0775/2010/ANA
E2010-129940

efsa
European Food Safety Authority

EXECUTIVE DIRECTOR

30 NOV 2010

Parma,
Ref.DD/AH/SG/rl (2010) - **out-5345394**

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

Re : Complaint 775/2010/ANA (S2010-126938)

Dear Mr Diamandouros,

I hereby acknowledge your letter dated 4 October 2010 related to the above complaint in which you request the European Food Safety Authority (hereinafter EFSA) to provide any available additional information documenting EFSA's assessment of the situation in relation to the move of a former EFSA staff member — Dr. Suzy Renckens — to a Swiss based biotechnology company. In this regard, please allow me to outline the following.

In relation to your request for any available additional information documenting EFSA's assessment of the situation with regard to the move of Dr. Suzy Renckens I confirm that the information previously supplied is complete. In line with the provisions of Article 16 of the EU Staff Regulations[1] the Appointing Authority of EFSA did not explicitly notify its consent to the new job assignment of Dr. Renckens.

In this context, given latest statements from the complainant it seems necessary to reiterate the organisational principles of the European Food Safety Authority set out in its founding Regulation (EC) No 178/2002 (Regulation 178/2002), as the understanding of the complainant of the structure and operations of the EFSA continues to be in contrast to the implementation of the legal provisions by EFSA and its operations based thereon.

At EFSA Dr. Suzy Renckens was acting as Head of the EFSA GMO Unit from 1 April 2003 until end of March 2008. The GMO Unit is providing secretarial support for administrative purposes to the Panel on genetically modified organisms (GMO Panel), as foreseen by Regulation 178/2002. The GMO Unit consists of EFSA staff members providing a permanent secretariat and administrative support to the external independent scientific experts, who are appointed by EFSA's Management Board (cf. Article 25 of Regulation 178/2002) as members of the different Scientific Panels as in detail laid down in Article 28 of Regulation 178/2002.

To this regard Article 28(1) of Regulation 178/2002 shows clearly that in the context of GMO applications — like in all other areas of EFSA's remit — only the members of the GMO Panel are approving EFSA's scientific opinions on the applications submitted in the

[1] 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, OJ 45, 14.6.1962, p. 1385.

context of the authorisation procedures regulated by Regulation (EC) No 1829/2003[2] (the Genetically Modified Food and Feed Regulation) or by Directive 2001/18/EC[3] (the Deliberate Release Directive). EFSA staff members cannot form part of any of EFSA's Scientific Panels or its Scientific Committee, as those are in line with Article 28(4) of Regulation 178/2002 composed only of independent (external) experts, who are appointed following an open and public call for expression of interest and the corresponding transparent procedure pursuant to Article 28(5) of Regulation 178/2002.

Consequently Dr. Renckens was neither a decision maker in relation to any of the scientific outputs of EFSA, as this – in line with the provisions of Regulation 178/2002 – is the exclusive role of the members of the GMO Panel, nor did Dr. Renckens take any decisions on any authorisation or approval, as that is according to the European legislation the role of the risk managers (i. e. the European Commission and the EU Member States), but not the task of EFSA.

Furthermore I would like to point out to you that EFSA is about to adopt implementation rules in relation to Article 16 of the Staff Regulations. We will submit to you the finalized procedure before the end of this year.

With regard to the second request of your letter concerning the job advertisement to which Dr. Renckens applied when she was appointed to her post at EFSA, her application, including any annexes and her staff reports, please find enclosed in Annex I the following documents:

1. the announcement of a call for expression of interest from DG SANCO with the indication of two specific profiles to which Dr. Renckens referred in her application (01T/EFA/2001 – General Scientific Functions – Temporary Agent [A5/A4]/Auxiliary Agent and 02T/EFA/2001 – Secretariat of Scientific Committee and Scientific Panels – Temporary Agent [A5/A4]/Auxiliary Agent respectively);
2. Dr. Renckens' application;
3. Dr. Rencken's job objectives covering the period from 1 March 2007 to 31 December 2007. Dr. Rencken's appraisal was not finalised by her reporting officer as the appraisal cycle was still ongoing at the time when she left EFSA.

I would like to highlight the fact that the documents No 2 and No 3 contain appraisal data and other personal data considered as being sensitive and confidential in line with Regulation (EC) No 45/2001[4].

Further to this you were requesting any internal rules and/or guidelines relevant to the issue (more specifically, (a) any information/guidelines communicated to staff regarding conflicts of interest, and (b) any rules on how EFSA itself deals with conflicts of interest, such as the rules on who assesses them and how and whether there is a conflict of interest in relation to Dr. Renckens' activities following the termination of her service at EFSA. In this regard, please find attached in Annex II the following documents as they were in force at the period of time when Dr. Renckens worked for EFSA:

4. the Decision concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their working groups (endorsed by the EFSA Management Board on 17 December 2009);
5. the EFSA Code of conduct on declarations of interests (in force between March 2004 and September 2007, subsequently replaced by No 7 and No 8 below);

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[2] OJ L 268, 18.10.2003, p. 1, as amended.

[3] OJ L 106, 17.4.2001, p. 1, as amended.

[4] OJ L 8, 12.1.2001, p. 1., i. e. Article 2(g). In this context please also consult the explanatory notes on data protection regarding EFSA staff recruitment on our website: http://www.efsa.europa.eu/en/aboutefsa/docs/dataprotection.pdf.

6. the Guidance on declarations of interests (endorsed by the EFSA Management Board on 16 December 2004, in force until September 2007, replaced by No 7 and No 8 below);
7. the EFSA Policy on declarations of interests (from September 2007, endorsed by the EFSA Management Board on 5 October 2007);
8. the Guidance Document on declarations of interest (from 8 September 2007);
9. the Document on the Procedure for identifying and handling potential conflicts of interest (from 8 September 2007);
10. the EFSA Code of conduct on good administrative behaviour (from 16 September 2007);
11. the EFSA decision on outside activities and assignments from 28 April 2004 (replaced by No 12 below);
12. the Decision of the Executive Director of the European Food Safety Authority on the adoption of implementing provisions of the Staff Regulations by analogy from 1 September 2009.

Finally you have been requesting details of the internal and external meetings in which Dr. Renckens participated during the last year of her employment at EFSA. In view of our records I can confirm that Dr. Renckens participated in the following events or meetings:

14. Brussels, 18-19 April 2007, Standing Committee on the food chain and animal health (SCFCAH);
15. Brussels, 10-11 May 2007, SCFCAH;
16. Ljubljana, 14 May 2007, 2nd Meeting of European Advisory Committees on Biosafety (MEACB);
17. Ljubljana, 15-16 May 2007, EFSA GMO Panel Plenary;
18. Brussels, 25 May 2007, Preparatory Meeting EFSA GMO MC sub-WG;
19. Brussels, 31 May 2007, EFSA WG on non food/non feed;
20. EFSA/Parma, 4 June 2007, Science Management Meeting;
21. EFSA/Parma, 6 June 2007, EFSA WG GMO MON863;
22. London, 15 June 2007, Media training;
23. Tabiano, 20-21 June 2007, EFSA Scientific Colloquium No 8
(report published in printed form as an EFSA publication, published also on the EFSA Website as pdf:
http://www.efsa.europa.eu/en/events/event/colloque070620.htm?wtrl=01);
24. EFSA/Parma, 25 June 2007, Science Management Meeting;
25. EFSA/Parma, 4-5 July 2007, EFSA GMO Panel Plenary;
26. Brussels, 16 July 2007, EFSA WG on allergenicity;
27. Brussels, 17 July 2007, Meeting with Chair of EFSA WG on animal feeding trials;
28. Brussels, 18 July 2007, EFSA WG on non food/non feed;
29. Brussels, 19 July 2007, Meeting with European Commission (DG SANCO) on GMO action plan;
30. Brussels, 9 August 2007, Meeting with Chair of EFSA Panel;
31. Bucharest, 10-11 September 2007, EFSA Management Board Meeting;
32. Brussels, 21 September 2007, European Commission WG on Guidance notes on monitoring;
33. Brussels, 24 September 2007, EFSA WG on allergenicity;
34. Brussels, 3-4 October 2007, EFSA support to US-EU technical meeting EC-USTR on WTO questions;
35. Brussels, 5 October 2007, Meeting with European Commission (DG ENV) on GMO action plan;
36. Brussels, 9 October 2007, SCFCAH;
37. Brussels, 12 October 2007, Meeting with Mr Koseki and Mr Takasuna, RAB Tokyo;
38. Brussels, 11 October 2007, EFSA WG on GMO MC;
39. Stockholm, 6-7 November 2007, 3rd meeting chairs of sc committees/panels in RA;
40. EFSA/Parma, 14 January 2008, Risk Assessment Team Meeting;
41. Brussels, 17 January 2008, PMM import & processing (European Commission);

