importance for the agency's reputation as an independent entity.	In accordance with a procedure foreseen in EFSA's Founding regulation Management Board members are appointed by the Council after consultation with the Parliament on the basis of a short list drawn up by the European Commission. EFSA plays no role. Management Board members act in the public interest and in accordance with EFSA's rules on DoIs, declarations of members of the Management Board are screened. In addition, members have voluntarily committed to a Code of conduct, which upholds core principles and values such as integrity, objectivity and serving in the public interest while providing guidance on standards expected by EU institutions and the general public. In September 2011, the Board adopted a revised version of its rules of procedure, which clarifies and strengthens even further the process for the screening of its members' DoIs. Furthermore, by law four members of the Board are from organisations "representing consumers and other interests in the food chain". Therefore it is by design that members of the Management Board have links with the food chain. They are selected for that very experience and expertise. Regarding the suggestion to better specify how administrative independence is ensured, we believe that this is already addressed by the paragraph on the institutional separation of EFSA from the Commission.
Chiara Tomalino, Eurocoop and Nina Holland, Corporate Europe Observatory	4, Organisational governance	(...) we would welcome the creation of a public body which could collect contributions from industry and from which the resources could then be shifted to EFSA. What we for sure would avoid is to have a direct relationship between service and a payment for the service.	EFSA's role is limited by law to providing scientific advice or scientific and technical assistance to EU Institutions or Member States.

5. Scientific decision making processes			
INRAN	5. Scientific decision-making processes	109 5.3 Information gathering: data from Member States, applicants and scientific literature I would suggest to add a reference to 1) systematically collecting results from European projects (in the past the FlairFlow project was implemented in the 4th framework programme and was operative until the 90s. Unfortunately now the project is not active - http://cordis.europa.eu/fair/src/results.htm 2) developing systematic literature review database both for white (several websites) and grey literature (www.greynet.org) 3) db on regulatory system 4) access to WHO, FAO and UN respositories 5) other European DB, like http://www.echim.org/docs/EXT2/pres2.pdf	The text can be revised to indicate that results from research projects funded by the EU, WHO or FAO are systematically taken into account. This matter is also addressed in EFSA's draft Science Strategy.
Corporate Europe Observatory	5. Scientific decision-making processes	The EU institutions should undertake a radical change in the general standards for risk assessment in order to remedy a fundamental flaw in the way EFSA judges food safety of products: it should not rely on (unpublished) industry tests studies to judge the safety of products. Instead of the food industry delivering its own studies (commissioned from its own labs or from external labs), industry money should be collected at arm's length by a publicly-controlled institution which would commission independent studies from independent and publicly-funded laboratories in Member States. EFSA should actively demand such change from the EU institutions. There are many more areas where EFSA should make radical changes in order to be truly independent and seen as such. For example, EFSA tends to overly rely on tests done according to so-called "good laboratory practice" (GLP) standards. EFSA was recently criticised by David Gee of the European Environment Agency for ignoring studies that are not GLP, saying that "GLP doesn't say anything about the quality of the science." Finally, in recent pesticide regulation 1107/2009 the EU decided "scientific peer-reviewed open literature" should be taken into account from now on. In its draft guideline for this provision, EFSA proposes "to let industry do the search and evaluation of the scientific literature and allow such narrow search-terms (basically only tests similar to standard industry tests) that it is clear academic science will keep on being denied." (PAN Europe). EFSA -with its core value of "scientific excellence" and "independence"- however should be fully open for scientific peer-reviewed literature.	EFSA's role is limited by law to providing scientific advice to EU Institutions or Member States and scientific and technical assistance to the European Commission. While EFSA can commission research, it should be considered that the burden of proof of submitting data proving the safety of the relevant substances or products has been put by the legislator on the applicant. The fact that GLP standards must be adhered for such dossier should not be confused with ignoring evidence that would have come from non GLP studies.

FEFANA asbl	5. Scientific decision-making processes	Line 116: Indeed, the fact that general good risk assessment practices and methodologies have been developed, helps avoiding a case-by-case approach that could otherwise be detrimental to the impartiality of the work of EFSA's scientific experts or the coherence of the scientific output. FEFANA members experience at present very inhomogeneous questions to application dossiers - maybe as a consequence of EFSA's outsourcing of evaluations to different third party experts / consultants. The way external experts are used is not transparent to the public and therefore there is an issue with the outsourcing. It is not known who is used as expert, these experts are not mentioned in the reports, and we are not able to monitor how the conflicts of interest are managed. For these reasons, FEFANA is calling for transparency in this context.	Line 116: In order to maximise resources and use the skill sets of its external contractors and EFSA experts optimally, EFSA awards grants and procurement contracts where applicable for preparatory work for its working groups which will evaluate the external work and make recommendations of their own before submitting to scientific panels for their consideration. It is worth noting that EFSA has already extended its DoI policy to include contractors and grant beneficiaries. For what concerns external experts, they are selected via a procedure that taking into account the fact that draft outputs prepared by working groups are discussed, amended and, when appropriate, adopted by Panels, corresponds to the same criteria used for the selection of members of the SC and SP. This will be clarified in the revised text of the draft Policy.
FEFANA asbl	5. Scientific decision-making processes	Line number 95: A significant share of EFSA's work is deriving from self-tasked mandates. FEFANA recognises the self-tasking as an important and useful feature. FEFANA has however the following remark: fundamentally, a self-tasked activity shall be restricted to the purely scientific field. There, it is appropriate. It should however not enter the field of Risk Management or regulatory matters as the borderline between Risk Assessment and Risk Management might then be blurred. Moreover, we see a need to underline that parties upon which the self-tasked activity has a potential impact, are involved in an adequate way. We therefore propose a regular and timely consultation (be it public or of the concerned stakeholders) in order to find out whether or not a self-tasked mandate is appropriate in a given situation, and for to receive external advice before the launch. Room for such a consultation would be there when the involved Scientific Panel or Working Group is proposing the self-tasking to the Executive Director. The Executive Director might then launch the consultation in advance of taking the decision on the approval of the self-tasked mandate. If this happens on a regular basis, the appropriate involvement of the concerned parties can be assured.	The text will be reviewed clarifying that approximately 5% of EFSA outputs (to date) are a result of self-task. However, EFSA agrees and confirms that self tasks do not look at regulatory or legal matters, as they concern scientific issues falling within each Panel or Committee's remit. Generally self-tasks concern guidance documents and are subject of public consultation. This matter is also addressed in EFSA's draft Science Strategy.

Sanofi	5. Scientific decision-making processes	5.Scientific decision-making processes [lines 80-125] Sanofi welcomes the EFSA's initiative for streamlining its scientific decision making processes. In particular we appreciate the development of standard methodologies to guide the work of its scientific committee, panels and staff. However we would welcome more details and explanations on the scientific considerations that lead to a decision. For an applicant seeking authorisation of substances, products or claims it is critical to well understand the specific regulatory requirements that are taken into account for the scientific decision. We consider that more regular communication between EFSA and the applicant during the development and the application review will improve the understanding of the regulatory requirements. Ultimately, this will stimulate the development of new products and claims addressing public health needs and food and feed safety. 5.4 Working groups [lines 120-125] Minutes of each working group meeting could be more informative especially on the draft position agreed by the panel. For example, in the minutes of the working group on claims, the discussion section is very short and does not provide any information on the claims discussed.	It should be borne in mind that this is a document on independence and scientific decision making processes, rather than an explanatory document re. EFSA's scientific workflows. As regards the interaction between applicants and EFSA, the Authority is committed to continue improving its interaction with interested parties, including applicants. This is why it has created an Application Desk Unit, which is meant to manage all questions related to the application assessment process from applicants, risk managers and other stakeholders. This may be further developed in the next few years should a cost recovery system be approved by the Union legislators. However, the procedures provided in the vertical legislation needs to be respected. EFSA is also committed to holding regular meetings with NGOs on issues such as GMOs. This will be further clarified in the document. Lines 120-125: EFSA is working on enhancing the informative level of minutes while balancing that with the need of protecting confidential data and information in accordance with the Union legislation.
National Food Institute	5. Scientific decision-making processes	As the independent national risk assessment body of Denmark the National Food Institute has the following comments/questions to above mentioned document: A. Under the section 4 'Organizational governance' the texts seems to suggest that the functional separation of risk assessment and risk management is only effectuated at European level, i.e. not at national level. As we are aware that this functional separation also governs deliberations in a number of Member States, including Denmark, it would make sense if the text is revised to reflect this important state of affairs. Likewise the text in this section would seem to suggest that European risk assessment is performed only in EFSA. It would again be important if the text could reflect present reality, which is that basic scientific risk assessment work in Europe is performed primarily in Member States, while EFSA performs the important task of integrating and jointly evaluating such risk assessment data, permitting	A. The text can be revised to clarify that the separation of risk assessment from risk management applies also in some Member States and that Member States also carry out risk assessments.

		joint European scientific agreement in key areas. B. In section 9 'Organisational culture' the paper refers to the set of comprehensive EFSA rules and procedures for identifying and handling potential conflicts of interest. This procedure specifically states that earlier involvement in an opinion of a national authority may constitute a conflict of interest. The background for this principle is not clear. It should be noted that if the reciprocal situation was implemented a national panel member having been involved in risk assessment work for EFSA would not be entitled subsequently to engage in risk assessment work at national level, because of CoI. This outcome would presumably hinder the members states' experts participation in EFSA panels. Conflict of interest rules are typically implemented so that managers, stakeholders and society at large can be sure that undue influence is avoided when scientific risk assessment is developed. It would not seem clear – and would thus most likely be impossible to communicate – how the participation in previous scientific work regarding the question at hand would in itself constitute a conflict of interest? More specifically the implementation of these procedures would seem to result in a situation where Panel Members who participate in drafting opinions under EFSA contracts can potentially have a conflict of interest. The consequence of this will in some cases lead to situations where another expert in the Panel, who has not been involved in the assessment, would have to present the opinion at the Panel meeting, resulting in a sub-optimal use of resources, and in some cases a poor scientific outcome. Finally it would be interesting to have a clarification if earlier involvement in an opinion of an international authority may also constitute a conflict of interest? It is suggested to change this practice and have clear, concise and communicable procedures for implementation of these policies, avoiding listing previous scientific work per se as a potential for conflict of interest.	B. For what concerns the comment on the assessment of previous involvement in a national authority, it should be borne in mind that in some specific instances it may be considered appropriate to consider that interest as a CoI when an expert from a NCA is called upon in EFSA to assess an opinion to whose development he or she has actively contributed.
Testbiotech	5. Scientific decision-making processes	In short at least three major problems can be identified in the current scientific decision-making process of EFSA that are related to the chapters 5-9: 1.There are no clear criteria / definitions for judging independence / conflict of interests of experts for panels or working groups. We do not think that the explanation given - "a candidate is not considered anymore for membership of the Scientific Committee or Scientific Panels when EFSA identifies a potential conflict of interest of such a magnitude that would prevent his or her active participation in the majority of the meetings of that Committee or Panel" - does serve to clarify matters. There needs to be a list of clear criteria to exclude, for example, experts with affiliations to industry-like institutions such as ILSI. The process for selecting candidates for working groups and expert panels also needs to be improved. Participation of relevant institutions and organisations that can function as a "watch dog" representing the interests of consumers and the protection of the environment has to be enabled by reorganising the management board. 2.There is a substantial weakness in the Guidance for risk assessment, at least in the context of genetically engineered plants. The comparative risk assessment used is not suited for exploring the specific risks related to this technology. The Guidance is mostly justified by referring to	**1.** The criteria for the adoption of preventive or remedial actions will be set out in the single implementing decision on declarations of interests. The draft policy highlights the main principles that will govern that decision, in addition to clarifying that the implementing rules will build on the current DoI policy. **2.** This comment falls outside the subject matter of the present consultation. **3.** EFSA operates under the legal framework foreseen by the Union legislators. The creation of a referee panel for the inclusion or rejection of scientific evidence would deprive the Panels of much of their deliberative power.

