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

Reference **NP/EFSA/LPA/2010/01**

January 20, 2011

*The views expressed herein are those of the consultants alone and do not necessarily
represent the views or position of the European Food Safety Authority*

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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 – EFSA
Catherine Geslain-Lanéelle
Executive Director

In accordance with the invitation to tender No NP/EFSA/LPA/2010/01 and the contract No CT/EFSA/LPA/2010/01 dated July 20, 2010 (the “Contract”), we have performed the procedures enumerated in the section 3 of this report, with respect to a sample of Declarations of Interests submitted by experts participating in certain scientific panels.

The procedures referred to above were performed solely to assist EFSA in assessing the effectiveness and the efficiency of the Policy on Declarations of Interests (“DoI”) and related implementing rules. Therefore those procedures were designed to check whether the screening performed and the decisions taken by EFSA staff have complied with the guidelines and procedures foreseen in EFSA’s Policy on DoI and related implementing rules.

Those procedures aim also to identify recommendations and suggestions on possible improvements of EFSA’s Policy on DoI.

Our findings and observations are presented thereafter in a summary form. Detailed information was communicated to the EFSA.

Brussels, January 20, 2011

<SIGNED>

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1. Introduction and background

The European Food Safety Authority (EFSA) was set up in January 2002, following a series of food crises in the late 1990s, as an independent source of scientific advice and communication on risks associated with the food chain.

EFSA was created as part of a comprehensive programme to improve EU food safety, ensure a high level of consumer protection and restore and maintain confidence in the EU food supply.

The independence of EFSA from any direct or indirect interests is critical for EFSA as it was one of the reasons for the creation of the Authority. Independence and high standards of professional conduct by all persons involved in the activities of EFSA are crucial for the work and the reputation of EFSA.

The 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 foresees 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, EFSA Policy on Declarations of Interests ("DoI"), adopted by its Management Board in September 2007, imposes on them to make 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". In addition, the members of the Management Board, the Executive Director, the members of the Advisory Forum, the members of the Scientific Committee and the Scientific Panels, as well as external experts participating in their working groups shall declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda.

EFSA Policy on DoI is implemented by the Guidance on DoIs and the Procedure for identifying and handling potential conflict of interests. EFSA's Policy on DoIs and its implementing documents apply the concept according to which having interests does not necessarily mean having a conflict of interest. The policy aims at facilitating in a transparent and consistent manner the prevention of the occurrence, or the mitigation, of potential conflicts of interests.

The Policy on DoIs foresees that EFSA shall review the efficacy of that Policy not later than three years from its adoption. Therefore, 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 the adoption of its Policy on DoIs in September 2007.

In order to be in a position to identify in an objective and transparent manner, possible improvements to its DoI Policy, and the potential weaknesses of the process, EFSA considered it was appropriate to delegate the analysis of samples of the past screenings of the DoIs and the implementation of the Policy to external independent professionals. These should be in a better position to objectively carry out a critical assessment of the work done and propose ways of improving the system.

2. Scope of our assignment

Upon EFSA's request, we carried out an external analysis of the screening performed by EFSA staff on the Annual Declarations of Interests ("ADoIs") and Specific Declaration of Interests ("SDoI") of members of 5 scientific panels and of members of one of the working groups managed by the Pesticide Risk Assessment Peer Review unit of EFSA, based on a sample of such declarations.

Statistical data for each panel and working group are detailed below:

Panel	Plenary session(s)	Number of experts invited	Number of experts present
ANS (Food additives and nutrient sources added to food)	12th plenary meeting held on Feb 9 to 11, 2010	21	18
CEF (Food contact materials, enzymes, flavouring and processing aids)	11th plenary meeting held on Jan 26 to 28, 2010	24	19
FEEDAP (Additives and products or substances used in animal feed)			
	65th plenary meeting held on Feb 2 to 4, 2010	20	15
	66th plenary meeting held on Mar 10 to 11, 2010	19	16
GMO (Genetically modified organisms)			
	55th plenary meeting held on Jan 27 to 28, 2010	21	19
	56th plenary meeting held on Mar 10 to 11, 2010	21	20
	57th plenary meeting held on Apr 28 to 29, 2010	21	16
NDA (Dietetic products, nutrition and allergies)			
	32th plenary meeting held on Feb 9 to 11, 2010	21	20
	33th plenary meeting held on Apr 28 to 30, 2010	21	18
PRAPeR (Pesticide Risk Assessment Peer Review)	PRAPeR 73 Mammalian Toxicology held on Mar 16 to 19, 2010	20	20

Our tests aim at verifying whether the screening performed and decisions taken by EFSA comply with the rules and guidelines set out in the "EFSA Policy on Declarations of Interests", the "Implementing Act to the Policy on Declaration of Interests" and in the "Procedure for Identifying and Handling Potential Conflicts of Interest".