42. Brussels, 24 January 2008, EFSA WG on statistics;
43. Brussels, 25 January 2008, Meeting with European Commission (DG ENV B3) on ERA;
44. Brussels, 11 February 2008, SCFCAH;
45. EFSA/Parma, 12-13 March 2008, EFSA GMO Panel Plenary.

The available meeting minutes for the meetings No 17, 25, 31 and 45 as well as the Scientific Colloquium Summary Report for event No 23 — enclosed in Annex III — are not confidential.

The documents referred to under points No 19, 20, 24, 26, 28, 32, 33, 34, 38, 40 and 42 and provided as enclosure in Annex IV to this letter are classified by EFSA as *confidential* in terms of Article 5(1) and Article 5(2) of the Decision of the European Ombudsman adopting implementing provisions.

With regard to the additional submission from the side of the complainant (cf. the complainant's e-mail to the European Ombudsman dating 5 October 2010), concerning a workshop in Berlin that took place at the former BBA (Biologische Bundesanstalt für Land- und Forstwirtschaft; predecessor to the JKI — Julius-Kühn-Institut) on 26 and 27 April 2007, it should be highlighted that the complainant submitted a pre-announcement that mentions Dr. Renckens as contributing with a speech and as co-chair for one session, whereas Dr. Renckens did not at all participate in this event (another EFSA staff member was representing EFSA for the above mentioned tasks, please see enclosure No 13).

Finally it should be reiterated that referring to Dr. Renckens in the pre-mentioned e-mail of the complainant as "head of the GMO panel" is factually incorrect. In this context I do refer to my above statement concerning her role at EFSA as the Head of the Secretariat to the GMO Panel and to the related provisions Article 8 and 9 of the Decision listed above under point 4.

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

ANNEX I

Enclosures No 1 to No 3

Please observe that documents No 2 and No 3 contain appraisal data and other personal data considered as being sensitive and confidential in line with Regulation (EC) No 45/2001.

(1)

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C1 - Follow-up and dissemination of scientific opinions

Brussels,
SANCO.C1 / D(2001) SA/cd/1701

Subject : Information about calls for expressions of interest

Dear Ms Moreno,

The Health and Consumer Protection Directorate-General of the European Commission is inviting expressions of interest for the following posts in the future European Food Authority. The purpose is to establish a list of suitably experienced candidates from which a small number of personnel to assist the Authority once it is established with its immediate operational and preparatory work could be selected.

01T/EFA/2001	GENERAL SCIENTIFIC FUNCTIONS - Temporary Agent (A5/A4)/Auxiliary Agent
02T/EFA/2001	SECRETARIAT OF SCIENTIFIC COMMITTEE AND SCIENTIFIC PANELS - Temporary Agent (A5/A4)/Auxiliary Agent
03T/EFA/2001	SECRETARIAT OF SCIENTIFIC COMMITTEE AND SCIENTIFIC PANELS - Temporary Agent (A7/A6)/Auxiliary Agent
04T/EFA/2001	COMMUNICATION FUNCTIONS - Temporary Agent (A5/A4)/Auxiliary Agent
05T/EFA/2001	COMMUNICATION FUNCTIONS - Temporary Agent (A7/A6)/Auxiliary Agent
06T/EFA/2001	PLANNING, MANAGEMENT AND ADVISORY FUNCTIONS - Temporary Agent (A5/A4)/Auxiliary Agent
07T/EFA/2001	PERSONNEL AND GENERAL ADMINISTRATIVE FUNCTIONS - Temporary Agent (A5/A4)/Auxiliary Agent
08T/EFA/2001	PERSONNEL AND GENERAL ADMINISTRATIVE FUNCTIONS - Temporary Agent (A7/A6)/Auxiliary Agent
09T/EFA/2001	FINANCE AND PROCUREMENT - Temporary Agent (A5/A4)/Auxiliary Agent

Ms Ana Dios MORENO
Rio Bibei 20, 3°D
ES - 32001 Ourense

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: C1 5/279
Telephone: direct line (+32-2)295.87.47, switchboard 299.11.11. Fax: 295.95.79

Internet: soeren.abildgaard@cec.eu.int

10T/EFA/2001	FINANCE AND PROCUREMENT - Temporary Agent (A7/A6)/Auxiliary Agent
11T/EFA/2001	INFORMATION AND COMMUNICATION TECHNOLOGIES MANAGER - Temporary Agent (A5/A4)/Auxiliary Agent
12T/EFA/2001	INFORMATION AND COMMUNICATION TECHNOLOGIES MANAGER - Temporary Agent (A7/A6)/Auxiliary Agent
13T/EFA/2001	SUPPORT FOR MANAGEMENT OF SCIENTIFIC COMMITTEE AND SCIENTIFIC PANELS - Temporary Agent (B3/B2)/Auxiliary Agent
14T/EFA/2001	SUPPORT FOR MANAGEMENT OF SCIENTIFIC COMMITTEE AND SCIENTIFIC PANELS - Temporary Agent (B5/B4)/Auxiliary Agent
15T/EFA/2001	PERSONNEL AND GENERAL ADMINISTRATIVE FUNCTIONS - Temporary Agent (B3/B2)/Auxiliary Agent
16T/EFA/2001	PERSONNEL AND GENERAL ADMINISTRATIVE FUNCTIONS - Temporary Agent (B5/B4)/Auxiliary Agent
17T/EFA/2001	FINANCE - Temporary Agent (B3/B2)/Auxiliary Agent
18T/EFA/2001	FINANCE - Temporary Agent (B5/B4)/Auxiliary Agent
19T/EFA/2001	INFORMATION AND COMMUNICATION TECHNOLOGIES - APPLICATION DEVELOPMENT - Temporary Agent (B3/B2)/Auxiliary Agent
20T/EFA/2001	INFORMATION AND COMMUNICATION TECHNOLOGIES - APPLICATION DEVELOPMENT - Temporary Agent (B5/B4)/Auxiliary Agent
21T/EFA/2001	INFORMATION AND COMMUNICATION TECHNOLOGIES - IT INFRASTRUCTURE SERVICES - Temporary Agent (B3/B2)/Auxiliary Agent
22T/EFA/2001	INFORMATION AND COMMUNICATION TECHNOLOGIES - IT INFRASTRUCTURE SERVICES - Temporary Agent (B5/B4)/Auxiliary Agent

Closing date : 30/11/2001

Place : The final seat of the European Food Authority has not yet been decided.

Further information, application forms, general conditions and information on the European Food Authority can be obtained by sending an e-mail to SANCO-EFA-VACANCIES@cec.eu.int. (Please give reference number(s) of post(s) of interest).

Yours sincerely,

S. ABILDGAARD

CONDITIONS GÉNÉRALES

Postes: Autorité alimentaire européenne (AAE)

Conditions générales d'admission: Les candidats doivent être ressortissants de l'un des États membres de l'Union européenne et jouir de leurs droits civiques. Ils doivent être en position régulière au regard des lois en matière militaire.