		standards such as developed by the OECD and working groups of the FAO, without any consideration whether those are indeed fulfilling the requirements as foreseen by European regulations (which place a much stronger emphasis on the precautionary principle). So the international standards and bodies that are referenced by EFSA panels have to be assessed for their compliance with standards within the EU. A process of reviewing these standards should involve a broad range of independent experts and define higher standards for a comprehensive risk assessment. 3.During risk assessment, only a part of the available publications and findings are used to come to the final opinions; others are dismissed for several reasons. To be sure that standards such as GLP or OECD are not abused in dismissing relevant findings, a referee panel including a broad range of independent experts should be established for dealing case by case with the quality of publications that are taken into account or are dismissed by the expert panels. This referee panel should have the power to reintroduce relevant publications and findings that were already dismissed by the expert panels into the process of risk assessment again. The same mechanisms should apply concerning the comments of experts from Member States during the risk assessment of genetically engineered plants. So far only a small percentage of relevant comments by the experts of Member States is taken into account by the GMO panel and integrated in its final opinions. (also relevant for chapter 6,7,8,9)	

Eurogroup for Animals	5. Scientific decision-making processes	Section 5.1 - lines 95-97 - The possibility of self-tasking for EFSA is essential. It would be good to know what the general principles are on which a self-mandate is based and to establish a process for stakeholders to suggest topics to EFSA for self- mandates. Section 5.3 - lines 110-118 - We are very concerned about the way data is checked after collection, to ensure that the data received are reliable. Recent examples where official reports on the implementation of transport regulation must be provided to the European Commission have shown that data transmitted by Member States can be unreliable or incomplete. Data provided by Member States must be thoroughly checked before they are used, or EFSA's assessments could be based on misleading figures. Given that this report states the existence of an internal capacity in fields such as statistics it is essential that an internal, or external statistical expert(s) participates in all risk assessment processes to act in a QA capacity to validate all data upon which decisions are subsequently made. Section 5.4. - lines 119-125 - All stakeholders should be permitted to send an observer to attend working groups meetings. It is not clear from the document if this is allowed. In addition, the minutes that are currently published are not very informative about the content of the discussions and do not provide transparency to the process.	The points raised about data quality and quality assurance are very relevant even if they fall outside the scope of this document. They are addressed in the draft Science Strategy. Lines 119-125: EFSA is currently looking into the possibility of allowing the attendance of observers to its Scientific Committee and scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. This will be clarified in a revised version of the document.
Confederazione Nazionale Colduretti	5. Scientific decision-making processes	5.2 ll 107 While EFSA pretends avoiding case-by-case analysis and assessment as detrimental to a reliable and clear assessment, there are areas of work (ie, health claims) in which the case by case approach seems the milestone. Clarification on that is needed to gain an overall coherence. We believe that case-by-case analysis -if under a Guidance Document framework of reference- is in any case a base for risk assessment, and that individual characterization of the hazards needs a case-by-case analysis. For instance, the debate still going on Thresholds of Toxicological Concern (TTC) leans toward avoiding case-by-case assessment. We believe that to maintain Independence avoiding allegations of bias towards industry EFSA should carefully consider any departure from sound principles of risk assessment based either on ADI /NOAEL or MOE /BMDL principles.	Every assessment is done on a case-by-case basis. When a guidance document has been adopted, the competent Panel follows the approach outlined therein. This matter is also addressed in the draft EFSA Science Strategy.

Confederazione Nazionale Coldiretti	5. Scientific decision-making processes	5.1, ll. 83 97 In order to add clarity in front of the European citizens on EFSA's work, It could be helpful: • to explicit the level of self-tasking activities on the total. • To explicit the number of requests from the EC without private actors (applicants) behind • To explicit the number of assessments due to applications A formal guarantee that self tasking and public health responses cannot be overcome by private mandates could make sense. Or at least, to find some balance: a minimum numbers of self-tasking opinions as % on the total could be reasonably fixed in order to reflect independence. Furthermore, we note that in the document no reference is made about the still pending discussion on "fees" for applicants. Even if no conclusion has been reached, it could be relevant to include it in the debate, explaining what is going on. In particular, the new organizational chart poses great challenges with the formal separation between "commercial" Directorate (ie Regulated Products) and the Risk Assessment and Scientific Assistance. Since a new resources allocation is in place, a deeper explanation of the (possible) next moves could be done, enumerating the potential options at the time being and the virtual pros and cons of each one (fees, not fees, options for applicants having many requests, etc).	This draft document cannot be considered a comprehensive document providing all the background information for all EFSA activities. For facts and figures on EFSA scientific activities, please refer to the Authority's work programme, published on its website.
University of Tartu	5. Scientific decision-making processes	5.Scientific decision making processes 5.4. Working groups Lines 120- 125 It is not clear, e.g. kept timid, how many reviewers do investigate one particular project. From personal contacts with Panel scientists it has been known that due to the high workload of Panels only one person - here named as " RAPORTEUR of the working group presents the data which are thoroughly discussed, amended, endorsed by the working group." However, if the raporteur may make some mistakes (willingly, unwillingly) the Panel can't detect these and correct the statements offered by the raporteur even during the thorough discussions' in Panel. As a matter of fact, in the two rejections on probiotic bacteria of Estonia we detected fully wrong statements on the number of publications bound to the application of health claims. We have marked these in our Joint Comments to Mr. Basil Mathioudakis from March 11, 2011 Claim serial No: 0283_EE p. 3 and From May3, 2011 p.2, Claim ID 3025. Namely, in two separate cases the Raporteur did not find the Patented and printed issues on L. plantarum TENSIA and voluntarily dropped the papers of two clinical studies on L. fermentum ME- 3. The Panel took these false data as granted. Such a situation could not happen if there were more than one reviewer. This is the practice in EVERY evaluation Panel over EU: Why not in EFSA where so scientifically and economically hard decisions have been tried to compose. Please kindly correct the Procedure.	The use of a rapporteur to report on a preparatory work does not change the fact that the adoption of a scientific opinion is the result of a collective review and decision process. Regarding the specific case EFSA takes note of the comment, however no clarification is considered necessary on this point in the document.

BEUC	5. Scientific decision-making processes	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panellists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	See above
Federation of European Specialty Ingredients	5. Scientific decision-making processes	Lines 113 to 115: Concerned and impacted by the ongoing re-evaluation of already authorised food additives by the Panel on Food Additives and Nutrient Sources Added to Food (ANS), ELC members would suggest adding a reference to the case of data submission (i.e. unpublished studies, concentration levels) by stakeholders who are not necessarily 'applicants' per se, upon EFSA's requests. Besides in order to enhance the quality of the decision-making process from a scientific point of view, the ELC would suggest exploring which procedures, respecting EFSA's independence and confidentiality of information when applicable, could be put in place to avoid situations where the work of the EFSA Panel Working Group starts from an inaccurate basis by misinterpretation of the information delivered by industry: 1. At the time when all the data are collected, so that the data could be verified before the risk calculation is done. 2. At the end of the evaluation process, we would suggest that EFSA should give consideration to stakeholders having provided data and information by providing them an advanced copy in order to bring to the attention of EFSA factual inaccuracies when taking on board their contribution. Consideration could also be given to having an exchange of views with stakeholders when the exposure calculation raises concerns, before running the next tier.	Already today, EFSA regularly carries out public calls for data, in order to gather all the available and relevant scientific evidence. This is going to be reflected in a revised § 5.3. The second part of the comment falls outside the subject matter of the present consultation.

Food Standards Agency	5. Scientific decision-making processes	This provides a good overview of the processes involved. However, it would be useful to also include some text about how EFSA responds in relation to issues where speed is required in the context of meeting the overall objectives of this policy. The policy could also usefully include some discussion on how uncertainty is dealt with, both in terms of its acknowledgement and follow up action. In terms of approaches, mention could be made of how other aspects of scientific independence and quality control, such as related outputs from other risk assessment bodies and wider external peer review, contribute to the overall confidence in the independence of EFSA outputs. Section 5.2 – Development of methodologies Lines 102 -104: The policy currently points out EFSA's development of good risk assessment practices and methodologies to guide work of EFSA's Scientific Committee, Scientific Panels and its scientific staff, and there is a footnote which provides details of where more information can be found. It has been suggested that this section would benefit from being expanded a little to explain in more detail what the guidance is and how it can help to improve the scientific processes and standards eg how it compares to standard systematic review type approaches. Section 5.3 – Information gathering: data from Member States, applicants and scientific literature Should this section also specifically mention sources such as outputs from equivalent bodies from around the world eg WHO/FAO and how these are taken into account in EFSA's work. Line 110: More clarity is needed on the extent to which the policy of openness applies to data submitted by Member States. For example, there may be cases where data could be submitted to meet an EFSA deadline, before it has been possible to publish the data by a Member State. Member States should be able to flag up where data is considered to be sensitive, so that EFSA does not make it identifiable in the public domain until there is agreement to do so. Delaying submission of data until the evidence is published may mean missing an EFSA deadline, and this would be particularly anomalous if the data in question had originally been gathered in response to a call from EFSA. Lines 109-118: As referred to above, the importance of the social sciences could be highlighted more in this policy document, for example, in exploring food safety practices, particularly in light of EFSA's emphasis on risk communication and consumer trust. (The reference "Trust in Food" by Kjaernes, Harvey & Warde (based on comparative European research), is cited as demonstrating that sociological as well as technical issues are subject to wide variations across Europe.)	The scope of this consultation is limited to independence and related scientific decision making processes. However, these matters are rather fit in the draft EFSA Science Strategy.
FoodDrinkEurope	5. Scientific decision-making processes	After line 106: We appreciate the high standards of scientific processes and standards followed by EFSA used to develop good risk assessment practices and methodologies. Could the Policy also include provisions to ensure that such risk assessment practices and methodologies are executed in a harmonized and consistent way?	The scope of the draft policy is limited to ensuring the appropriate framework for ensuring EFSA's independence. It cannot be considered a Science Strategy or a comprehensive document providing all the background information for all EFSA activities. However, these matters are addressed in the draft EFSA Science Strategy.
University College	5. Scientific decision-making processes	The Authority's core values are sometimes challenged when mandates are under negotiation because there is a perception that food safety is a food quality parameter and not a stand alone criterion that is a sine qua non for trade in food. This misclassification has to be guarded against both within and outwith the Authority. As an example see the EC's SCVMPH Opinion on Meat Inspection adopted 20-21 June 2001, a document that currently has been offered for consideration by EFSA Panels when addressing a number of mandates.	EFSA acknowledges the importance of differentiating food safety from food quality, which indeed is not related to EFSA's mission.

		EFSA's core values are sometimes challenged in the course of negotiation of mandates. There is a perception by those posing the question that food safety is one of a number of food quality parameters. This tendency has to be guarded against both within and outwith the Authority; otherwise the objectivity and primary function of the Authority is open to compromise. Food safety is a sine qua non for trade in food at every level and is not to be regarded or classified as another food quality "aspect" e.g. see Opinion of SCVMPH on meat inspection adopted 20-21 June 2001.	
C. R.I.S.K. Consultancy	5. Scientific decision-making processes	Re: Sec. 5.3: Founding Reg. Art. 33 is not explicit, but if you do desire that scientific data be "fit for purpose" (lines 117-8), you cannot deny the logic that you must gather ALL available scientific data on an issue. Additionally you have some mandates to do exactly that, e.g. the new pesticide regulation (REACH also mandates that). So please state in this guiding policy statement that EFSA will always search for all relevant information on an issue before it, including (explicitly) the independent published scientific literature (always simply found in one database, PubMed). In evaluating the quality of the data, you must explain why the PPP mandate to collect it all does not imply that each study's quality should be evaluated. Instead, you simply declared any study not meeting a very narrow quality standard (e.g. Klimisch score, featuring OECD Guideline & GLP. All such studies that you accept as high quality in fact have a massive design flaw, the party with huge pots of money to make in it being declared safe enough to use gets to do the safety studies, including the key NOAEL setting study. These studies have other massive flaws, including only testing a tiny portion of the D/R curve; and killing the animals before they have a chance to develop hardly any disease that may have been induced. In sum, please make it clear that you will always both collect, and fully analyze, all available scientific data on a question, instead of grossly and with bias throwing out data when the EU forces you to collect it. Looking competently at all data is after all is why you were created!	The scope of the draft policy is limited to ensuring the appropriate framework for ensuring EFSA's independence. It cannot be considered a Science Strategy or a comprehensive document providing all the background information for all EFSA activities.
Robert Ollinson, independent consultant on food issues	5. Scientific decision-making processes	A very important difference is that once an opinion is published, it's published. What you need to have in the process is a process whereby the draft opinion can be scrutinised by independent science. I've spoken to an awful lot of independent scientists who are very frustrated about this, who would get involved, who would like to get involved, but they're not in a position to because they're not on the panel. So, if you could look at ways of opening that up to the wider scrutiny, which only goes along with the normal peer review process, then I think you would be overcoming an awful lot of problems.	EFSA is committed to engaging in a continuous dialogue with its interested parties to constantly improve its scientific outputs. This is already reflected in the current document. EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will however be revised in order to clarify this aspect and to link this to quality control.