Our testing scope included a sample of ADoIs and SDoIs related to one to three (plenary) meetings for each of the five selected panels and a sample of ADoIs and SDoIs related to a meeting of the working group managed by the Pesticide Risk Assessment Peer Review unit.

The minutes of the selected meetings and a sample of two scientific outputs per panel were included in the documentation made available to us. Please note that the working groups of PRAPeR do not adopt any scientific opinions.

Further details on our testing scope are disclosed in the next section.

3. Tests performed

For each meeting included in our sample, we completed the following activities:

1. We examined the invitation to the meeting (including the agenda) to check whether the invitation was sent to the experts prior to the meeting;
2. We compared for consistency the points mentioned in the agenda with those referred to in the meeting minutes;
3. We compared for consistency the items listed in the SDoI with the items listed on the agenda;
4. We compared for consistency the subject matters discussed during a meeting (as disclosed in the meeting minutes) with the mandate/ objective of the panel/ working group the experts belong to, the agenda items, the scientific opinion, if any (including any reference to the above mentioned mandate/ objective) and the ADoI.

For each expert invited to a meeting, we completed the following activities:

1. We read the meeting minutes of the respective meeting to check whether the expert participated in the meeting ;
2. We examined the ADoI to check whether the ADoI was completed and submitted prior to the meeting date;
3. We scanned the observations/ comments saved in the DoI IT tool supporting the screening process to check whether the last available ADoI was subject to a review by the respective Head of Unit and by the Director of Risk Assessment prior to the meeting date;
4. We examined the SDoI to check whether the SDoI was completed and submitted prior to the meeting date;
5. We scanned the observations/ comments saved in the DoI IT tool supporting the screening process to check whether the SDoI was subject to a review by the Head of Unit concerned prior to the meeting date;
6. We checked that the interests declared in the ADoI and the SDoI were properly classified under the right category (i.e. ownership of other investments) defined in the EFSA rules and guidelines;
7. We compared the interests declared in the ADoI with the mandate of the relevant panel/ working group, role of the expert, subjects listed on the agenda of the meeting and the scientific opinion discussed, if any, for possible detection of conflicts of interest;
8. We compared the interests declared in the SDoI with subjects listed on the agenda of the meeting and the scientific opinion discussed, if any, for possible detection of conflicts of interest;
9. We compared the ADoI and the SDoI for consistency. In particular, we checked whether specific interests declared in the ADoI needed to be reported in the SDoI;
10. We verified that interests declared in the ADoI, if any, were addressed by the Head of Unit concerned and approved by the Director of Risk Assessment;
11. We verified that the interests declared in the SDoI, if any, were addressed by the Head of Unit concerned;
12. We verified that the declared interests, if any, were discussed and conclusions reached in light of any potential conflict detected by us (see above);
13. We verified that indicative levels of potential conflicts of interest were properly assigned, on basis of the documentation made available to us and the analysis completed by EFSA;
14. We verified that the decision on a (non-) participation in a meeting in full or in part was documented in the DoI IT Tool, consistent with the indicative levels of potential conflicts and the meeting minutes.

4. Summary of findings/ observations

Our findings and observations are summarized below:

	Number of occurrences	Number of experts assessed	Rate of Occurrence
Interests not declared by experts at the SDoI level as required by the DoI policy while such interests were disclosed in the related ADol. Those interests were nevertheless spotted by EFSA and assessed in light of the mandates given to the respective panel.	4	181	2%
Experts invited to a panel meeting although their ADol was not valid anymore	3	181	2%
Presence or absence in a meeting not disclosed accurately in the minutes	1	181	1%
Exemption from filling in an ADol and a SDoI with respect to the admission to a panel and the participation in a meeting not foreseen in the DoI policy if the expert is a member of another panel or working group mandate of which is to discuss the same topic as the one discussed in the panel or the meeting subject to screening.	1	181	1%

5. Recommendations

Below we elaborate on suggestions and recommendations for improvement of EFSA DoI Policy with a view to the simplification and the optimisation of the process.