Lieu d'affectation: Le siège définitif de l'Autorité alimentaire européenne n'a pas encore été fixé.

Conditions générales: Le personnel de l'AAE est soumis aux règles et réglementations applicables aux fonctionnaires et autres agents des Communautés européennes.
La nomination des agents temporaires ne pourra avoir lieu qu'après la nomination du directeur exécutif de l'AAE par le Conseil de direction.
Un emploi d'agent auxiliaire pourra être offert aux candidats. La durée des contrats est décidée par l'autorité investie du pouvoir de nomination. Les candidats retenus seront inscrits sur une liste et pourront se voir proposer un contrat (renouvelable) conformément aux dispositions du régime applicable aux autres agents des Communautés européennes.

Pour la constitution de leur dossier, les candidats ne peuvent se référer à des documents, actes de candidature ou fiches de renseignement déjà déposés à l'occasion de candidatures antérieures. Aucun élément du dossier de candidature n'est retourné aux candidats. Une réponse complète doit être donnée à toutes les questions du formulaire même si un curriculum vitae est joint en annexe. Le formulaire dûment daté et signé, doit être retourné, accompagné de toutes les pièces justificatives, **au plus tard le 30 novembre 2001** (la date du cachet de la poste faisant foi) à l'adresse suivante:

Commission européenne
Direction générale "Santé et protection des consommateurs"
Direction C- Avis scientifiques
Réf. Sélection **xxT/EFA/2001**
M. S. Abildgaard
1, Rue de Genève, 5/279 B - 1140 Bruxelles

ou, par voie électronique à l'adresse suivante:
"sanco-efa-vacancies@cec.eu.int"

IMPORTANT

Le formulaire de candidature original doit être accompagné de photocopies des diplômes, certificats et autres documents attestant que le candidat possède l'expérience professionnelle requise. Tous les justificatifs doivent indiquer les dates de début et de fin des emplois précédents et la date de début de l'emploi actuel. Les candidatures ne seront acceptées que si toutes les pièces justificatives sont fournies et que le formulaire de candidature a été dûment rempli et signé. Les candidats qui n'auront pas soumis toutes les pièces justificatives précisées pour la date limite de dépôt des candidatures seront disqualifiés.

Égalité des chances: l'AAE appliquera une politique d'égalité des chances entre hommes et femmes.

Conditions d'admission:

Études, certificats et diplômes: Les candidats doivent fournir des photocopies des certificats ou diplômes attestant qu'ils ont terminé les études du niveau requis par l'avis de vacance. En cas de spécialisation ou de perfectionnement professionnel, les candidats doivent préciser s'il s'agit de cours à temps plein ou à temps partiel, les matières traitées et la durée officielle des cours.

Expérience: Seule est prise en considération l'expérience professionnelle acquise par le candidat après l'obtention du certificat ou du diplôme requis.

Les candidats doivent fournir les pièces justificatives prouvant la durée et le niveau de leur expérience. Si pour des raisons de confidentialité, ils ne peuvent fournir les attestations de travail nécessaires pour leur emploi actuel, ils doivent fournir des photocopies du contrat de travail, de la lettre d'embauche et/ou de la première fiche et obligatoirement de la dernière fiche de rémunération.

Pour les activités professionnelles relevant de l'exercice d'une profession libérale ou indépendante, les candidats fourniront soit une attestation de l'ordre ou du registre professionnel concerné, soit toute autre pièce officielle (par exemple fiscale) faisant apparaître clairement la durée de l'expérience professionnelle concernée.

L'expérience ci-dessous sera également prise en considération à condition qu'elle ait été acquise après l'obtention du diplôme requis:

Stages ou périodes de spécialisation ou de perfectionnement préparant aux tâches décrites dans l'avis de vacance.
Périodes complémentaires de formation, d'études ou de recherche préparant aux tâches décrites dans l'avis de vacance et sanctionnées par un certificat ou un diplôme au moins équivalent à celui requis.

Les candidats doivent utiliser le formulaire de candidature fourni en annexe. *S'il est envoyé par voie postale*, ce formulaire doit être rempli **intégralement** à l'**ENCRE NOIRE.** Les candidats y joindront les photocopies de toutes les pièces justificatives nécessaires pour prouver qu'ils remplissent toutes les conditions. Ils doivent dater et signer le formulaire de candidature rempli (*candidature électronique??*). Par cette signature, les candidats déclarent sur l'honneur que les informations qu'il contient sont exactes et complètes. Ils vérifieront auparavant s'ils **remplissent** bien toutes les conditions énoncées dans les conditions générales et l'avis de vacance, notamment en ce qui concerne les qualifications et l'expérience professionnelle.

Autorité alimentaire européenne

Comme la proposition de la Commission l'indique, l'Autorité aura pour tâche principale de fournir des avis scientifiques indépendants, une aide et des informations sur toutes les questions relatives à la sécurité alimentaire. Disposant d'un vaste mandat, elle pourra avoir une vue globale de la chaîne alimentaire et fournir une base scientifique cohérente sur laquelle fonder les politiques et la législation. Elle effectuera ses travaux avec l'aide de scientifiques internes et, dans une large mesure, en réseau avec les instituts spécialisés des États membres.

L'AAE remplira six fonctions principales:

(1) fournir des avis scientifiques indépendants sur toutes les questions ayant une incidence directe ou indirecte sur la sécurité alimentaire, y compris la santé et le bien-être des animaux et la santé des végétaux. Elle s'occupera également des OGM et de la nutrition; la Commission, le Parlement européen (PE) et les États membres pourront lui demander des avis sur lesquels seront fondées les décisions de gestion des risques;

(2) conseiller la Commission sur des question techniques afin d'étayer l'élaboration des politiques et de la législation dans le domaine de la chaîne alimentaire;

(3) recueillir et analyser les données sur l'exposition diététique et les autres informations pertinentes sur les risques potentiels, qui sont nécessaires pour évaluer les risques et surveiller la sécurité de la chaîne alimentaire dans l'Union européenne;

(4) identifier et lancer des avertissements précoces sur les risques émergents;

(5) aider la Commission en cas de crise;

(6) communiquer avec le grand public sur toutes les questions relevant de son mandat.

Le sommet européen de Nice tenu en décembre 2000 a clairement exprimé l'avis que l'AAE devrait être opérationnelle pour le début de 2002. La Commission fait tout son possible pour que l'Autorité soit légalement instituée avant cette date et pour qu'elle puisse commencer ses activités dès que possible en 2002.

Organisation de l'AAE

L'Autorité alimentaire européenne sera une entité juridique distincte et indépendante des autres institutions communautaires. Elle sera composée de quatre organes: un conseil d'administration, un directeur exécutif, un forum consultatif ainsi qu'un comité scientifique et huit groupes scientifiques.

Le directeur exécutif sera aidé par un forum consultatif composé de quinze représentants, soit un par État membre, provenant d'organismes des États membres qui accomplissent des tâches similaires à celles de l'AAE. L'association étroite de ces organismes nationaux est essentielle, par exemple, pour assurer un travail en réseau efficace avec les organismes scientifiques nationaux.

Le comité scientifique et les huit groupes spécialisés seront composés d'experts scientifiques indépendants sélectionnés à la suite d'un appel à manifestation d'intérêt ouvert et désignés par le conseil de direction. Les groupes constitués seront les suivants:

- groupe sur les additifs alimentaires, les arômes, les auxiliaires technologiques et les matières en contact avec les aliments
- groupe sur les additifs et produits ou substances utilisés dans l'alimentation animale
- groupe sur la santé des végétaux, les produits phytopharmaceutiques et leurs résidus;
- groupe sur les organismes génétiquement modifiés;
- groupe sur les produits diététiques, la nutrition et les allergies;
- groupe sur les risques biologiques (ESB/EST inclus);
- groupe sur les contaminants de la chaîne alimentaire humaine;
- groupe sur la santé et le bien-être des animaux.