Didier Yance	5. Scientific decision-making processes	When the risk assessment methodology are established, and that's maybe an area we should invest more dialogue and more effort. Once the methodology is there most of the people will behave in a fair way.	EFSA is committed to engaging in a continuous dialogue with its interested parties to constantly improve its scientific outputs. This is already reflected in the current document. EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will however be revised in order to clarify this aspect and to link this to quality control.
Nina Holland, Corporate Europe Observatory	5. Scientific decision-making processes	What we think should be changed is that there should be a strong conflict of interest policy, EFSA should proactively go out and call for independent scientists to join the EFSA panels and not just wait and see who replies to the call of interest (...)	This has been indeed an ongoing practice at EFSA for a few years. When it publishes a call for expression of interest for membership of its SC and SP, EFSA also proactively disseminates this information and tries to trigger as many qualified applications as possible.
6. EFSA's Scientific Committee and Panels			
Euro Coop	6. EFSA's Scientific Committee and Panels	Lines 133-135: As regards the composition of the Scientific Committee and Scientific Panels, Euro Coop very much welcomes the acknowledge from EFSA of the importance of guaranteeing the diversity of scientific expertise and disciplines. Euro Coop indeed considers that the effective application of this principle is essential to provide high-quality independent scientific advice.	No need to make changes in the draft policy.
Sanofi	6. EFSA's Scientific Committee and Panels	6.1 Selection of experts [lines136-146] Access to EFSA's external expert database is currently restricted to the agency, member states, EEA/EFTA countries and the European Commission with their declaration of interests only accessible to EFSA (see EFSA's document on the selection of scientific experts, p.10 http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf). To enhance transparency, we propose that this information is posted on EFSA website or could be available to stakeholders on request.	EFSA will explore the feasibility of this suggestion, but there are data protection issues which may prove problematic to overcome concerning the sharing of personal data. The text will not be revised.

National Food Institute	6. EFSA's Scientific Committee and Panels	Further comments from the National Food Institute: C. Section 6 .1 'Selection of experts' presents a clear and transparent procedure for the selection of experts for EFSA's Scientific Committee and Scientific Panels. However, there would not seem to be similar clear and transparent procedures for the selection of experts for working groups. It would be interesting to have this discrepancy explained, or maybe simply describe a transparent selection process for working group members also. D. Since EFSA, the European Commission and Member States all have an interest in the coordination of international food safety work, as pertains both risk assessment and risk management, it would seem remiss to not include in a paper of this nature a mention of the need for further international collaboration, also in relation to conflict of interest rules. More specifically a number of FAO/WHO risk assessment bodies would seem to operate under conflict of interest rules described in the UN system. Would it make sense for an EFSA policy paper to in some way acknowledge the need and potential for further international coordination also in this area? Best regards, Jørgen Schlundt Deputy Director	C. For, what concerns external experts, they are selected via a procedure that taking into account the fact that draft outputs prepared by working groups are discussed, amended and, when appropriate, adopted by Panels, corresponds to the same criteria used for the selection of members of the SC and SP. This will be clarified in the revised text of the draft Policy. D. The text will be revised clarifying that international cooperation will be sought in the field of conflict of interest and independence and that benchmarking with international bodies and partners will be maintained.
National Food Institute	6. EFSA's Scientific Committee and Panels	As the independent national risk assessment body of Denmark the National Food Institute has the following comments/questions to above mentioned document: A. Under the section 4 'Organizational governance' the texts seems to suggest that the functional separation of risk assessment and risk management is only effectuated at European level, i.e. not at national level. As we are aware that this functional separation also governs deliberations in a number of Member States, including Denmark, it would make sense if the text is revised to reflect this important state of affairs. Likewise the text in this section would seem to suggest that European risk assessment is performed only in EFSA. It would again be important if the text could reflect present reality, which is that basic scientific risk assessment work in Europe is performed primarily in Member States, while EFSA performs the important task of integrating and jointly evaluating such risk assessment data, permitting joint European scientific agreement in key areas. B. In section 9 'Organisational culture' the paper refers to the set of comprehensive EFSA rules and procedures for identifying and handling potential conflicts of interest. This procedure specifically states	A. The text can be revised to clarify that the separation of risk assessment from risk management applies also in some Member States and that Member States also carry out risk assessments.

		that earlier involvement in an opinion of a national authority may constitute a conflict of interest. The background for this principle is not clear. It should be noted that if the reciprocal situation was implemented a national panel member having been involved in risk assessment work for EFSA would not be entitled subsequently to engage in risk assessment work at national level, because of CoI. This outcome would presumably hinder the members states' experts participation in EFSA panels. Conflict of interest rules are typically implemented so that managers, stakeholders and society at large can be sure that undue influence is avoided when scientific risk assessment is developed. It would not seem clear – and would thus most likely be impossible to communicate – how the participation in previous scientific work regarding the question at hand would in itself constitute a conflict of interest? More specifically the implementation of these procedures would seem to result in a situation where Panel Members who participate in drafting opinions under EFSA contracts can potentially have a conflict of interest. The consequence of this will in some cases lead to situations where another expert in the Panel, who has not been involved in the assessment, would have to present the opinion at the Panel meeting, resulting in a sub-optimal use of resources, and in some cases a poor scientific outcome. Finally it would be interesting to have a clarification if earlier involvement in an opinion of an international authority may also constitute a conflict of interest? It is suggested to change this practice and have clear, concise and communicable procedures for implementation of these policies, avoiding listing previous scientific work per se as a potential for conflict of interest.	B. For, what concerns the comment on the assessment of previous involvement in a national authority, it should be borne in mind that in some specific instances it may be considered appropriate to consider that interest as a CoI, for instance when an expert from a NCA is called upon in EFSA to assess an opinion to whose development he or she has actively contributed.
Testbiotech	6. EFSA's Scientific Committee and Panels	See chapter 5	See above
Anses	6. EFSA's Scientific Committee and Panels	It could be appropriate to precise the selection criteria and procedure for the experts working in the EFSA WG.	For, what concerns external experts, they are selected via a procedure that taking into account the fact that draft outputs prepared by working groups are discussed, amended and, when appropriate, adopted by Panels, corresponds to the same criteria used for the selection of members of the SC and SP. This will be clarified in the revised text of the draft Policy.
Eurogroup for Animals	6. EFSA's Scientific	Section 6.2. - lines 152-154 - EFSA does not currently 'prevent any form of bias of its output.' See point above about making a decision based upon available and potentially 'biased' data.	Lines 152-154: See above

	Committee and Panels	Section 6.3. - line 156 - If EFSA committees, panels and working groups are purely populated by scientists this in itself introduces a bias to the decisions. A mix of individuals with scientific, veterinary and/or medical backgrounds would be more appropriate given EFSA's remit.	Line 156: This is already the case now, as EFSA's interpretation of the term "scientist" includes also veterinarians, food technologists, statisticians, medical professionals, etc. The text will however be revised in order to clarify this aspect.
Confederazione Nazionale Coldiretti	6. EFSA's Scientific Committee and Panels	Par. 6.3 Collegial decision making We think that could really be helpful for a wider EFSA's acceptance in front of the external public to open up sometime some panels to observers. This proposal was formerly advanced by the EFSA's Legal Office. We think there are enough international successful cases in many agencies on that to speed up the implementation of that policy	EFSA is currently looking into the possibility of opening up the meetings of its Scientific Committee and Scientific Panels when horizontal matters are discussed. In 2012, EFSA will test the feasibility of opening up the Risk assessment process to observers from interested persons. The text will however be revised in order to clarify this aspect.
Confederazione Nazionale Coldiretti	6. EFSA's Scientific Committee and Panels	6.1, ll. 142-145 . Coldiretti welcomes the new ESS (Expert Selection System) and linked new electronic format of Declaration of Interests. In fact, it can be really helpful in tracking along time and over years potential conflict of interests which can raise prejudices on the EFSA's independence.	No need to make changes in the draft policy.
BEUC	6. EFSA's Scientific Committee and Panels	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panellists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	See above

ILSI Europe aisbl	6. EFSA's Scientific Committee and Panels	Line 137-139: "Public-private partnerships are an established feature of research in the EU and worldwide and hence many of the scientific experts who contribute to EFSA will inevitably have links with the private sector." In our opinion, this statement does not adequately reflect the importance of public-private partnerships. We therefore would like to propose the following change to the text cited above: "Public-private partnerships are an established feature of research in the EU and worldwide. They greatly stimulate innovation (e.g. OECD 2004) and thereby human progress. Also, public-private partnerships are a key element in the 'fifth freedom' (free circulation of researchers, knowledge and technology) that should stimulate European competitiveness as outlined in the vision for the European Research Area (European Council, 2008). Hence, many of the scientific experts who contribute to EFSA will inevitably have links with the private sector." European Council (2008) Council conclusions on the definition of a "2020 Vision for the European Research Area" (http://register.consilium.europa.eu/pdf/en/08/st16/st16767.en08.pdf). OECD (2004) Public-private partnerships for research and innovation: an evaluation of the Dutch experience (http://www.oecd.org/dataoecd/49/18/25717044.pdf).	As this comment is in line with the overall Union policy on research, the text will be revised accordingly.
Food Standards Agency	6. EFSA's Scientific Committee and Panels	There is broad support for the independence of scientific experts championed by EFSA both in the way that experts are recruited to EFSA's Scientific Panels and the proportionate and pragmatic approach to potential conflicts of interest.	No need to make changes in the draft policy.
FoodDrinkEurope	6. EFSA's Scientific Committee and Panels	After line 158: Are there general rules established for the decision making process to adopt the output of the Scientific Committee, Scientific Panels and Working Groups (eg. How is a consensus reached, when is a majority decision taken...).	Those rules are foreseen in the rules of procedure of EFSA's scientific committee, scientific panels and their working groups, as clarified in § 6.2 of the document. However, as the scope of the document is limited to independence, the text will not be revised.

Federal Institute for Risk	6. EFSA's Scientific Committee and Panels	Line 130-135: While the selection procedure for EFSA's Scientific Committee and Scientific Panels is laid out in detail, this section provides no information regarding the selection of experts for the working groups. As the working groups carry out the basic work for the risk assessments of the Scientific Committee and the panels, a transparent selection process for the working group members might be necessary and is strongly recommended. Therefore a reference with regard to the selection of working group members in this chapter might be useful.	For what concerns external experts, they are selected via a procedure that taking into account the fact that draft outputs prepared by working groups are discussed, amended and, when appropriate, adopted by Panels, corresponds to the same criteria used for the selection of members of the SC and SP. This will be clarified in the revised text of the draft Policy.
ADAS UK Ltd	6. EFSA's Scientific Committee and Panels	Line 136: In addition to using experts from academia and research organisations, EFSA should explore the feasibility of making greater use of experts working in the commercial sector. Many of these are highly qualified individuals involved in the practical application of science, and their participation in Panels and Working Groups would enhance EFSA's risk assessment process. Potential problems associated with conflicts of interest can be avoided through the DoI process.	EFSA tries to gather all relevant scientific views through its meetings with hearing experts, who are invited to present their views to the scientific meetings irrespective of CoI. However, they do not become members of the SC/SP and cannot be involved in the drafting of EFSA's output. The text will be revised accordingly.
Delft University of Technology	6. EFSA's Scientific Committee and Panels	EFSA's committee, panels and working groups are collegial bodies, yet experts may adopt a minority opinion. As far as I know, the experience also in other agencies is that this rarely happens. The question is whether this is because deliberation has led to consensus among experts or whether consensus is forced upon experts. How does the agency ensure the former, while avoiding the latter? A key question underlying the scientific decision-making process is what criteria are used. Only scientific or also non-scientific (which are not necessarily political) criteria? Different from other agencies, notably EMA, where national authorities are represented in the board and their experts are involved in the assessment work, EFSA does not co-opt the national authorities in its managerial or scientific decision making structures (the Advisory Forum is merely consultative). How then does the agency involve national authorities and make sure their concerns are heard, whilst not compromising its independence?	This document is about EFSA's policy on independence and does not provide a detailed overview of all the processes and workflows enacted by the Authority. In its deliberations, only scientific criteria are used, and national authorities are regularly consulted via dedicated *fora* or networks and networking activities.
PAN Europe	6. EFSA's Scientific Committee and Panels	• ILSI, SETAC, etc. do not allow people who are heavily involved in industry lobby clubs to be represented in EFSA. On European level the organisations threatening independent science most are the many industrial "NGO's" like ILSI, ECETOC, SETAC etc. who are fully industry-sponsored and are no more than industrial lobby clubs. EFSA should keep full distance [from] these organisations. The EFSA meeting on genotoxic carcinogens sponsored by ILSI in November 2005 for instance was a big mistake and threatens EFSA's impartiality. This should never happen again. ILSI is restricted of access to WHO because ILSI	This is a public consultation on a draft policy document. No discussion of specific cases is allowed in this context.

