

PROCEDURE FOR IDENTIFYING AND HANDLING POTENTIAL CONFLICTS OF INTERESTS

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 individual Members of the Scientific Committee, the Scientific Panels and their Working Groups 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 interests (MB – 10.09.2007) which is implemented in the Guidance on Declarations of Interests (MB – 10.09.2007) 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 and D) EFSA Staff.
4. The procedure provides:
 - A formal procedure for the screening of declarations of interests 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 interests, rather they are considered to reflect all relevant interests.

A) MEMBERS OF THE MANAGEMENT BOARD

1. The Chairperson and vice-chairpersons shall make their best efforts to refrain from involving themselves in any activity that would result in a conflict of interest. The chairperson shall inform the Management Board of any changes in either his or the vice-chairpersons' 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.*

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 Interests (MB – 10.09.2007) 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.
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 chairman 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.

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) either the absence of any interests or any interests which might be considered prejudicial to their independence in an annual public declaration.
2. The Executive Director of EFSA, chair of the Advisory Forum, will review the declarations of interests 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, THE PANELS AND OTHER EFSA EXPERTS

1. EFSA applies detailed Annual Declaration of Interests (ADol) in combination with a Specific Declaration of Interests (SDol). The latter is linked to a specific activity/work performed for EFSA.
2. Due to their nature, for *ad hoc* working groups the ADol needs to be completed. For panels and for standing working groups, *i.e.* groups which are established on an ongoing basis, both an ADol and an SDol shall be used.
3. The EFSA secretariat will screen the ADols and SDols. The results will be summarised in the evaluation form provided in Annex 1.

I. The Annual Declaration of Interests (ADol)

1. The ADol aims to invite the experts to provide a detailed description of their interests.
2. The ADol is completed on an annual basis. Upon their receipt, the EFSA secretariat will screen the ADols in order to highlight interests, including those that may give rise to possible conflicts.

II. Specific Declarations of Interests (SDol)

1. In view of the need to declare interests in relation to each meeting, the SDol is applied. The SDol is without prejudice to the oral request for declarations of interests at the beginning of any EFSA expert meeting as required in accordance with Article 37 of Regulation 178/2002.
2. The SDol is linked to a specific subject matter or set of subject matters (e.g. substance/product) at a specific meeting or a specific mandate to be covered at one or several meetings.
3. It allows the expert to declare either of the following:
 - a. there are no additional interests to be declared with respect to his/her ADol;
 - b. there are no new interests to be declared with respect to a previous SDol;
 - c. additional interests. In this case the SDol takes up the format of the ADol to allow for a detailed declaration.
4. The SDol will be distributed together with the invitation to a respective meeting or mandate. It is to be completed and returned before or by 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 SDol will be performed by the EFSA secretariat while also considering the interest previously declared in the ADol.
6. On the occasion of specific meetings, the EFSA secretariat will inform the Chair on the results of the screening. Any potential conflict of interest will be recorded in the minutes of the meeting. This may lead to:
 - the conclusion that no further action is required as the level of potential conflict is compatible with the activity envisaged or

- the conclusion that action is needed with regard to the nature of the participation.

III. The levels

1. There are three levels of potential conflict of interest: "A", "B", or "C"². 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 a level "C" and a level "B", respectively. "A" means that there is no conflict of interest.
2. It should be noted though that the level can only be attributed with regard to a specific activity. As an example, an expert currently working for a company which 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 expert is employed by, he/she will be classified as "C". This is also the case if it concerns a product that is a potential competitor a complementary product.

IV. The nature of participation based on the screening

The principle

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.

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.

The maximum permitted level for interests concerning product-related issues that are discussed is an "A" while for interests impacting on general matters discussed it is a "B".

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

The following table shows the *permitted* involvement level in EFSA activities:

² See Annex I to this document where the level of conflict of interest based on a specific agenda or mandate is classified.

Role/phase	Nature of the input required	
	Specific product-related matters	General matters (such as guidelines/data collection)
Chair	A B or C level not permitted	A B or C level not permitted
Rapporteur or equivalent leading/coordinating role	A B or C level not permitted	A and B C-level not permitted
Evaluation/drafting phase ³	A The B -level expert addresses orally or in writing specific questions raised during the evaluation of products, but cannot draft assessment reports or parts of them. C -level not permitted	A The B -level expert may contribute to the drafting of general guidance documents. The individual can participate in working groups, or report on his/her professional experience. C -level not permitted
Decision phase/adoption	A The B -level expert cannot actively participate in the final discussion. However, he/she can be present to answer questions addressed specifically to him/her. C -level not permitted	A and B C -level not permitted

Potential conflict of interest level A

Involvement in all activities is permitted.

Potential conflict Level B

As shown in the table above, the level of involvement of the member/expert 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.

Potential conflict Level C

1. The expert 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 expert's involvement in a particular activity is considered to be essential and where no suitable alternative expert can be found, the Head of Unit of the concerned Panel should consult the Director of Science together

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

with the Head of Department Risk Assessment and the Head of Department Scientific Cooperation and Assistance for a decision on whether to grant a waiver.

3. For persons that have been assigned the level "C", the availability of alternative experts in the field has to be considered prior to any submission to the Director of Science and the two Heads of Department. 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 Heads of Department and the Director of Science.
4. Thus, the Director of Science and the two Heads of Department should only be consulted in relation to such experts when a search for alternative experts has already been carried out and the outcome of that search was negative. Such 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 expert. The Director of Science shall inform the Executive Director on the conclusion reached by the Director of Science and the two Heads of Department. This shall include all relevant information on which the conclusion is based.
5. If a waiver is granted the expert will then be considered to be at level "B" as regards the involvement in the EFSA activities for which involvement is sought.

D) EFSA STAFF

1. Whilst the 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 external experts, using a similar system for the verification thereof. These declarations will be screened by the respective line manager, allowing the Executive Director to take appropriate measures.
2. EFSA staff is subject to obligations laid down under the 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. Whilst the EFSA's founding regulation requires the Executive Director to publish an **ADoI**, the EFSA Management Board has decided that the **ADoI** of the Deputy Executive Director will also be published.

ANNEX 1
EVALUATION FORM OF DECLARATIONS OF INTERESTS

(to be completed according to the Procedure for identifying and handling potential conflict of interests)

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

First Name: _____ Surname: _____

Profession: _____

EFSA's Activities¹: _____

SUBJECT MATTER²: _____

Nature of Activities and subject matter		Interest Level based on <u>Annual Declaration of Interest</u>³		Conflict of Interest Level based on the <u>Specific agenda or mandate</u>⁴		
		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	Y/N	Y/N	C	B	A
VI	Research funding	Y/N	Y/N	B	A	A
VII	Intellectual property	Y/N	Y/N	B	A	A
VIII	Other membership or affiliation	Y/N	Y/N			
IX	Other	Y/N	Y/N			
X	Interests of close family members should be listed as appropriate under category I to IX	X	X	X	X	X

Evaluated by _____ **Date:** _____

¹ Please specify the activities within EFSA (e.g. member of the Scientific Committee or a Scientific Panel, external expert).

² Please specify the activity within EFSA (e.g. mandate or Meeting and insert details e.g. agenda).

³ Please circle the letter Y (Yes), N (No), as appropriate.

⁴ Please circle the letter A, B or C as appropriate (except for "Other membership or affiliation" and "Other", where the appropriate interest level should be inserted).