1. Until now, the experts are not requested to express their opinion on the existence of conflicts of interest while completing a DoI. EFSA is therefore currently exposed to the risk that no conflict of interest is flagged by EFSA staff in some instances while an expert would be in the opinion that his/ her independence could be impaired. It is of the utmost importance that the expert contributes further to the detection of the conflict of interest. As a consequence, we advise EFSA to ask each expert for each category of interests declared whether she/ he is in the opinion that such a conflict is likely to emerge or not. Such questions should be included in the DoI IT tool used to fill in the DoI forms. In any case, the experts' opinions are not binding for EFSA and the final conclusion that a conflict exist still lies with the Authority.
2. Safeguards used by EFSA to eliminate or reduce threats to independence to an acceptable level fall into the category of person-centered measures (i.e. role assigned to the expert according to the criticality of the conflicts identified). Instead of focusing to a great extent on such individual measures, we advise EFSA to have a more balanced DoI Policy and include measures for eliminating or mitigating potential effect of conflicts of interests to an acceptable level at a group level. This is likely to reduce the impact of the scarcity of scientific resources EFSA is confronted by. Such measures can include:
 - a. Having a number of experts sufficient to reduce the impact of one single vote,
 - b. Requiring higher quorum for voting
 - c. Reaching a quite significant geographic and cultural diversity,
 - d. Having a gender balance.

Accordingly, a person having a conflict could be admitted to a panel, a working group or a meeting as far as the effect of such threat is isolated and likely to be mitigated by such collegial safeguards. In any case, such a conflict should be made known to the other participants.

3. In order to better focus on the risks which are likely to impair the experts' independence, we suggest that EFSA requires the experts to declare any activities that are no longer ongoing as far as they have been completed in the past 2 years. Going back 5 years is disproportionate to the benefits gained from such a backward process.
4. In order to increase the experts' awareness of the DoI Policy, we advise EFSA to combine E-learning solutions including questionnaires used to gauge the experts' knowledge of the independence matters with the on-site training sessions currently in place.
5. As some experts participated in meetings although their ADoI has expired at the time the invitations were sent, monitoring the validity of the ADoI and timely taking remedial actions for renewal is recommended.
6. In a few cases, although the conclusion that there is a conflict or not was disclosed, the argumentation leading to such a conclusion was not accurately documented in the DoI IT tool. In order to increase the transparency of the screening process, we advise EFSA to provide further explanation supporting the conclusion reached on the existence or absence of conflicts for each category of interests declared. The information saved in the DoI IT tool show nevertheless that the EFSA staff has the necessary skills and experience to analyze the interests declared and detect the existence of a conflict of interest.
7. By comparing SDoI with ADoI, we noted that a few experts omitted to declare in their SDoI interests already declared in their ADoI. In some instances the expert was not expected to update the SDoI as those interests were assessed in light of the mandates given to the panel. Nevertheless, requesting the experts to declare systematically in SDoI interests as far as there is a related item on the agenda and applying the guidelines consistently across all the panels is highly recommended.
8. EFSA is invited to assess the opportunity to structure the documentation of the screening in the IT tool in a way that there is a conclusion drawn separately for each type of interest declared (i.e. financial interest – ownership of shares).
9. The DoI Policy needs to include further guidance on the exposure to conflict of interest in relation to membership of evaluation/ advisory committees acting on behalf of National Authorities or scientific media.
10. By completing our procedures, we noted that an item listed on the agenda was not disclosed in the template used for the SDoI. The reason why such item has not been disclosed is that it relates to a presentation made by the EFSA staff with no exposure to risk of conflict of interest. In order to guarantee the completeness of screening, we recommend that both lists match. In such a case, if the experts are not requested to identify any interest for a specific subject, the EFSA staff should mark "not applicable" on the SDoI template for the subject concerned.
11. The DoI policy does not foresee exemption from filling in an ADoI and a SDoI with respect to the admission to a panel and the participation in a meeting if the expert is a member of another panel or working group mandate of which is to discuss the same topic as the one discussed in the meeting subject to screening. We advise EFSA to address such exemption in the DoI policy.