		'has a demonstrated history of putting the interests of its exclusively corporate membership ahead of science and health concerns' (http://www.powerbase.info/index.php/ILSI). People who are heavily involved in these lobby-lubs like Alan Boobis who was even in Board of ILSI, and who is in EFSA panels and others like Harry Kuiper (GMO-panel), Angelo Moretto (PPR-panel formally), John Christian Larsen and Gerrit Speijers (ANS-panel), should never be allowed to participate as a neutral scientist. Reports published by CEO, EOS and Testbiotech should have alarmed EFSA. Being prominent in ILSI and similar means you are happy to endorse industrial campaigns on lowering safety factors, eliminating data requirements and opposing hazard approaches. If you would do a simple Science Direct-search for Boobis, you would see that his last 20 articles are mainly ILSI-opinions (no real science but largely proposals for deleting tests and reducing costs for industry) most likely written by ILSI staff and Boobis functioning as ghost writer to make it look independent given his 'flag' of university professor. Independence is the victim if you allow these people in EFSA panels. It is very remarkable to see that the one from EFSA responsible for this very consultation (Banati) was at the European Board of directors of ILSI. • Do not allow people in EFSA's panels from institutes/universities who have contracts or grants of any pesticide producer or intermediate to a pesticide producer, nor commission work to people of these institutes. Many institutes and universities are forced to get money from the market given the reduced grants available from governments. They turn to companies and loose their independence. It is widely known if you are commissioned to do a study for industry, an unfavourable outcome is not appreciated very much by the contractors and the automatic search for an alternative outcomes starts. If you start compromising, you loose your independence. We see for instance Institute ALTERRA getting parts of their work paid by industry while at the same time they work for Dutch pesticide authority CTbG and are part of EFSA's panels like in the case of Theo Brock. ALTERRA was also heavily involved in higher tier risk assessment methodologies HARAP and CLASSIC, sponsored by industry. These methodologies are part of European guidelines. If you want to get to a full independence, these links should prevent anyone being member of an EFSA panel. Any financial link between an institute and a commercial party is corrupting science. The policy of industrial spin doctors of course is get full grip on science (see book "Doubt is their products, Michaels, 2008) and eliminate independence.	Already today in the context of EFSA's policy on DoI experts who have been employed by a certain company or have provided advice to that company are automatically barred from participating to discussions on a product from that company. The text however will not be revised as this kind of detailed rules will be specified in the single implementing document on DoI.

7. Other elements of quality assurance			
Euro Coop	7. Other elements of quality assurance	Line 168: Euro Coop very much supports the objective of strengthening the dialogue with the civil society. Euro Coop welcomes the efforts to regularly consult and meet interested parties on key issues. Euro Coop indeed believes it is a key priority that should be supported further in order to guarantee a fair balancing of interests. Line 185: Euro Coop considers that guaranteeing full transparency of EFSA' scientific decision-making process is fundamental. Euro Coop would thus suggest EFSA to allow European citizens to access all documents supporting the scientific decision-making process, including the scientific advices which might be the most sensitive.	Line 185: EFSA has been doing this for years. All non-confidential supporting documents are either proactively published in EFSA's Register of Questions or are accessible upon request. In addition, EFSA has just created an Application Desk as a front office and support desk for applicants, Member States and other stakeholders who have questions regarding applications. In the future, it will also be responsible within EFSA for centralising and processing the initial administrative steps of all applications. This is clarified in § 7.2.
Sanofi	7. Other elements of quality assurance	7.1 Consultation: scientific experts from Member States, civil society, interested parties and partners [lines 167-183] Sanofi considers that a close collaboration with the European Commission and SANCO related agencies is critical for shaping a transparent and predictable regulatory framework and harmonized scientific decision making process in the field of food, health animal and plants-related work. We will welcome more regular interactions between these EU bodies and that a workplan of the activities undertaken under this collaboration be made public with outcome of the discussions.	Lines 167-183: While respecting EFSA's independence from Union risk managers, EFSA is fully committed to ongoing and systematic interaction with these, including DG SANCO. EFSA has put in place a series of arrangements that ensure effective interaction with the Commission (bilateral meetings, systematic presence of Commission officials at EFSA meetings, presence of SANCO representative on EFSA's MB etc).
Testbiotech	7. Other elements of quality assurance	See chapter 5	See above
Eurogroup for Animals	7. Other elements of quality assurance	Section 7.1. lines 167-174 - It is not clear who "partners" are and how networks are formed and used. It would be good to add a reference to EFSA's webpage on existing networks. It would be good for transparency reasons to also publish the annual workplans of these networks. line 178 - The term "hearing" experts might be confusing, especially when they are invited to participate in discussions. It is not clear from this section of the document to which meetings these experts are invited, who selects them and on what basis. This should be clarified, as should the statement that 'they are invited to participate in discussions...without directly influencing the scientific decision making process.'	Lines 167-174: The reference to the EFSA webpage on networks will be included in the revised text. Line 178: The text will be revised to clarify the role of the hearing experts, and to which fora they are invited.

		lines 182-183 - Inviting stakeholder experts to technical meetings or workshops is very important, but the stage of the process at which workshops are organised is important too and it is not clear from the document that these workshops take place early enough to allow the results to feed into the preparation of EFSA's opinions and scientific reports. For example a technical meeting on transport took place only 6 weeks before final report which is a very short time to take the external stakeholders input into account. Section 7.2. lines 188-189 - The principles to be applied, as exposed in the guidance document linked to note 18, in paragraphs Data and data sources and Inclusion and exclusion of data, would not detect the risk of having wrong data submitted, especially by the Member States.	Line 182-183: This document is about EFSA's policy on independence and does not provide a detailed overview of all the processes and workflows enacted by the Authority. Lines 188-189: The suggestion is already addressed by the text in § 5.3.
BEUC	7. Other elements of quality assurance	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panellists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	See above
Food Standards Agency	7. Other elements of quality assurance	Section 7.1 – Consultation: scientific experts from Member States, civil society, interested parties and partners. The arguments regarding public and stakeholder consultation would be enhanced if there was evidence cited of how the outputs have impacted on subsequent policy. Section 7.2 – Process transparency Lines 185-186: Consideration should be given to openness and the publication of industry dossiers. For example in the food allergy area, the exemptions from labelling requirements for a number of highly processed derived ingredients were based on dossiers submitted by industry, but the evidence, and more crucially the specifications for the derived ingredients, were not published. Highly refined soya oil is exempt from allergen labelling but the detailed refining process and the specification of the oil were not included in the EFSA opinion, which makes it difficult for businesses to know whether or not their specific ingredient should be labelled or not. Section 7.3 – Quality review programme Lines 192-193: The high quality of EFSA's scientific outputs is an asset in itself, for example in areas likely to invite public controversy, such as public perception of GMOs. At the end of line 192 should the word "programme" be replaced by "review"?	§ 7.1: After each public consultation, EFSA publishes a report outlining all the comments received and whether and how they were addressed in the final text. This document is not supposed to analyse the outcome of previous consultations, but simply to explain the different rules and policies in place that ensure the institutional independence of the Authority.

			Lines 185-186: EFSA is obliged already now to make public all background documents used for its scientific opinions but for those documents that are considered confidential by the Authority or by the Commission, when that is foreseen by the applicable legal framework.
			Line 192: The text will be revised.
PAN Europe	7. Other elements of quality assurance	• Develop strict rules on stakeholder participation and full balance in participation. We know industry lobbyist are knocking on EFSA's doors continuously to be involved in EFSA meetings as an "independent" expert. And we know, depending on the chairs of the meeting of EFSA, industry experts were invited in meetings while in no single case NGO's representing consumers were invited as an expert. So we would propose to develop a strict EFSA policy: it is either a stakeholder meeting with a balanced representation (one person from each 'interest' only) or a scientific meeting where never an industry representative should be allowed in the room.	Today EFSA does not allow industry representatives to take part in its scientific meetings, with the exception of hearing experts, whose presence is justified by the business need of acquiring certain data or information.
Bavarian health and food safety authority	7. Other elements of quality assurance	There is no definition for "key scientific issues" (L170) and therefore it remains open when a public consultation is (has to be) initiated. Both, the choice of the members of the network and the selection of topics for public consultation are subjective processes. This offers the possibility to intentionally exclude certain interested parties and to avoid certain scientific conflicts. A general inclusion of public consultations would rebut this objection and allow all interested parties to be heard.	This draft document aims at providing the necessary background information for the reader to conclude on EFSA's institutional independence.
R.I.S.K. Consultancy	7. Other elements of quality assurance	Sec. 6-10 my comment of issue of the critical issue of conflict of financial interests (fCoI) On lines 142-4 you say a consulted expert is forbidden if you decide their fCoI is of a too great "magnitude". Yet for staff you say you tolerate no fCoI at all (lines 208-9). Under your founding regulation, how can you tolerate such a discrepancy? Rather, given the thousands of fCoI-free academics who are expert in your various issues, is not your mission better served by recruiting experts without fCoI? After all, as the former editor	Lines 142-144: The legal basis for staff on conflicts of interest provides a broader basis for action compared to the provision on independence laid down in Article 37 of Regulation (EC) No 178/2002.

		of the BMJ Richard Smith once wrote, none of us can say what the effect of money on our subconscious and our actions really is (needs of our family, the prestige of being part of a powerful organization, etc. etc.). In fact, your mandate that EFSA parties shall undertake to act independently (line 218) is literally impossible once the nexus between the scientist or evaluator/staff and the financial benefit has occurred. You must acknowledge that there is no such thing as a potential fCoI, and state that you will strive much harder to eliminate all non-insignificant fCoI from your staff and advisors. That will minimize the bias to scientific data that money may have caused. On line 242 it is critical you delete from your definition of an fCoI the elective word: "...are CONSIDERED incompatible with that person's role" -- make it mandatory instead: "...are in conflict with that person's...".	Line 242: The definition will be revised to incorporate the OECD definition of CoI (2007).
8. Enhanced contribution of scientific staff			
Euro Coop	8. Enhanced contribution of scientific staff	Lines 203-206: Euro Coop welcomes the efforts to re-define working methods developing a strategy which foresees the employment of internal resources for scientific advice. This could be a solution in further guaranteeing EFSA's independence - but we wish to underline that it could be undermined if fees should be introduced.	No need to make changes in the draft policy.
Testbiotech	8. Enhanced contribution of scientific staff	See chapter 5	See above
Eurogroup for Animals	8. Enhanced contribution of scientific staff	Lines 203-204 - See above point regarding the requirement for internal, or external statistical experts to review and validate data prior to its use within the decision making process.	See above

BEUC	8. Enhanced contribution of scientific staff	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panelists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be a member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferential treatment and could affect EFSA's work on ensuring transparency and independence.	See above
Delft University of Technology	8. Enhanced contribution of scientific staff	On the independence of EFSA staff: Through the scientific and technical advice and secretarial support they provide, staff may in practice exert an important influence over the scientific decision-making process. It is therefore of great importance that they fulfill their tasks independently. In this light, one should be careful with enhancing the contribution of scientific staff, as is suggested under section 8. Whereas a minimal level of in-house scientific expertise is of course necessary for the agency to function, building up a permanent scientific staff (and relying less on external experts) could turn out to be detrimental for the agency's independence, as it could be difficult to control this group of internal experts. Scientific advice has to come from many different sources and be decentralized for both scientific demands and the agency's independence.	Internal scientific staff are already now involved in several scientific activities, including the drafting of certain EFSA's scientific outputs. However, an enhanced contribution from EFSA staff would be fully subject to the requirements of independence and impartiality applying to all EU staff. They would work full time with the agency, which would have control on any activity outside the institutional ones, including speeches and publications. This would prevent insurgence of conflict of interest with industry, other interested parties and national authorities. Finally, this body of internal scientists would not replace members of the Scientific Commitee, Scientific Panels or external experts, nor networking activities with Member States, but rather ensure an additional source of available scientific knowledge.