Le comité scientifique sera responsable de la coordination générale nécessaire pour assurer la cohérence des avis scientifiques des différents groupes.

Personnel et budget

L'AAE sera financée sur le budget communautaire et, lorsqu'elle sera pleinement opérationnelle, elle bénéficiera d'une aide interne scientifique substantielle. L'Autorité emploiera jusqu'à 250 personnes après trois ans, avec un budget de 40 millions d'euros. Celui-ci sera revu après trois ans.

Siège de l'Autorité

Une décision politique concernant le siège final devrait être prise d'ici la fin de l'année (2001).

ANNEX II

Enclosures No 4 to No 12

(EFSA policies, guidance and related legal provisions)

4

efsa
European Food Safety Authority

DECISION CONCERNING THE ESTABLISHMENT AND OPERATIONS OF THE SCIENTIFIC COMMITTEE, SCIENTIFIC PANELS AND OF THEIR WORKING GROUPS

Done in Stockholm
on December 17, 2009

Signed by

Prof. Díana Bánáti
Chair

efsa
European Food Safety Authority

Risk Assessment Directorate

Decision concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups

Having regard to Regulation (EC) No 178/2002/EC (hereinafter referred to as 'the Regulation') of the European Parliament and the Council of 28 January 2002 laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in relation to food safety, and in particular to Chapter III thereof[1],

Having regard to Commission Regulation (EC) No 1304/2003 of 23 July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it[2],

Whereas:

1. The rules governing the establishment and operations of the Scientific Committee and Scientific Panels should be in line with the requirements of the Regulation, and in particular Article 28(9) thereof, which requires that the procedures for the operation and co-operation of the Scientific Committee and the Scientific Panels shall be laid down in the Authority's internal rules, specifying in particular:

    a. the number of times that a member can serve consecutively on a Scientific Committee or Scientific Panel;
    b. the number of members in each Scientific Panel;
    c. the procedure for reimbursing the expenses of members of the Scientific Committee and the Scientific Panels;
    d. the manner in which tasks and requests for scientific opinions are assigned to the Scientific Committee and the Scientific Panels, including tasks and requests addressing multisectoral issues;
    e. the creation and organisation of the Working Groups of the Scientific Committee and the Scientific Panels, and the possibility of external experts being included in those Working Groups;
    f. the possibility of observers being invited to meetings of the Scientific Committee and the Scientific Panels;
    g. the possibility of organising public hearings.

[1] *Official Journal* L 31, 1. 2. 2002, p. 1, as last amended.
[2] *Official Journal* L 185, 24.7.2003, p. 6, as corrected by Corrigendum, OJ L 186, 25.7.2003, p. 46.

2. This document should also be in line with Article 29(7) of the Regulation, requiring that the Authority's internal rules shall specify implementing rules in regard to format, explanatory background and publication of a scientific opinion.
3. The Authority has adopted implementing provisions regarding the Selection of Members of the Scientific Committee, Scientific Panels and External Experts to assist EFSA with its Scientific Work[3].
4. The Authority has adopted implementing provisions regarding the publication of a scientific opinion[4].
5. The Authority has drafted common templates for scientific opinions and a guide for their coherent use[5].

The Management Board of the Authority has adopted the following Decision.

TITLE I
Scientific Committee and Scientific Panels

Article 1: Appointment of members of the Scientific Committee and Panels and their Terms of Office

1. Members of the Scientific Committee or Scientific Panels shall be appointed by the Management Board, acting upon a proposal from the Executive Director, following publication in the Official Journal, in relevant leading scientific publications and on the Authority's website of a call for expressions of interest. Candidates found suitable for the position but not appointed shall be invited to be included on a reserve list. The Executive Director draws up implementing rules for the selection of members of the Scientific Committee and Scientific Panels.
2. When appointing members, the Authority shall ensure a high level of collective scientific competence and expertise to fulfil the mandate of the Scientific Committee and Scientific Panels, and, consistent with this, a geographical distribution that reflects the diversity of scientific problems and approaches in the European Union.
3. Members of the Scientific Committee and of the Scientific Panels shall be appointed for a three year term of office that may be renewed twice.
4. Members who have just completed three or less consecutive terms of office in the Scientific Committee shall be eligible for membership of a Scientific Panel. Likewise, members who have just completed three or less consecutive terms of office in a Scientific Panel shall be eligible for membership of the Scientific Committee or a different Scientific Panel.

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[3] 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 last amended, available at www.efsa.europa.eu.

[4] Decision of the Management Board concerning implementing measures of transparency and confidentiality requirements MB 10.03.2005 – 10.

[5] An Internal EFSA Guidance for Scientific Outputs. Templates and Style Guide 2nd Revision has been implemented by the Authority as from the 16 October 2009.

Article 2: Delegation of responsibilities

1. The members of the Scientific Committee and Scientific Panels are appointed in a personal capacity. They shall therefore not delegate their responsibilities to another member or to a third person.
2. If the Chair is not in a position to fulfil his/her function, he/she may be replaced by one of the vice-Chairs or, failing that, by another member in common accord of the members.

Article 3: Number of members in the Scientific Panels

1. The number of members of a Scientific Panel should be sufficient to fulfil its mandate but shall not exceed 21. The Authority may however decide to defer nomination of some of the members of a Scientific Panel to allow for the need to add expertise in the light of practical experience.
2. The term of office of members nominated at a later date shall terminate at the same time as other members.

Article 4: Election of the Chairs and vice-Chairs of the Scientific Committee and Scientific Panels

1. The Scientific Committee and Scientific Panels shall elect from among their members a Chair and two Vice-Chairs. The terms of office of the Chair and Vice-Chairs shall be three years, renewable.
2. The Chair shall be elected by secret ballot. Subject to a unanimous decision by the Scientific Committee or the relevant Scientific Panel, the secrecy requirement for the ballot may be waived. The Executive Director or his/her designated representative shall chair the election procedures. The procedure shall be as follows:
    a. The names of those wishing to stand as candidates shall be notified to the Secretariat before the meeting or be announced at the meeting. Members may present themselves as candidates in their own name or be proposed by another member in compliance with the principles referred to in Article 33 of this Decision.
    b. Where there is a single candidate or where the other candidates withdraw, leaving a single candidate, that candidate shall be elected provided that he or she receives the majority of votes cast.
    c. Where there are several candidates, election shall take place in accordance with the following procedure:
        - The candidate who receives at least a two-thirds majority of the votes of all members is elected. Where none of the candidates receives a two-thirds majority of the votes of all members, at each round the candidate(s) with the lowest number of votes shall withdraw.
        - When only two candidates are left and after three rounds none of them obtains a two-thirds majority, the candidate receiving the majority will be elected.
    d. Candidates may withdraw their candidature at any time during the procedure.

3. Two Vice-Chairs shall be elected following a procedure identical to that of the Chair. The vice-Chairs shall be elected separately. The names of the Chair and Vice-Chairs shall be recorded in the minutes of the meeting and shall be made public. If the office of Chair falls vacant, the Scientific Committee / the relevant Scientific Panel will decide which of the Vice-Chairs shall replace him or her until later elections. If the Chair is unable to attend a meeting or part of a meeting, the Chair indicates which of the Vice-Chairs shall chair the Scientific Committee or the relevant Scientific Panel. If both the Chair and the Vice-Chairs are unable

to attend a meeting, the meeting shall be chaired by the member of the Scientific Committee or the relevant Scientific Panel chosen by the other members.

