

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 safety¹ 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 individual².
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 ADol.

- 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 Panel³ 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 ADol. 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 SDol. 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	<p>A</p> <p>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.</p>	<p>A</p> <p>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.</p>
Decision phase/adoption	<p>A</p> <p>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.</p>	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 Regulations for 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 <u>Annual Declaration of Interest</u> ⁸		Indicative conflict of Interest Level based on the <u>Specific</u> agenda or mandate		
		Current activity	Previous activity	current	past	none
I	Ownership of other investments, including shares	Y/N	X	C	X	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	X	X	X	X	X

⁸ Y (Yes), N (No)