9. Organisational culture			
Corporate Europe Observatory	9. Organisational culture	We strongly object to the following statement: “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.” (231-234) Instead of using the current situation whereby privatisation of public research is being promoted by the EU and national governments alike (‘public private partnerships’), EFSA should demand a flourishing public research environment with its main clients: the EU institutions. It should also demand the resources to pay experts, so that public scientists More particularly, the EFSA Declaration of Interest system does not prevent Conflicts of Interest, and leaves it up to ad hoc decisions by heads of unit to decide when a CoI exists and to take measures. As we point out in our article published 15 June 2011 on conflicts of interest on the ANS panel, EFSA does not have any rules excluding anyone a priori from joining its panels, but instead makes decisions based on the individual case. This is unacceptable. There needs to be a list of clear criteria to exclude for example experts with affiliations to industry-alike institutions in particular industry lobby groups like ILSI. The definition given in the policy paper is ambiguous to the extreme: Conflicts of interest which shall be considered as any “situation whereby one or more of the interests held by, or entrusted to, a single person are considered incompatible with that person’s role in the context of his or her cooperation with EFSA”. Considered by whom? Based on what criteria? Stricter rules on conflicts of interest and fundamental changes in the way EFSA opinions are shaped are urgently needed. EFSA should also proactively identify and recruit independent experts for its scientific committee and panels. On cases of "revolving doors", the draft policy states: In order to foster even further the general obligation that EFSA staff operate in the public interest, EFSA has adopted implementing rules of the Staff Regulations that bind all EFSA staff leaving the Authority to get a prior authorisation for any occupational activity that they intend to engage in over a period of two years after the termination of service with the Authority (273- 276) But considering the ways in which the "revolving doors" cases of	Lines 231-234: EFSA’s role is limited by law to providing scientific advice or scientific and technical assistance to EU Institutions or Member States.

		Laura Smillie and Suzy Renckens were handled by EFSA, CEO considers that significant changes are needed to both the staff regulations, and how they are implemented, to ensure that they are effective in preventing conflicts of interest. These changes include: 1.Agreement on a comprehensive definition of conflicts of interest. 2. A mandatory cooling-off period of at least two years for EFSA staff members from entering lobbying or lobby advisory jobs 3.A clear ban on any EFSA staff member undertaking a sabbatical which involves lobbying 4.A clear ban on any EFSA staff member starting any new external post within two years of leaving an EU institution until authorisation has been given for the post concerned under the staff regulations. Application to all staff working in EFSA (including those on temporary or fixed-term contracts). 6. Application to all those joining EFSA who go through the "reverse revolving door". In practice, this would mean a mandatory two-year cooling off period for all staff joining EFSA from a lobby job.	Lines 273-276: EFSA is implementing the rules of the Staff Regulations. After having learnt some lessons from past cases, EFSA has adopted a strengthened framework decision for staff who leave EFSA, which better details the process and the steps that are to be followed. This has already been successfully implemented in one case, with the application of certain limitations to the staff member leaving EFSA. In addition, a DoI screening system similar to that adopted for experts has been applied also to staff members (administrators, contract agents FG IV and seconded national experts). This allows the Appointing authority to have at any time a complete picture of the interests of her staff, with a view to preventing the occurrence of a CoI (such as reassignment).
Imperial College London GBR	9. Organisational culture	Line 244: Reference is made to the "DoI pillar of this policy is implemented by a single decision of the Executive Director". It is not clear what this will entail, and whether there will be further detail that is publicly available. If so, no date is given for this occurring.	The content of the single implementing decision is described in lines 244 to 260.
Testbiotech	9. Organisational culture	See chapter 5	See above

BEUC	9. Organisational culture	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panelists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferrential treatment and could affect EFSA's work on ensuring transparency and independence.	See above
ILSI Europe aisbl	9. Organisational culture	Lines 244-260: Is the implementation document the same as mentioned in line 279, and will it be open for public consultation?	Yes, it is the same implementing document. The principles of the implementing document are discussed in the draft policy. The public consultation and the workshop provided the appropriate opportunities on gathering suggestions on how to improve that further.
FoodDrinkEurope	9. Organisational culture	After line 258: There is an urgent need for clarity and transparency as to what is in the 'implementing document' and in particular precision as to whether being associated with exactly which, if any, non-profit science organisations would be considered a conflict of interest for scientists working in EFSA panels.	The principles of the implementing document are discussed in this policy. For the rest, the implementing document will build on the present Policy on Declarations of Interest adopted by the Board in 2007. That Policy does not differentiate between for profit and not for profit entities.

Federal Institute for Risk	9. Organisational culture	In line 224, the EFSA Document "Implementing Act to the Policy on Declaration of Interests: Procedure for identifying and handling potential conflicts of interest" is referenced as footnote 22. Chapter C III of this EFSA document (i.e. footnote 22) explains the procedure to assess and decide on potential conflicts of interest. Chapter C III No. 6 specifies the following: "…earlier involvement in an opinion of a national authority that will be assessed by the Scientific Committee or Panel may cause a conflict of interest for the concerned person". BfR strongly suggests revision of this exclusion clause for the following reasons: Regulation (EC) No 178/2002, the Founding Regulation of EFSA, states in preamble (51) the need to involve Member States in scientific procedures of EFSA and that EFSA is to assign certain tasks to organisations in the Member States. In addition Article 22 (7) states that EF-SA "…shall act in close cooperation with the competent bodies in the Member States carrying out similar tasks to these of…" EFSA. Considering above cited regulations, including recently published EFSA guidelines such as the brochure "Scientific Cooperation between EFSA and Member States", involvement of national experts in a national risk assessment is in our view a proof of competence and should be an asset to the group rather than a conflict of interest. In addition, mutual recognition of risk assessments conducted by risk assessors in Member States would help to enhance further cooperation between EFSA and the Member States in order to avoid double work, to use European resources efficiently and to relieve EFSA's scientific panels of their increasing workload. Recusing experts of national risk assessment bodies would impede the mutual assistance in the field of food safety, which is ultimately demanded in Regulation (EC) No 178/2002, Article 22 (7) and preamble (51). Cooperation of EFSA and Member States in the risk assessment of pesticides (PRAPeR, Pesticide Risk Assessment Peer Review), is an example for close cooperation between national risk assessors and EFSA. In a peer review process conducted by EFSA and MS the draft assessment report (DAR), which was prepared by risk assessors in one MS, is finalized and forwarded to the European Commission. This process supports the formation of a shared vision within EFSA and MS and increases the robustness and quality of the assessment. Therefore, it has been suggested to apply this approach to risk assessment activities in fields other then PRAPeR, e.g. novel foods or health claims. In the light of reasons listed above, it is not evident why the involvement of an expert previously involved in a national risk assessment might bear a conflict of interest when serving in EFSA panels or EFSA working groups. As a result of the present EFSA public consultation the "Implementing Act to the Policy on Declaration of Interests: Procedure for identifying and handling potential conflicts of interest" should be amended as described above. This amendment should be pointed out in the final and revised EFSA document on "Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority".	EFSA's cooperation with member states' authorities should not be confused with the independence of the members of EFSA's Scientific Committee, Scientific Panels or of their Working Groups. In this respect it should be borne in mind that in some specific instances it may be considered appropriate to consider that interest as a CoI, for instance when an expert from a NCA is called upon in EFSA to assess an an opinion to whose development he or she has actively contributed.

Delft University of Technology	9. Organisational culture	Beyond declarations of interests: Throughout the draft policy, a lot of attention is paid to the declarations of interest that members of EFSA's bodies are supposed to submit. However important such declarations may be, they are not more than "paper promises"; it eventually comes down to the actual practice of the members of EFSA's bodies, ie whether they refrain from activities that could result in a conflict of interest or that are likely to be perceived as such by the public. In this regard it is also important to point out that in order to refrain from such activities, the members of EFSA's bodies should all be fully aware of the (kind of) activities that could result in a conflict of interest or are likely to be perceived as such by the public. In other words, there should be some level of common understanding of what are such activities and shared norms about the desirability to refrain from them. This not only requires individual members of EFSA's bodies to submit declarations of interests, but also necessitates active efforts from the organization and its management to foster a common understanding and shared norms, all the way from recruiting people, to training and promoting them (as well as, if necessary, firing them). The draft policy - even though it has a section 9 titled 'organizational culture' and the first paragraph of this section does indeed outline some of the agency's efforts - could be much more specific on the arrangements used to nurture a real culture of independence in which conflicts of interests are simply 'not done'.	As clarified in § 9, EFSA does organise training sessions for its staff and for the scientific experts so that they are fully aware of what they are expected to declare.
Rod Harbinson, independent consultant (CEO)	9. Organisational culture	My question to EFSA is: have you considered looking at approaches to a grading system because I think that the EMA has, and you're all regulatory organisations together and there may be lessons to be learnt.	EFSA's Policy on DoI foresees since its adoption in 2007 a grading system comparable to the one enacted by EMA in 2011. However, the text will be revised to clarify that the new implementing act will better detail that grading scheme.
Nina Holland, Corporate Europe Observatory	9. Organisational culture	(...) what I found interesting in the morning session, the European Medicines Agency has developed a new policy setting clear criteria for interests that are not allowed on the panels, that is a radically different approach from EFSA. My question to EFSA right now is why don't you consider a similar approach as the EMA?	
Ortwin Renn, University of Stuttgart	9. Organisational culture	(...) it would be very important to see that interest is not just economic interest and I think we are negating and we are denying all social science evidence that commitment to one course or the other can be caused by money, by power, by prestige and by value commitment and they are equally strong... if you just stigmatise economic bias we are on the wrong path.	It is widely acknowledged that CoI can be also of a non-economic nature. EFSA's draft policy tries to capture all relevant interests that may be considered prejudicial to the independence of the concerned persons, insofar as those are reflected in an objective, traceable activity of the concerned person.

Dr Schlundt, DTU	9. Organisational culture	I think it's a very important thing to take that out and to bring in conflict of interest in relation to economical conflict of interest and only that.	It is widely acknowledged that CoI can be also of a non-economic nature. EFSA's draft policy tries to capture all relevant interests that may be considered prejudicial to the independence of the concerned persons, insofar as those are reflected in an objective, traceable activity of the concerned person.
Dr Christoph Then, Testbiotech	9. Organisational culture	We would propose to have a new institution which is dealing with conflict in scientific opinions	EFSA's role is limited by law to providing scientific advice or scientific and technical assistance to EU Institutions or Member States.
Mariana Nicholls, European poultry industries	9. Organisational culture	We would very much like to see more industrial experts on the boards or in the committees, just a few of them because we have so much data that we would like to share.	EFSA does its utmost to select the best available scientists, irrespective of their background, as long as that does not result in conflicts of interest. Waivers are foreseen and recorded in the minutes of the relevant meeting.
Arnaud Apoteker	9. Organisational culture	And perhaps something like an annual reporting may be something that is needed to further communicate on what happens over a year, how we deal with it. So that could be perhaps even part of our annual reporting system.	The draft Policy will be amended in order to reflect this new EFSA commitment to report annually on the implementation of its Policy on Independence as of 2012.

10. Staff operating in the public interest			
Testbiotech	10. Staff operating in the public interest	The case of Suzy Renckens (http://www.testbiotech.org/en/taxonomy/term/180, http://www.testbiotech.org/en/node/316) shows significant weakness in the implementation of EFSA´s rules 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". It should be explained if and how the case of Suzy Renckens was used to strengthen relevant rules and procedures.	Without reference to individual cases, this is addressed and explained already in lines 273-276 of the draft policy. Nonetheless, the text has been reviewed to make it clearer that EFSA has adopted a streamlined procedure to address this kind of instances.
Confederazione Nazionale Coldiretti	10. Staff operating in the public interest	Beyond the DoI document, panellists' Curriculum Vitae should be public on the EFSA's website in order to let citizens have a direct scrutiny on who decides about food safety (= their health) in Europe. If EFSA intends to take seriously the perception about independence, a complete and detailed C.V. should be the ordinary rule.	This is already the case since some time. Please check EFSA's website.
Eurogroup for Animals	10. Staff operating in the public interest	This comment concerns section 11. on implementation but it is not listed. Lines 277-282: The document does not explain how the application of the principles outlined in this policy is going to be controlled. Will an external audit be carried out at one point? If this is part of another EFSA procedure, a reference should be included.	EFSA will review the text clarifying that the system on DoIs will be systematically submitted every other year to a comprehensive evaluation or audit. It should be borne in mind that EFSA has had already several audits of the existing system (internal audit, internal audit service of the Commission, Court of Auditors).
Confederazione Nazionale Coldiretti	10. Staff operating in the public interest	Overall issues: With regard to the Call for tender for an EFSA's External Evaluation, 2011/ S1 00173, published last 04-01-2011 on the Official Journal of the European Commission, we wonder if there is any prejudice on the Authority's independence considering that the proposals are expected to be delivered to EFSA's hands for scrutiny and selection of the executor.	EFSA's approach as outlined in that call for tender is in accordance with Article 61 of Regulation (EC). No 178/2002 (EFSA's Founding regulation).
Confederazione Nazionale Coldiretti	10. Staff operating in the public interest	Par. 10, ll. 278-282 While it is very welcome this policy against "revolving doors" between industry and the Authority, we think it could be better formulated. We think that it could be useful to focus also on getting authorization and screening for human resources coming from industry and entering EFSA, not only for researchers departing from EFSA to start other for-profit activities. In general, the revolving doors operate both at the beginning and at the end	The text will be revised in order to clarify that CoIs are prevented also when a staff member is assigned to his or her post.