Article 5: Dismissal and Replacement of members

A member of the Scientific Committee and/or a Scientific Panel may be dismissed by the Management Board, on a proposal of the Executive Director, for not contributing effectively to the work of the Scientific Committee and/or Scientific Panels or for actions which are conflicting with EFSA's internal rules. In those cases, or if a member wishes to resign, the Management Board, acting on a proposal of the Executive Director, may appoint a replacement from the reserve list referred to in Article 1 paragraph 1.

Article 6: Requests for scientific advice, scientific and technical assistance and support

1. The Executive Director, after having consulted the Mandate Review Committee[6], shall assign requests for a scientific opinion to either:

The Scientific Panels in accordance with their mandate as set out below[7];

- for the **Panel on food additives and nutrient sources added to food**: safety in the use of food additives, nutrient sources and other substances deliberately added to food, excluding flavourings and enzymes.
- for the **Panel on food contact materials, enzymes, flavourings and processing aids**: safety of use of materials in contact with food, enzymes, flavourings and processing aids, safety of processes.
- for the **Panel on additives and products or substances used in animal feed:** safety for the animal, the user/worker, the consumer of products of animal origin, the environment and to the efficacy of biological and chemical products/substances intended for deliberate addition/use in animal feed.
- for the **Panel on plant protection products and their residues**: safety of plant protection products for the user/worker, the consumer of treated products and the environment.
- for the **Panel on plant health**: plant health.
- for the **Panel on genetically modified organisms**: genetically modified organisms, such as micro-organisms, plants and animals, relating to deliberate release into the environment and genetically modified food and feed, including products deriving from GMOs.
- for the **Panel on dietetic products, nutrition and allergies**: dietetic products, human nutrition and food allergy, and other associated subjects such as novel foods.
- for the **Panel on biological hazards**: biological hazards relating to food safety and food-borne disease, including food-borne zoonoses and transmissible spongiform encephalopathies, microbiology, food hygiene and associated waste management.
- for the **Panel on contaminants in the food chain**: contaminants in food and feed, associated areas and undesirable substances such as natural toxicants, mycotoxins and residues of non authorised substances not covered by an other Scientific Panel.

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[6] The Mandate Review Committee (MRC) is entrusted with the task of advising the Executive Director on the allocation of requests of scientific opinion or of scientific or technical assistance received by the European Food Safety Authority or issued by EFSA on its own initiative. The members of the MRC are: The Chair of the Scientific Committee; The Director of Risk Assessment; The Director of Scientific Cooperation and Assistance; The Director of Communication; The Director of Administration; The Head of the Scientific Committee and Advisory Forum Unit; The Head of Legal and Policy Affairs Unit. The MRC is chaired by the Executive Director).

[7] The mandates of the Scientific Panels are described in Article 28, paragraph 4 of the Regulation.

– for the **Panel on animal health and welfare**: all aspects of animal health and animal welfare, primarily relating to food producing animals including fish.

Or the Scientific Committee for tasks on multi-sectoral issues and on issues which do not fall within the competence of any of the Scientific Panels.

2. The Scientific Committee or a Scientific Panel may ask the Secretariats to clarify a question or a task assigned to it and/or to supply additional information.
3. Requests for a scientific opinion shall be presented by the Secretariat. They will consist of the question, the scientific background and the Community interest. Where necessary a deadline will be specified.

Article 7: Risk-related issues raised by the Scientific Committee or Scientific Panels

1. The Scientific Committee or a Scientific Panel may draw the Executive Director's attention to any specific or emerging issue falling within its remit which it considers to pose an actual or potential risk to consumer, animal or plant health. The Scientific Committee shall also be informed of issues raised by a Scientific Panel.
2. The Executive Director shall determine the action to be taken including, if appropriate, a request for a scientific opinion or report on the matter. In any event, the Secretariats shall inform the Scientific Committee and the relevant Scientific Panel(s) of the Executive Director's decision.

Article 8: Secretariats of the Scientific Committee and the Scientific Panels

The Secretariat shall be responsible for providing the support needed to facilitate the efficient functioning of the Scientific Committee and Scientific Panels. Specific duties of the Secretariats include but are not limited to:

- Ensuring best use of the resources allocated to the Scientific Committee or Scientific Panels and planning to meet priorities and time-limits;
- Ensuring compliance with internal rules of the Authority such as those regulating the Declarations of interests, transparency *et cetera*;
- Exercising vigilance in order to identify at an early stage any potential source of divergence between the scientific opinion of the Scientific Committee or Scientific Panel and those issued by other bodies carrying out similar tasks;
- Providing information on the legal or public policy aspects of questions;
- Preparing the work of the Scientific Committee and Scientific Panels, in consultation with their chairs;
- Drafting agendas and minutes of meetings;
- Providing support to the work carried out within and between the Scientific Committee or Scientific Panels;
- Ensuring that relevant background information is made available to the Scientific Committee or Scientific Panels;
- Assisting the Chairs of the Scientific Committee and Scientific Panels in the preparation of draft opinions before adoption;
- Dealing with requests by the Commission to provide scientific or technical assistance in accordance with Article 31 of Regulation (EC) No 178/2002;
- Ensuring the consistency and quality of editorial aspects of the scientific opinions adopted by the Scientific Panel.

Article 9: Co-ordination of the work of the Scientific Committee and the Scientific Panels

1. The Secretariats of the Scientific Committee and of the Scientific Panels shall assist in ensuring:
    a. that the Scientific Committee and Scientific Panels work in close co-operation with each other,
    b. the avoidance of overlapping or inconsistent opinions, or of diverging opinions issued by bodies carrying out similar tasks.
2. The Chairs of the Scientific Panels shall keep the Scientific Committee informed of their activities through regular reports at meetings of the Scientific Committee.
3. The Scientific Committee shall assist in ensuring consistency in the approach to risk assessment and proper assessment of multi-sectoral issues.

Article 10: Planning of meetings[8], invitations, agenda, documentation, time limits

1. The Scientific Committee and Scientific Panels shall establish a schedule of their meetings for the forthcoming calendar year.
2. As a general rule, the Secretariats will endeavour to confirm a meeting of the Scientific Committee and of a Scientific Panel not less than 10 working days before the date of the meeting and shall give notification of cancellation not less than two working days before the date of the meeting.
3. Meetings of the Scientific Committee or Scientific Panels may be called at short notice according to the urgency of the matter.
4. The draft agendas of the meetings of the Scientific Committee and Scientific Panels shall be drawn up by the Secretariats in consultation with the Chair. The draft agenda shall be circulated to members, generally within two weeks of the meeting. They shall be published on the Authority's website before the meeting. The agenda shall be adopted at the beginning of the meeting taking account of any agreed amendments.
5. Wherever possible, documents including reports and draft opinions prepared by a Rapporteur or a Working Group shall be available to the members one week before that meeting. As regards time-limits for the delivery of scientific opinions, the Authority applies the provisions laid down in Article 7 of Commission Regulation (EC) No 1304/2003. The Scientific Committee and Scientific Panels shall prioritise their work to ensure that time-limits are respected.

Article 11: Accelerated Procedures

1. Without prejudice to Regulation (EC) No 178/2002 and Commission Regulation (EC) No 1304/2003, and when not otherwise established, the procedure to be followed in order to address an urgent matter shall depend *inter alia* on the degree of urgency and the nature of the question and may be either:
    a. A response that may take the form of a statement or opinion adopted either by the Scientific Committee or the relevant Scientific Panel and issued by the Authority. The development and adoption of a statement or an opinion shall be undertaken by the Scientific Committee or the relevant Scientific Panel as far as possible in accordance with standard operating procedures, under the Executive Director's

[8] The definition of meetings includes physical meetings and meetings held by video/audio/web conference, hereinafter referred to as tele-meeting. By way of exception, Article 4, paragraphs 1,2,3 first sentence shall be considered as referred to only to meetings.

direction and taking into account the limited time allocated for the response to the question (fast track).

b. A statement by the Authority prepared by the Authority's members of staff. The Chair of the Scientific Committee or of the relevant Scientific Panel shall be informed of the question and the process. Experts from the Scientific Committee or the relevant Scientific Panel and/or a Working Group may be consulted during the process.