BEUC	10. Staff operating in the public interest	BEUC, the European consumer's organisation, wishes to make some brief general comments on the issue of independence and conflicts of interest: BEUC can see and appreciate the work that EFSA is doing to try to ensure independence of panel members (and their staff) and we appreciate their continued work in this area. We acknowledge that EFSA has to trust the members of panels at a given stage and it is down to individuals to be open and honest about their activities and any potential conflicts of interest they may have. We do question as to whether perhaps EFSA can be more vigorous in checking DoI of potential and nominated panelists to ensure that no conflicts are apparent or omitted. We also believe that it would be beneficial for EFSA to be more transparent as to what happens when anomalies are found in the declarations as it is not very clear what happens in such situations. Also, while we agree that members of a panel must have an interest in the issue in order to be member of that panel, more transparency and clarification is needed as to when this interest can be considered a conflict of interest. Finally, we believe that having open meetings of panels is important in terms of transparency but also allow stakeholders and the general public understand how the panels function etc. We would, however, strongly discourage previous suggestions from other stakeholder groups that they should be involved in panel discussions (through presenting results of studies etc.) as this could be taken that specific groups are being given preferrential treatment and could affect EFSA's work on ensuring transparency and independence.	See above
Chiara Tomalino, Eurocoop	10. Staff operating in the public interest	(...) revolving door effects should be avoided. We know that it's costly but we think that the only way out is to put in place a cooling down period, which in our opinion should be of three years.	The text will be revised in order to clarify that CoI are prevented also when a staff member is assigned to his or her post.

Appendix

A. TEXT OF THE PUBLIC CONSULTATION FROM THE EFSA WEBSITE

Public consultation on a Policy on Independence and Scientific Decision making processes of the European Food Safety Authority

Deadline: 16 September 2011

The European Food Safety Authority (EFSA) has launched an open consultation on its Draft Policy on Independence and Scientific Decision-Making Processes. This document provides a comprehensive overview of the various measures in place at EFSA to safeguard independence and scientific integrity.

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from all interested parties, EFSA has launched a public consultation on the draft policy. Interested parties are invited to submit written comments by 16 September 2011. Please use exclusively the electronic template provided with the documents to submit comments and refer to the line and page numbers. Please note that comments submitted by e-mail or by post cannot be taken into account and that a submission will not be considered if it is:

- submitted after the deadline set out in the call
- presented in any form other than what is provided for in the instructions and template
- not related to the contents of the document
- contains complaints against institutions, personal accusations, irrelevant or offensive statements or material
- is related to policy or risk management aspects, which is out of the scope of EFSA's activity.

EFSA will assess all comments from interested parties which are submitted in line with the criteria above. The comments will be explored in more detail in a dedicated meeting that EFSA will hold in the autumn. Feedback from the consultation and the outcomes of this meeting will be compiled in a report and, where appropriate, incorporated into a revised draft of the policy to be presented to the EFSA Management Board for possible adoption before the end of 2011.

Publication date: 7 July 2011

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

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

References	• Regulation (EC) No 178/2002

Relevant Documents	Policy on Independence and Scientific Decision-Making Processes of EFSA, adopted by the Management Board on 15 December 2011

Decision History

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

Abbreviations	*Cf. Decision*

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 178/2002[1] 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 Communities[4] 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 observers[6]. 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 creativity[11] 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 group[12] 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 ADoI.

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

the purpose to update the Declaration on the missing information. In case an internal procedure is opened as referred to in Article 15 of this decision, the data subject will be notified.

9. Data subjects also are entitled to have recourse at any time to the European Data Protection Supervisor: http://www.edps.europa.eu.

Article 28- Entry into force and transitional measures

1. The present decision repeals the previous decisions of the Executive Director dated 8 September 2009 implementing EFSA's Policy on Declarations of Interests and her Decision on declaration of interest in the context of EFSA procurement contracts and grants of 5 April 2011.

2. The present decision shall enter into force as of the day of its signature for the selection and appointment procedures of the members of EFSA's Scientific Committee and Scientific Panels on Animal Health and Welfare (AHAW), on Biological Hazards (BIOHAZ), on Contaminants in the Food Chain (CONTAM), on Plant Health (PLH), on Additives and Products or Substances used in Animal Feed (FEEDAP), on Dietetic Products, Nutrition and Allergies (NDA), on Genetically Modified Organisms (GMO) and on Plant Protection Products and their Residues (PPR). For all other concerned individuals and processes, the decision shall enter into force as of 1 July 2012, with a four months transition period.

Done at Parma on 21 February 2012

(*signed*)

Catherine Geslain-Lanéelle
Executive Director

Annexes: Annex I Annual Declaration of Interest

Annex II Declaration concerning confidentiality and of commitment

Annex III Specific Declaration of Interest

Annex IV Reference Table of allowable interests – ADoIs

Annex V Reference Table of allowable interests – SDoIs

Annex VI Institutional Declaration of Interest for participants to procurement and grants procedures

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 interest[4]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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.

II. Member of a Managing Body or equivalent structure[5]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 the remit of the scientific group.
5. Please indicate 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[6]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 the remit of the scientific group.
6. Please indicate any participation in the works of a scientific advisory body, created permanent and 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 past participation in scientific activities carried out with EFSA, such as membership of Scientific Panels, Working Groups and Networks. Any advice related to product development shall be declared exclusively under "Ad hoc or occasional consultancy".

IV. Employment [7]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 and whether it is a Food Safety Organisation or not.
3. Please indicate the activity of the entity, e.g. types of substances, products, guidance documents, processes or policies and how it relates to the remit of the scientific group.
7. Please indicate 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.

V. Ad hoc or occasional consultancy/Advisory [8]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 the remit of the scientific group.
8. Please indicate 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 [9]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 the remit of the scientific group.
9. Please indicate 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. The overall proportion of each funding with respect to the annual funding that comes under the professional sphere of influence of that person shall be indicated. It includes grants, rents, reimbursement of expenses, sponsorships and fellowships, also received from EFSA. Grouping by funders and supporters or by subject matters shall be accepted.

Please also indicate 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 you for the area under concern or that is otherwise benefiting you, including research funding by your organisation (Yes or No): _____

VII. Intellectual property [10]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 the remit of the scientific group.
10. Please indicate any right on the subject matter granted to creators and owners of works that are the result of human intellectual creativity and led to a financial gain. Plain authorship and publications shall not be declared.

VIII. Other membership or affiliation[11]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 the remit of the scientific group.
11. Please indicate 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[12]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 all organisations.
3. Please indicate the activity of the entity, e.g. types of substances, products, guidance documents, processes or policies and how it relates to the remit of the scientific group.
4. Please indicate the domain in which the activity was or is carried out (e.g. zoonoses, fish welfare, mycotoxins, food additives, novel foods).
12. Please indicate any interest not falling under the definitions provided above and relevant for the purposes of the present decision.

I confirm that:

- **I consider myself to be in a potential CoI with respect to the following EFSA activity _____ for the following reason _____ or**
- **I consider myself not to be in a potential conflict of interest with respect to my activities at EFSA.**

I hereby declare that I have read the Implementing Decision of EFSA's Policy on Independence and scientific decision making processes regarding declarations of interest and that the above declaration is truthful and complete.

Date: _____ Signature: _____

If you need more sheets to declare your interests, do not hesitate to use blank ones or to ask for them, but please sign each one of them and attach them to this form.

ANNEX II

DECLARATION OF COMMITMENT AND CONFIDENTIALITY

First name: _____

Surname: _____

Position or capacity in which the undersigned is involved with EFSA activities:

[ ] Member of EFSA's Scientific Committee or Scientific Panel on ……..
[ ] External expert in a Working Group on ……
[ ] Expert of the EFSA Network, peer review meeting, networking meeting or Task Force on …….
[ ] Management Board member
[ ] Advisory Forum member/Expert in Focal Point meetings
[ ] External evaluator of the selection process of EFSA scientific committee and panels
[ ] External reviewer of EFSA scientific outputs
[ ] Other; *please specify:* …….

1. Commitment

While contributing to EFSA activities, the undersigned shall:

- Respect the EFSA internal security policy and measure made available to me;
- Always set an exemplary conduct in all activities linked to EFSA;
- Comply with EFSA's rules on Declarations of interest and independence;
- Comply with the confidentiality rules detailed in point 2 of the present Declaration;
- As far as applicable, comply with the rules on reimbursement of travel expenses and payment of allowances and indemnities laid down in the EFSA Experts Compensation Guide;
- Read and understand the way personal data are processed as detailed in point 3 of the present Declaration;
- Ensure appropriate use of scientific publications provided by EFSA and respect copyrights as explained in point 4 of the present Declaration;
- When communicating with media, stakeholders or the general public on a matter that falls within the EFSA's remit always contact the EFSA press office of the 'Communication Channels' Unit.

Duration: The validity of the present Declaration is limited to one year from the date of signature, unless the expert or member informs EFSA on the termination of her/his activities within EFSA. The renewal of this commitment will be done on an annual basis.

2. Confidentiality

Should the undersigned receive *confidential information* or *restricted information* in the course and context of her/his duties for EFSA, it shall be treated under conditions of strict confidentiality, be used exclusively for the purpose for which it was made available to him/her and it shall not be divulged to any third party.

The above implies that the undersigned:

- will not divulge, publish or otherwise make available to any third party information received from EFSA, without prior written consent of EFSA, also not after completion of the event or assignment involved in with EFSA. The duty of confidentiality exists vis-à-vis any third party, including employees, employers or affiliates or the general public ;
- will not use information received from EFSA for a personal benefit or that of any third party ;
- will ensure safe storage of the Confidential Information and Restricted Information, applying appropriate security measures if the information is managed electronically and not retain the information for longer than needed for the completion of the assignment or event with EFSA. In case EFSA provides the undersigned with a password to access information available on the EFSA servers, this access password shall be kept for him/herself and not be shared with any other person, using it only in order to carry out the relevant assignment ;
- will compensate EFSA for any damages arising directly or indirectly from the breach of any of the above-mentioned statements or of any other obligation laid out in EFSA's internal rules with regard to the tasks or role of the undersigned.

As needed, the undersigned may be required to accept more specific confidentiality requirements by means of a dedicated statement pertaining to the specific event or assignment involved in with EFSA.

- *'Confidential information'* means information transmitted to EFSA and classified as confidential according to Union food legislation and/or declared as 'confidential' by the applicant/owner of the document in compliance with applicable law. Furthermore, *'confidential information'* means any information which is not made available or disclosed to unauthorized individuals or entities.
- *'Restricted information'* includes all documents, notes, analyses, studies, reports, comments and any other materials produced during evaluation processes and to which authorized EFSA staff have access, directly or indirectly. Furthermore*, 'restricted information'* means any information whose unauthorized or uncontrolled external disclosure may harm the interests of EFSA or of any third party.

3. Personal data processing & respect of privacy

Regulation (EC) N° 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 applies to EFSA's activities as Union Agency.