2. Where necessary, implementing rules for the procedures described in paragraph 1, letters a and b will be adopted by the Executive Director.

Article 12: Written Procedure

In the event that the nature, urgency or circumstances do not necessitate or allow discussion at a meeting, a draft opinion, a statement or a guidance may be adopted by written procedure. In this case, the Secretariats shall send the draft opinion to the members of the Scientific Committee or the relevant Scientific Panel with a request for approval by a specified date. The draft shall be adopted if the majority of the members of the Scientific Committee or Scientific Panel have expressed their approval before the deadline. If a majority is not reached, the draft opinion must be placed on the agenda for the next meeting of the Scientific Committee or the relevant Scientific Panel or, if the urgency requires this, an ad-hoc meeting shall be convened at the earliest date at which the quorum can be assured. The conclusion of the written procedure needs to be included in the minutes of the meeting.

Article 13: Quorum and majority

1. A quorum of at least two thirds of the members of the Scientific Committee or of a Scientific Panel shall have to be present in order to be able to adopt opinions validly.
2. The Scientific Committee and Scientific Panels shall adopt opinions by a majority of their members.

Article 14: Access to meetings and confidentiality of individual views of participants

1. The representatives of the Commission's departments shall be entitled to be present in the meetings. If invited to do so, they may assist for the purposes of clarification or information but shall not seek to influence discussions.
2. The Executive Director may invite observers to attend the meetings of the Scientific Committee and the Scientific Panels upon their suggestion. Observers shall not in any way participate or intervene in the discussions, drafting, voting or in other activities carried out in the meetings they attend.
3. With the exception of minority opinions referred to in Article 16, individual views, whether expressed orally or in writing by members during deliberations within the Scientific Committee or Scientific Panels shall be confidential.

Article 15: Adoption of scientific opinions

1. Upon suggestion of the Scientific Committee or a Scientific Panel the Authority may decide to publish a draft opinion on the Authority's website with an invitation to provide scientific comments by a specified deadline. The Scientific Committee or the relevant Scientific Panel will take account of the comments received when adopting its final opinion[9].
2. The Scientific Committee and individual Scientific Panels shall adopt their scientific opinions at their plenary meetings or, exceptionally, by one of the procedures set out in Article 11 or 12.
3. A scientific opinion shall comprise the question posed by the Commission, the Parliament, a Member State or the Authority itself, the terms of reference, the background to the request, the information considered the scientific reasoning and the opinion of the Scientific Committee or the Scientific Panel.
4. The full scientific opinion shall be published without delay on the Authority's website. Detailed rules relating to public access to scientific opinions are established in the Decision of the Management Board of the European Food Safety Authority concerning implementing measures of transparency and confidentiality requirements, according to Article 41 of the Regulation[10].

Article 16: Minority Opinions

The opinions of the Scientific Committee and Scientific Panels within the meaning of Article 29 of the Regulation shall include any minority opinions expressed by individual members of the Scientific Committee and Scientific Panels. Minority opinions shall be presented and explained by their authors at the latest at the meeting where the draft opinion is put on the agenda for adoption. Minority opinions shall include supporting argumentation, shall clearly identify the part of the main opinion to which they refer, shall be attributed to their authors and shall be discussed by the relevant Scientific Panel or the Scientific Committee. The outcome of the discussions shall be recorded in the minutes of the relevant meeting.

Article 17: Technical Hearings

1. Upon suggestion of the Scientific Committee or a Scientific Panel, technical hearings with individuals, petitioners or other stakeholder representatives may be organized by the Secretariats if it considers it necessary for the development of a scientific opinion.
2. Hearings shall be indicated clearly in the draft agenda of the meeting during which it is to take place.
3. The Scientific Committee or a Scientific Panel shall not take any decisions during hearings.

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[9] Public consultations shall be organized by EFSA on a regular basis in order to ensure the possibility for the public to comment draft scientific opinion of the Scientific Committee or Scientific Panels even if it is not explicitly foreseen in the applicable legal framework. Public consultations on draft opinions shall be carried out in accordance with EFSA's paper on public consultations, endorsed by the Management Board and available at www.efsa.europa.eu.

[10] MB 10.03.2005 – 10.

Article 18: Minutes

1. In accordance with Article 8 of the present Decision, the Secretariats of the Scientific Committee and Scientific Panels shall prepare draft minutes of plenary meetings. These shall contain, *inter alia*:
   - the list of participants;
   - conflicts of interests identified by the Secretariat screening Declarations of Interests (ADoI and/or SDoI) filled in by participants and the action taken, in accordance with EFSA's DoI Policy and its Implementing Rules;
   - a summary of discussions, including agreed actions;
   - a record of decisions taken and opinions adopted.
2. The draft minutes shall be circulated to members for comments and agreed either at the next meeting or in writing.
3. The minutes shall be placed on the Authority's website after they have been agreed.

TITLE II
Working Groups

Article 19: Working Groups

1. The Scientific Committee and Scientific Panels may establish Working Groups whenever they deem it necessary for reasons related to the need for external expertise or their capacity to fulfil their mandates or in order to enhance the multi-.disciplinary nature of their expertise. The Scientific Committee and Scientific Panels shall entrust the Working Groups with tasks that are clearly defined. In particular, the Working Group may be asked to undertake all necessary preparatory tasks in relation to a draft contribution. The Scientific Committee or the relevant Scientific Panel can require that these tasks be completed within a set period.
2. Working Groups shall report to the Scientific Committee or the relevant Scientific Panel that convened them and shall be chaired by a member of the corresponding Scientific Committee or the relevant Scientific Panel.
3. The names of participants, including the Chair, of Working Groups shall be made public.

Article 20: Delegation of responsibilities

The members of the Working Groups are appointed in a personal capacity. They shall therefore not delegate their responsibilities to another member or to a third person.

Article 21: Number and composition of members of the Working Groups

The number and the scientific expertise of members of a Working Group should be sufficient to fulfil its mandate.

Article 22: Nomination of the Chairs and vice-Chairs of Working Groups

1. The Chair of the Working Group is nominated by the Chair of the Scientific Committee or the relevant Scientific Panel, following consultation with the Secretariat in compliance with the principles referred to in Article 33.
2. When appropriate, vice-Chairs of the Working Groups may be nominated by the Chair of the Scientific Committee or the relevant Scientific Panel, following consultation with the Secretariat.

Article 23: External experts

1. Without prejudice to Regulation (EC) No 178/2002, external experts possessing particular and relevant scientific knowledge may be invited to contribute to the work of the Working Groups. The Executive Director draws up implementing rules for their selection procedure and their designation[11].
2. An external expert may be excluded from further activity within the Authority by the Executive Director in consultation with the Chair of the Working Group for not contributing effectively to the work of the Working Group or for actions which are conflicting with the Authority's internal rules.

Article 24: Rapporteurs

1. At the first meeting after the acceptance of a request for a draft opinion, the Chair of the Working Group in consultation with the Secretariat supporting that Working Group shall designate one or more Rapporteurs, if possible. Rapporteur(s) shall ensure that the draft opinion is prepared, if necessary within a set time period. If that is not possible, the Chair endeavours to designate one or more Rapporteurs at a later stage. The Rapporteur(s) shall work in close co-operation with the relevant Secretariat and may present the draft opinion of the Working Group to the relevant Scientific Panel.
2. The work of a Rapporteur ends when the Authority issues the opinion.

Article 25: Support to Working Groups

The Secretariats of the Scientific Committee and Scientific Panels shall be responsible for providing the support needed to facilitate the efficient functioning of Working Groups. Specific duties of the Secretariats include but are not limited to:

- Ensuring best use of the resources allocated to Working Groups and planning to meet priorities and time-limits;
- Ensuring compliance with internal rules of the Authority such as those regulating the Declarations of interests, transparency *et cetera*;
- Exercising vigilance in order to identify at an early stage any potential source of divergence between draft contributions of Working Groups and those issued by other bodies carrying out similar tasks;
- Providing information on the legal or public policy aspects of questions;
- Preparing the work of Working Groups, in consultation with their chairs;
- Drafting agendas and minutes of meetings;
- Providing support to the work carried out within Working Groups;

[11] 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 last amended, available at www.efsa.europa.eu.

- Ensuring that relevant background information is made available to Working Groups;
- Assisting the Chairs of Working Groups in the preparation of draft contributions;
- Ensuring the consistency and quality of editorial aspects of the draft contributions.

Article 26: Quorum

No quorum shall be required for meetings of the Working Groups to be valid.

Article 27: Access to meetings and confidentiality of individual views of participants

1. The representatives of the Commission's departments shall be entitled to be present in the meetings. If invited to do so, they may assist for the purposes of clarification or information but shall not seek to influence discussions.
2. The Executive Director may invite observers to attend the meetings of Working Groups upon their suggestion. Observers shall not in any way participate or intervene in the discussions, in the drafting or in other activities carried out in the meetings they attend.
3. Individual views, whether expressed orally or in writing by members during discussion within Working Groups shall be confidential.

Article 28: Finalisation of a draft contribution

1. The Working Group shall finalise their draft contribution to the work of the Scientific Committee or the Scientific Panels at their meetings or in writing. The Chair of the Working Group shall decide when the Terms of Reference of the relevant mandate or question have been addressed in the draft contribution.
2. Upon decision of the Chair of the Working Group, the draft contribution shall be forwarded to the Scientific Committee or the relevant Scientific Panel(s) as a draft contribution. Diverging views expressed by members of the Working Group shall be reported by the Chair of the Working Group to the Scientific Committee or the relevant Scientific Panel(s) for consideration.

Article 29: Technical Hearings

1. Upon suggestion of Working Groups, technical hearings with individuals, petitioners or other stakeholder representatives may be organized by the Secretariat if it considers it necessary for the development of a draft contribution.
2. Hearings shall be indicated clearly in the draft agenda of the meeting during which it is to take place.

Article 30: Minutes

1. According to its tasks, as laid down in the present Decision, the Secretariat providing support to the Working Group shall prepare draft minutes of Working Groups' meetings. These shall contain, *inter alia*:
   - the list of participants;
   - conflicts of interests identified by the Secretariat screening Declarations of Interests filled in by participants and the action taken, in accordance with EFSA's DoI Policy and its Implementing Rules;
   - a summary of discussions.
2. The draft minutes shall be circulated to members for comments and agreed not later than the next meeting or in writing.
3. The minutes shall be placed on the Authority's website after they have been agreed.

TITLE III
Common Provisions

Article 31: Mission expenses of members, external experts and indemnities

1. Travel and subsistence expenses incurred by members in connection with meetings relating to the Scientific Committee or Scientific Panels or incurred by members or external experts in connection with meetings relating to one of their Working Groups shall be reimbursed by the Authority in accordance with the scales laid down in the Authority experts compensation guide, in line with the Commission Decision related to the experts compensation.
2. Members and external experts shall be entitled to an indemnity of 300 €[12] for each full day of meeting attendance to defray other costs derived from their contribution to and participation in the work of the Scientific Committee or a Scientific Panel or one of their Working Groups. As a compensation for costs incurred by the preparatory work for meetings, the Chairs of the Scientific Committee, Scientific Panels and Working Groups shall be entitled to one additional daily indemnity per meeting.
3. Members and external experts shall be entitled to an indemnity of 100 € per hour of attendance of tele-meeting to defray costs derived from their contribution to and participation in the work of the Scientific Committee or a Scientific Panel or one of their Working Groups. The ceiling per meeting per day shall be 385 €. As a compensation for costs incurred by the preparatory work for meetings, the Chairs of the Scientific Committee, Scientific Panels and Working Groups shall be entitled to an additional indemnity of 50 € per any hour of chairing a tele-meeting. The ceiling per meeting per day for chairs shall be 770 €.
4. Each Rapporteur shall be entitled to an indemnity of up to 600 €[13] to defray costs linked to the co-ordination of preparatory work for draft scientific opinions.
5. Implementing rules may be adopted by the Executive Director in order to establish in which cases the Authority may reimburse travel and subsistence expenses incurred by hearing experts and grant them the indemnities referred to in paragraphs 1 and 2.

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12 As of 1 July 2010, the indemnity shall amount to 385 €.
13 As of 1 July 2010 the indemnity shall amount to 770 €.

Article 32: Confidentiality

1. Members of Scientific Committee or Scientific Panels as well as external experts and hearing experts participating in their Working Groups, or acting as observers, shall not divulge to third parties information specifically identified by the Authority as "restricted" or "confidential".
2. Members of the Scientific Committee or Panels as well as external experts and hearing experts participating in their Working Groups, or acting as observers, shall sign a written declaration that they will comply with the rules of confidentiality set out in paragraph 1[14].
3. Members of the Scientific Committee or Scientific Panels and external experts participating in their Working Groups, or acting as observers, shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy.

Article 33: Independence

1. Members of the Scientific Committee and Scientific Panels, Working Groups as well as external experts shall undertake to act independently of any external influence. For this purpose, they shall make a Declaration of Commitment[15] and an Annual Declaration of Interests[16] in accordance with the Guidance Document on Declarations of Interest[17].
2. These declarations shall be made annually in writing and shall be published on the Authority's website.
3. The members of the Scientific Committee, Scientific Panels, Working Groups as well as external experts, at each meeting shall declare any interests which might be considered prejudicial to their independence in relation to the items on the agenda (Specific Declaration of Interests)[18], in accordance with the Guidance document on declarations of interest.

Article 34: Entry into force

1. The present Decision shall enter into force on 1 February 2010.
2. The Management Board may return to these rules whenever deemed necessary and adopt any modifications needed.

Stockholm, 17 December 2009

Prof. Diána Bánáti
Chair

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[14] Annex 4 of the Guidance Document on Declaration of Interests, available on EFSA's website.
[15] Annex 1 of the Guidance Document on Declaration of Interests, available on EFSA's website.
[16] Annex 2 of the Guidance Document on Declaration of interest, available on EFSA's website.
[17] See EFSA's Policy on declaration of interests adopted by the MB, available on EFSA's website.
[18] Annex 3 of the Guidance Document on Declarations of Interests, available on EFSA's website.

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MB Doc. 10.03.2004 - 5

European Food Safety Authority

EFSA CODE OF CONDUCT ON DECLARATIONS OF INTERESTS

Introduction

Regulation 178/2002 establishing the European Food Safety Authority (EFSA) highlights the importance of ensuring the confidence of the Community institutions, the general public and interested parties in the Authority. To that effect it is essential to ensure its independence, high scientific quality, transparency and efficiency.

Integrity and high standards of professional conduct by all those involved in the activities of the European Food Safety Authority - members of the Management Board, Advisory Forum, scientific committee and panels, external experts and staff - are therefore crucial for its independence and for its reputation.

The EFSA has now become fully operational and it is clear that some guidance is needed in relation to several points of critical importance relating to direct and indirect interests and the necessity to declare them in order to avoid potential conflicts of interest.

1. Legal basis

Article 37 of Regulation (EC) No 178/2002 as amended lays down provisions which require that

1. The members of the Management Board, the Members of the Advisory Forum and the Executive Director shall undertake to act independently in the public interest.

   For this purpose, they shall make a declaration of commitment and a 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. Those declarations shall be made annually in writing.

2. The members of the Scientific Committee and the Scientific Panels shall undertake to act independently of any external influence.