The present Declaration constitutes a legal act in the sense of Article 23 of the aforementioned Regulation and the undersigned is considered to be a processor of personal data on behalf of EFSA in the sense of Article 2(e) of the Regulation. As a processor of personal data, the undersigned is subject to the following obligations:

- To process the data received in the context of the assignment with EFSA solely for the purpose for which it was transmitted ;
- To act only on instruction of EFSA, in its capacity of controller with regard to any personal data processing in the context of the assignment with EFSA;
- To ensure the confidentiality and security of personal data processing in the sense of Articles 21 and 22 of the Regulation, without prejudice to the obligations regarding confidentiality and security laid down in the national data protection legislation of the EU Member State, in which the undersigned is having her/his residence;
- To follow specific instructions of EFSA in the case of transfer of personal data to any third party, therefore observing appropriate security safeguards to avoid unauthorised processing and disclosure.

4. Copyrights and library working tools provided by EFSA

In case the undersigned is involved in the preparation of scientific outputs, she/he may receive from EFSA scientific publications and journals protected by copyrights through the "Sciencenet" electronic tool, as handouts or via e-mail.

The undersigned will be allowed to make limited use of journals and scientific publications, but shall not:

- Distribute copies of articles and journals to third parties;
- Use articles or journals for commercial purposes;
- Use the materials for other purposes than the EFSA's assignment.

5. Duty of care of EFSA

The undersigned takes note of EFSA's commitment to:

- provide him or her with appropriate and up to date information, training and guidance to facilitate compliance with the rules and principles mentioned above;
- defend his or her reputation in the media in case unfounded allegations are put forward by third parties; and
- provide him or her with the adequate administrative, communication and scientific support to allow him or her to carry out in an effective manner the tasks linked to his or her role at EFSA.

Date: …/…/……

Signature: _____

ANNEX III: SPECIFIC DECLARATION OF INTERESTS (SDoI)
ACTIVITIES IN EFSA[15]: _____

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

First Name: _____

Surname: _____

Profession: **_____**

Meeting of …….. Scientific Committee/Scientific Panel/Network
Meeting of the …….. Working Group
EFSA Mandate ……

Meeting dates:	
Question numbers discussed:	

#	Items on the agenda

[15] Please specify the current activities within EFSA (*e.g.* Mandate or Meeting) and insert details (*e.g.* agenda).

SPECIFIC DECLARATION OF INTERESTS (SDoI)

hereby declares to have the following interests relating to the items on the agenda of the meeting indicated above, unless already declared in an ADoI

(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 interest[4]	**Current** [1] *Please answer Yes or No*	**Past Period** [1] *From/To (Month/Year)*	**Name of Organisation** [2]	**Subject matter** [3]

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. Please also specify how it relates to the item on the agenda of the relevant meeting.
3. Please indicate the activity of the entity, e.g. types of substances, products, guidance documents, processes or policies and how it relates to the item(s) in the agenda or the mandate.
4. Please indicate any economic stake or share in a body with an interest in the items on the agenda, 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.

II. Member of a Managing Body or equivalent structure[5]	**Current** [1] *Please answer Yes or No*	**Past Period** [1] *From/To (Month/Year)*	**Name of Organisation** [2]	**Subject matter** [3]

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. Please also specify how it relates to the item on the agenda of the relevant meeting.
3. Please indicate the activity of the entity, e.g. types of substances, products, guidance documents, processes or policies and how it relates to the item(s) in the agenda or the mandate.
5. Please indicate any participation in the internal decision-making (e.g. board membership, directorship) of a public or private entity with an interest in the subject matters on the agenda

III. Member of a Scientific Advisory Body[6]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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. Please also specify how it relates to the item on the agenda of the relevant meeting.
3. Please indicate the activity of the entity, e.g. types of substances, products, guidance documents, processes or policies and how it relates to the item(s) in the agenda or the mandate.
6. Please indicate any participation in the works of a scientific advisory body, created permanent and created ad hoc, managed by a body with an interest in the subject matters on the agenda, with the right to have an influence on its output(s). This includes also past participation in scientific activities carried out with EFSA, such as membership of Scientific Panels, Working Groups and Networks. Any advice related to product development shall be declared exclusively under "Ad hoc or occasional consultancy".

IV. Employment [7]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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. Please also specify how it relates to the item on the agenda of the relevant meeting.
3. Please indicate the activity of the entity, e.g. types of substances, products, guidance documents, processes or policies and how it relates to the item(s) in the agenda or the mandate.
7. Please indicate 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 matters of the agenda. This also includes employment by EFSA.

V. Ad hoc or occasional Consultancy [8]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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. Please also specify how it relates to the item on the agenda of the relevant meeting.
3. Please indicate the activity of the entity, e.g. types of substances, products, guidance documents, processes or policies and how it relates to the item(s) in the agenda or the mandate.
8. Please indicate 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 of the agenda. This includes also services provided on a 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 [9]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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. Please also specify how it relates to the item on the agenda of the relevant meeting.
3. Please indicate the activity of the entity, e.g. types of substances, products, guidance documents, processes or policies and how it relates to the item(s) in the agenda or the mandate.
9. Please indicate any funding for research or developmental work in the subject matters on the agenda 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. The overall proportion of each funding with respect to the annual funding that comes under the professional sphere of influence of that person shall be indicated. It includes grants, rents, reimbursement of expenses, sponsorships and fellowships, also received from EFSA. Grouping by funders and supporters or by subject matters shall be accepted. Please also indicate whether the research (co-)funding received from the private sector during the last five years exceeds 25% of the annual budget that is managed by you for the area under concern, including projects funded by your organisation.

Please also indicate 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 you for the area under concern or that is otherwise benefiting you, including research funding by your organisation (Yes or No): _____

VII. Intellectual property [10]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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. Please also specify how it relates to the item on the agenda of the relevant meeting.
4. Please indicate the activity of the entity, e.g. types of substances, products, guidance documents, processes or policies and how it relates to the item(s) in the agenda or the mandate.
10. Please indicate any right on the subject matter granted to creators and owners of works that are the result of human intellectual creativity and led to a financial gain with respect to the items on the agenda. Plain authorship and publications shall not be declared.

VIII. Other membership or affiliation[11]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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. Please also specify how it relates to the item on the agenda of the relevant meeting.
3. Please indicate the activity of the entity, e.g. types of substances, products, guidance documents, processes or policies and how it relates to the item(s) in the agenda or the mandate.
11. Please indicate 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 matters on the agenda, including professional organisations.

IX. Other[12]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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. Please also specify how it relates to the item on the agenda of the relevant meeting.
3. Please indicate the activity of the entity, e.g. types of substances, products, guidance documents, processes or policies and how it relates to the item(s) in the agenda or the mandate.
12. Please indicate any interest not falling under the definitions provided above and relevant for the purposes of the present decision.

I confirm that:

- **I consider myself to be in a potential CoI with respect to the following agenda items _____ for the following reason _____ or**
- **I consider myself not to be in a potential conflict of interest with respect to the agenda above.**

I hereby declare that I have read the Implementing Decision of EFSA's Policy on Independence and scientific decision making processes regarding declarations of interest and that the above declaration is truthful and complete.

Date: _____ Signature: _____

If you need more sheets to declare your interests, do not hesitate to use blank ones or to ask for them, but please sign each one of them and attach them to this form.

ANNEX IV Reference table of allowable interests for Annual Declarations of Interests (ADoI) pursuant to Article 10 of the Implementing Rules

IMPORTANT: The acceptance of an expert based on the ADoI is supplemented by screening of the Specific (Art. 11) and Oral (Art. 12) Declarations of Interest. **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.

<table>
<tr><th colspan="2" rowspan="3">Sector of external activity**</th><th colspan="4">Participation to the relevant EFSA activity</th></tr>
<tr><th colspan="2">Chairmanship and Vice-Chairmanship</th><th colspan="2">Membership</th></tr>
<tr><th>Scientific Committee, Panels and multiple mandate Working Groups</th><th>One Mandate Working Groups</th><th>Scientific Committee, Panels and multiple mandate Working Groups</th><th>One Mandate Working Groups</th></tr>
<tr><td rowspan="2">I. Economic interest*</td><td>CURRENT</td><td colspan="2">not allowed</td><td colspan="2">not allowed
when the expert has a potential conflicts of interest of a general nature that would regularly lead to the exclusion of the expert’s from the meetings of the scientific group.</td></tr>
<tr><td>PAST</td><td colspan="4">allowed</td></tr>
<tr><td rowspan="2">II. A. Member of a management body or equivalent, of FSO*</td><td>CURRENT</td><td colspan="2">not allowed</td><td colspan="2">allowed</td></tr>
<tr><td>PAST</td><td colspan="4">allowed</td></tr>
<tr><td rowspan="2">II. B. Member of a management body or equivalent, other than FSOs*</td><td>CURRENT</td><td colspan="2">not allowed</td><td colspan="2">not allowed
when the expert has a potential conflicts of interest of a general nature that would regularly lead to the exclusion of the expert’s from the meetings of the scientific group.</td></tr>
<tr><td>PAST</td><td colspan="2">not allowed
when interest ended within past two years.</td><td colspan="2">allowed</td></tr>
</table>

* The same consequences are to be applied when the relevant interests are declared with reference to a partner or dependent person.

** For the complete definitions, please refer to Article 1 of the Implementing Decision of the Policy on Independence and Scientific Decision Making Processes regarding Declarations of Interest.

ANNEX IV Reference table of allowable interests for Annual Declarations of Interests (ADoI) pursuant to Article 10 of the Implementing Rules

IMPORTANT: The acceptance of an expert based on the ADoI is supplemented by screening of the Specific (Art. 11) and Oral (Art. 12) Declarations of Interest. **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.

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<tr><td rowspan="2">III. A. Member of a scientific advisory body managed by an FSO*</td><td>CURRENT</td><td>allowed</td><td>not allowed</td><td colspan="2">allowed</td></tr>
<tr><td>PAST</td><td colspan="4">allowed</td></tr>
<tr><td rowspan="2">III. B. Member of a scientific advisory body, other than scientific groups of FSOs*</td><td>CURRENT</td><td colspan="2">not allowed</td><td>allowed</td><td>not allowed
when the expert has a potential conflicts of interest of a general nature that would regularly lead to the exclusion of the expert’s from the meetings of the scientific group.</td></tr>
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ANNEX IV Reference table of allowable interests for Annual Declarations of Interests (ADoI) pursuant to Article 10 of the Implementing Rules

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<tr><td rowspan="2">IV. A. Employment with an FSO*</td><td>CURRENT</td><td>allowed</td><td>not allowed</td><td colspan="2">allowed</td></tr>
<tr><td>PAST</td><td colspan="4">allowed</td></tr>
<tr><td rowspan="2">IV. B. Employment, other than FSO*</td><td>CURRENT</td><td colspan="2" rowspan="2">not allowed</td><td colspan="2">not allowed
when the expert has a potential conflicts of interest of a general nature that would regularly lead to the exclusion of the expert’s from the meetings of the scientific group.</td></tr>
<tr><td>PAST</td><td colspan="2">not allowed
when the expert has a potential conflicts of interest of a general nature that would regularly lead to the exclusion of the expert’s from the meetings of the scientific group and interest ended within past two years.</td></tr>
</table>

* The same consequences are to be applied when the relevant interests are declared with reference to a partner or dependent person.

** For the complete definitions, please refer to Article 1 of the Implementing Decision of the Policy on Independence and Scientific Decision Making Processes regarding Declarations of Interest.

ANNEX IV Reference table of allowable interests for Annual Declarations of Interests (ADoI) pursuant to Article 10 of the Implementing Rules

IMPORTANT: The acceptance of an expert based on the ADoI is supplemented by screening of the Specific (Art. 11) and Oral (Art. 12) Declarations of Interest. **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.

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<tr><td rowspan="2">V. A. Ad hoc or occasional consultancy to FSOs*</td><td>CURRENT</td><td>allowed</td><td>not allowed</td><td colspan="2">allowed</td></tr>
<tr><td>PAST</td><td colspan="4">allowed</td></tr>
<tr><td rowspan="2">V. B. Ad hoc or occasional consultancy to bodies other than FSOs*</td><td>CURRENT</td><td colspan="2" rowspan="2">not allowed</td><td colspan="2">not allowed
when the expert has a potential conflicts of interest of a general nature that would regularly lead to the exclusion of the expert’s from the meetings of the scientific group.</td></tr>
<tr><td>PAST</td><td colspan="2">allowed</td></tr>
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* The same consequences are to be applied when the relevant interests are declared with reference to a partner or dependent person.

** For the complete definitions, please refer to Article 1 of the Implementing Decision of the Policy on Independence and Scientific Decision Making Processes regarding Declarations of Interest.

ANNEX IV Reference table of allowable interests for Annual Declarations of Interests (ADoI) pursuant to Article 10 of the Implementing Rules

IMPORTANT: The acceptance of an expert based on the ADoI is supplemented by screening of the Specific (Art. 11) and Oral (Art. 12) Declarations of Interest. **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.

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<tr><td rowspan="2">VI. Research funding from the private sector exceeds 25% for the area under concern*</td><td>CURRENT</td><td colspan="2">not allowed</td><td colspan="2">not allowed
when the expert has a potential conflicts of interest of a general nature that would regularly lead to the exclusion of the expert’s from the meetings of the scientific group.</td></tr>
<tr><td>PAST</td><td colspan="4">allowed</td></tr>
<tr><td rowspan="2">VII. Intellectual property rights*</td><td>CURRENT</td><td colspan="2">not allowed</td><td colspan="2">not allowed
when the expert has a potential conflicts of interest of a general nature that would regularly lead to the exclusion of the expert’s from the meetings of the scientific group.</td></tr>
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** For the complete definitions, please refer to Article 1 of the Implementing Decision of the Policy on Independence and Scientific Decision Making Processes regarding Declarations of Interest.

ANNEX IV Reference table of allowable interests for Annual Declarations of Interests (ADoI) pursuant to Article 10 of the Implementing Rules

IMPORTANT: The acceptance of an expert based on the ADoI is supplemented by screening of the Specific (Art. 11) and Oral (Art. 12) Declarations of Interest. **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.

Sector of external activity**	Participation to the relevant EFSA activity			
	Chairmanship and Vice-Chairmanship		Membership	
	Scientific Committee, Panels and multiple mandate Working Groups	One Mandate Working Groups	Scientific Committee, Panels and multiple mandate Working Groups	One Mandate Working Groups
VIII and IX. Other membership or affiliation or other relevant interest, including professional organisations, regarding the relevant matter*	**allowed or not allowed** depending on the mission, scope of activities, funding of the relevant organisation, etc.			

* The same consequences are to be applied when the relevant interests are declared with reference to a partner or dependent person.

** For the complete definitions, please refer to Article 1 of the Implementing Decision of the Policy on Independence and Scientific Decision Making Processes regarding Declarations of Interest.

ANNEX V Reference table of allowable interests for Specific Declarations of Interests (SDoI) pursuant to Article 11 of the Implementing Rules
IMPORTANT: The acceptance of an expert based on the SDoI is supplemented by screening of the Annual (Art. 10) and Oral (Art. 12) Declarations of Interest. **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.

Sector of external activity**		Specific item on the agenda of the EFSA meeting Participation of the expert to the specific agenda item irrespective of his or her role (under no circumstances an expert is allowed to review his or her own work)
I. Economic interest*	**CURRENT**	**Participation not allowed** to the specific agenda item where the potential CoI was identified
	PAST	**Not applicable** (as interest has already been addressed at ADoI level)
II. Member of a management body or equivalent*	**CURRENT**	**Participation not allowed** to the specific agenda item where the potential CoI was identified
	PAST	**Not applicable** (as interest has already been addressed at ADoI level)

* The same consequences are to be applied when the relevant interests are declared with reference to a partner or dependent person.
** For the complete definitions, please refer to Article 1 of the Implementing Decision of the Policy on Independence and Scientific Decision Making Processes regarding Declarations of Interest.

ANNEX V Reference table of allowable interests for Specific Declarations of Interests (SDoI) pursuant to Article 11 of the Implementing Rules
IMPORTANT: The acceptance of an expert based on the SDoI is supplemented by screening of the Annual (Art. 10) and Oral (Art. 12) Declarations of Interest. **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.

Sector of external activity**		Specific item on the agenda of the EFSA meeting Participation of the expert to the specific agenda item irrespective of his or her role (under no circumstances an expert is allowed to review his or her own work)
III. Member of a scientific advisory body*	**CURRENT**	**Participation not allowed** to the specific agenda item where the potential CoI was identified
	PAST	**Not applicable** (as interest has already been addressed at ADoI level)
IV. Employment*	**CURRENT**	**Participation not allowed** to the specific agenda item where the potential CoI was identified
	PAST	**Not applicable** (as interest has already been addressed at ADoI level)

* The same consequences are to be applied when the relevant interests are declared with reference to a partner or dependent person.
** For the complete definitions, please refer to Article 1 of the Implementing Decision of the Policy on Independence and Scientific Decision Making Processes regarding Declarations of Interest.

ANNEX V Reference table of allowable interests for Specific Declarations of Interests (SDoI) pursuant to Article 11 of the Implementing Rules
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Sector of external activity**		Specific item on the agenda of the EFSA meeting Participation of the expert to the specific agenda item irrespective of his or her role (under no circumstances an expert is allowed to review his or her own work)
V. Ad hoc or occasional consultancy*	**CURRENT**	**Participation not allowed** to the specific agenda item where the potential CoI was identified
	PAST	**Not applicable** **(**as interest has already been addressed at ADoI level)
VI. Research funding from the private sector exceeds 25% for the area under concern*	**CURRENT**	**Participation not allowed** to the specific agenda item where the potential CoI was identified
	PAST	**Not applicable** (as interest has already been addressed at ADoI level)

* The same consequences are to be applied when the relevant interests are declared with reference to a partner or dependent person.
** For the complete definitions, please refer to Article 1 of the Implementing Decision of the Policy on Independence and Scientific Decision Making Processes regarding Declarations of Interest.

ANNEX V Reference table of allowable interests for Specific Declarations of Interests (SDoI) pursuant to Article 11 of the Implementing Rules

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Sector of external activity**		**Specific item on the agenda of the EFSA meeting** **Participation of the expert to the specific agenda item irrespective of his or her role (under no circumstances an expert is allowed to review his or her own work)**
VII. Intellectual property rights*	**CURRENT**	**Participation not allowed** to the specific agenda item where the potential CoI was identified
	PAST	**Not applicable** (as interest has already been addressed at ADoI level)
VIII. Other membership or affiliation, including professional organisations, regarding the relevant matter*		**Participation allowed or not allowed** to the specific agenda item where the potential CoI was identified (depending on the mission, scope of activities, funding of the relevant organisation, etc.)
IX. Other relevant interest		**Participation allowed or not allowed** to the specific agenda item where the potential CoI was identified (depending on the mission, scope of activities, funding of the relevant organisation, etc.)

* The same consequences are to be applied when the relevant interests are declared with reference to a partner or dependent person.

** For the complete definitions, please refer to Article 1 of the Implementing Decision of the Policy on Independence and Scientific Decision Making Processes regarding Declarations of Interest.

Annex VI
Institutional Declaration of Interest for participants to EFSA's public procurement / grant procedures (Institutional DoI)

N.B. Any modification made by the tenderer / applicant to the structure and content of the present template will make the document invalid.

To allow for electronic completion, you find the DoI form also in a separate Annex in MS Word format

Declaration of Interests

Participation in EFSA call for tenders / call for proposals related to Scientific Evaluation of Regulated Products, Risk Assessment and Scientific Assistance, Science Strategy and Coordination

Legal basis:

- Article 94 of Regulation (EC, Euratom) N° 1605/2002 on the Financial Regulation applicable to the General Budget of the European Communities, dated 25 June 2002, OJ L 248, 16/9/2002, p.1
- Article 133a of Regulation (EC, Euratom) N° 2342/2002 laying down detailed rules for the implementation of the Financial Regulation, dated 23 December 2002, OJ L 357, 31/12/2002, p.1
- Articles 25, 26 and 27 of the Implementing Decision of EFSA's Policy on Independence and Scientific Decision Making Processes regarding Declarations of interests
- Tender specification / Call for proposal stipulating that the contracts / grants may not be awarded to tenderers / applicants who are subject of a conflict of interest

Reference of the Call for tenders/Call for proposal: **CFT/EFSA/nn/20nn/nn**

Title:

Name of tendering organisation:
_____

Name of consortium partner(s) *(if any)*:_____

Name of subcontractor(s) *(if any)*:_____

The tenderer / applicant hereby declares the following interests:

*(Tenderers / applicants are aware of the fact that a declared interest does not necessarily mean to have a conflict of interest. EFSA will apply the **principle of proportionality** laid down in Article 133a of Regulation (EC, Euratom) N° 2342/2002 cited above)*

I. Economic interest[4]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

1. Please indicate activities which are currently ongoing, with an indication of the starting 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 the subject matter of the call.
4. Please indicate any economic stake or share in a body with an interest in the subject matter of the call, including the stocks, equities or bonds thereof, or of one of its subsidiaries or of a company in which it has a holding. Also any substantial interests of the tenderer's / applicant`s proposed subcontractor(s) and consortium partner(s) should be indicated**.** Financial instruments on which the tenderer / applicant has no influence are not to be considered relevant.

II. Member of a Managing Body or equivalent structure[5]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 the subject matter of the call.
5. Not applicable to legal persons such as undertakings. Please indicate 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 of the call.

III. Member of a Scientific Advisory Body[6]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 the subject matter of the call.
6. Not applicable to legal persons such as undertakings. Please indicate any participation in the works of a scientific advisory body, created permanent and created ad hoc, managed by a body with an interest in the subject matter of the call, with a right to have an influence on its output(s). This includes also past participation in scientific activities carried out with EFSA, such as membership of Scientific Panels, Working Groups and Networks. Any advice related to product development shall be declared exclusively under "Ad hoc or occasional consultancy".

IV. Employment[7]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 the subject matter of the call.
7. Not applicable to legal persons such as undertakings. Please indicate 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 of the call. This also includes employment by EFSA.

V. Ad hoc or occasional consultancy [8]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 the subject matter of the call.
8. Please indicate 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 of the call. 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. Also any substantial interests of the tenderer's / applicant`s proposed subcontractor(s) and consortium partner(s) should be indicated**.**

VI. Research funding [9]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 the subject matter of the call.
9. Please indicate any funding for research or developmental work on the subject matter of the call received from any public or private body by the tenderer / applicant and their proposed subcontractor(s) and consortium partner(s) in their personal capacity or falling under the sphere of influence of that legal or natural person. The overall proportion of each funding with respect to the annual funding that comes under the professional sphere of influence of that person shall also be indicated. It includes grants, rents, reimbursement of expenses, sponsorships and fellowships, also received from EFSA. Grouping by funders and supporters or by subject matters are accepted.

Please also indicate whether the research (co-)funding received from the private sector in the year preceding the submission of the DoI exceeds 25% of the annual research budget that is managed by you for the area under concern or that is otherwise benefiting you, including research funding by your organisation (Yes or No): _____

VII. Intellectual property [10]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 the subject matter of the call.
10. Please indicate any right on the subject matter of the call granted to tenderer / applicant and their proposed subcontractor(s) and consortium partner(s) that are the result of human intellectual creativity and led to a financial gain. Plain authorship and publications shall not be declared.

VIII. Membership or affiliation [11]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 the subject matter of the call.
11. Please indicate any residual membership or affiliation of the tenderer / applicant and their proposed subcontractor(s) and consortium partner(s) to any entity with an interest in the subject matter of the call, including professional organisations.

IX. Other[12]	Current [1] *Please answer Yes or No*	Past Period [1] *From/To (Month/Year)*	Name of Organisation [2]	Subject matter [3]

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 the subject matter of the call.
12. Please indicate any interest not falling under the definitions provided above and relevant for the purposes of the present call.

If you need more sheets to declare interests, do not hesitate to use blank ones, but please sign each one of them and attach them to this form.

I confirm that:

- **I consider myself to be in a potential CoI with respect to the present call for the following reason _____ or**
- **I consider myself not to be in a potential conflict of interest with respect to the present call.**

The tenderer's / applicant`s legal representative, as well as any proposed subcontractors *(if any)* **or members of the consortium** *(if any)* **hereby declare that the information contained in this declaration is correct and complete to their best knowledge and ability:**

Name of tendering / applicant organisation:	*[complete]……..*
Name of tenderer's / applicant`s legal representative & Signature:	*[complete + signature]……..*
Seal of tendering / applicant organisation:	
Date:	**…./…./20….**

Name of subcontractor:	*[complete]……..*
Name of subcontractor's legal representative & Signature:	*[complete + signature]……..*
Seal of subcontracting organisation:	
Date:	**…./…./20….**

Name of organisation, member in the consortium:	**[complete]……..**
Name of the consortium member's legal representative & Signature:	***[complete + signature]……..***
Seal of consortium organisation:	
Date:	**…./…./20….**

If you need more sheets to declare interests, do not hesitate to use blank ones, but please sign each one of them and attach them to this form.