   For this purpose, they shall make a declaration of commitment and a 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. Those declarations shall be made annually in writing.

3. 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.

The Executive Director has decided that the requirement to declare interests should extend to the Deputy Executive Director/Director of Science and all A grade staff in the Authority's Science, Communications, Institutional and Legal Departments.

The forms for the declaration of commitment and annual declaration of interests are annexed to the respective implementation instruments[1] and are set out in Annex.

2. *Who should declare interests?*

- All Management Board, Advisory Forum, Scientific committee and Panels members and external experts
- The Executive Director, the Deputy Executive Director and all A grade staff in the Science, Communications, Institutional and Legal Departments.
- The EFSA Code of Conduct will apply by analogy to all visiting staff (e.g. national experts on secondment, trainees or visiting experts).

3. *What to declare?*

Each individual is responsible for the declaration of his interests and those held by members of his household.[2] Interests may include those held by members of his household, membership of interest group etc. In order to maintain privacy, the names of household members do not need to be declared.

What is an interest?

There are essentially three categories of interests:

(a) Financial interests
Any financial interests in a company operating in the food or feed business[3], including holding of stocks and shares, equity, bonds, partnership interests[4] in the capital of a company, one of its subsidiaries or a company in the capital of which it has a holding.

The holding of financial interests connected with a pension scheme previously contracted prior to the nomination or appointment at EFSA and/or interests in non-nominal unit trusts or similar arrangements would not, in principle, have particular consequences providing the individual has no influence on financial management.

(b) Work carried out for a company operating in the food or feed business
During the preceding five years, all activities performed for or on behalf of a company operating in the food or feed business[5], whether or not these activities have been subject to regular or occasional remuneration in cash or kind, including:

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[1] Decision concerning the establishment and operations of the Scientific Committee and Panels, (adopted by the Management Board on 17.10.2002); Rules of procedure of the Management Board (as last amended on 16.9.2003); Rules of Procedure of the Advisory Forum (as last amended on 18.6.2003)

[2] Spouse or partner and dependent children living in the same household.

[3] By reference to the definitions set out in Article 3 of Regulation (EC) 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.

[4] When declaring financial interests e.g. stocks and shares, only the kind, number and company name need be stated.

[5] Company name, position held and activities performed should be set out clearly and precisely. Where activities relate to (a) specific product(s) or substance(s), declarations must indicate product or substance name and nature of the work.

- Participation in the internal decision-making of a company (e.g. Board membership, executive or non executive directorship)
- Permanent or temporary member of the personnel of a company. Other activities performed within a company (e.g. traineeship) are also subject to declaration.
- Work contracted out by companies, through consultancy or otherwise.

(c) Other links with the food or feed business
During the preceding five years, all assistance and support received from the food or feed business, whether associated with direct or indirect pecuniary or material benefits, including:
- Grants for study or research
- Fellowships or sponsorships endowed by a company operating in the food or feed business

(d) "Intellectual" interests
Interests of non-pecuniary or material benefits to the individual, arising from professional activities or affiliation with national or international organisations or bodies with tasks similar to EFSA or participation in public interest groups, professional societies, clubs or organisations which have an agenda or an interest or involvement in the Authority's work.

What are direct and indirect interests?

Interests can be direct or indirect depending on their likely or potential impact on the individual's behaviour at a given point in time.

Direct interests: Interests of personal benefit to the individual at the time of declaration, likely to influence or give the appearance of influencing his behaviour (e.g. employment with a company operating in the food or feed business, financial interests of a certain magnitude)

Indirect interests: Other interests that may have some influence over the individual's behaviour and therefore have to be neutralised.

The holding of direct interests of a certain magnitude would in principle be incompatible with membership or affiliation to EFSA. Regulation (EC) 178/2002 does not prohibit the holding of indirect interests, which are subject to public declaration. Indirect interests should be scrutinised so that precautions can be taken in order to ensure impartiality of decision taking. Appropriate actions could include precluding the individual from certain functions or tasks (e.g. rapporteur) or requiring abstention from part of the relevant proceedings or voting in a meeting.

4. When to declare?

Initial declaration
Upon nomination or appointment, each individual concerned is required to fill out a commitment of independence and declaration of interests' form.

Appointment as rapporteur
Members of the Scientific committee, a panel or working group should not accept appointment as rapporteur for an opinion if it becomes apparent that there could be a conflict of interest because that person has personal involvement in the studies contained in the dossier.

Spontaneous declarations
If during assessment or advisory work, a potential conflict becomes apparent to a member or expert, then it must be declared to the chairperson immediately who will notify the Secretariat and appropriate action agreed to. This in particular would include a situation where an expert is asked to assess data of his own research or his own expert report in a dossier.

Updates
Declarations of interests must be updated at least annually or as soon as an update is required for any new situation arising.

5. *Operational aspects*

Tasks of EFSA staff

The EFSA Scientific staff, under the direct responsibility of the Director of Science, undertakes the following:

- To remind all parties concerned of their obligation to declare the interests;
- To monitor regularly declarations and preliminary appraisal of compatibility of interests declared with general or specific office or duties of the individuals concerned;
- To initiate and facilitate handling of issues in close liaison with the meeting chairperson (e.g. scientific committee, panel or working group).

In accordance with Article 38 of Regulation (EC) 178/2002, the Authority will also ensure the public availability of annual declarations of interests. Declarations made at meetings and the outcome of discussions shall be duly recorded in meeting minutes.

Obligations of individuals concerned

Members of the Management Board, Advisory Forum, Scientific Committee, Panels and experts have a primary obligation to disclose at any time the existence of possible conflict of interests that may place the impartiality of EFSA at risk. The individual should state in particular the type and nature of interests, specifying whether they are general or relate to a specific product or substance. If the conflict is product or substance-related, prior involvement in relation to competing products and past and current links with companies should also be declared.

Meeting proceedings

Individuals have the primary responsibility for spontaneously declaring any conflict of interest at all times.

In accordance with Article 38 (d) of Regulation (EC) 178/2002, meeting chairpersons should at each meeting request whether interests with specific items on the agenda exist. The outcome should be recorded in minutes of meetings together with statements on interests declared.

On the basis of the type and nature of interests noted, the Chairperson, in consultation with EFSA staff, could consider various options, including:

- Fundamental incompatibility with membership
- Temporary exclusion from the meeting
- Active participation in proceedings, no voting
- Passive participation in proceedings, no voting
- Active participation in proceedings, voting

ANNEX 1: COMMITMENT OF INDEPENDENCE

Name: _____

Position : [ ] Member of the SC
[ ] Member of a Panel on :.....
[ ] Member of a Working Group

I hereby undertake to act independently of any external influence. In particular I know that I am obliged to make an annual written declaration of interests and to declare at each meeting of the Scientific Committee or the Scientific Panels or of their Working Groups any interest which might be considered prejudicial to my independence in relation to the items on the agenda.

DONE AT _____ ON _____

ANNEX 2: ANNUAL DECLARATION OF MEMBER'S INTERESTS

Name: _____

Position : [ ] Member of the SC
[ ] Member of a Panel on :.....
[ ] Member of a Working Group

Information on direct or indirect interests of relevance to the mission of the Authority

(1) Direct interest (financial benefits arising from, for example, employment, contracted work, investments, fees etc.):

(2) Indirect interests (indirect financial, e.g. grants, sponsorships, or other kind of benefits):

(3) Interests deriving from the professional activities of the member or his/her close family Members:

(4) Any Membership role or affiliation that you have in organisations/bodies/club with an interest in the work of the Authority:

(5) Other interests or facts that the undersigned considers pertinent:

Declaration:
I declare on my word of honour that the information provided above is true and complete.

Done at_____ on _____

Signature: _____

European Food Safety Authority

GUIDANCE ON DECLARATIONS OF INTERESTS

(endorsed by the Management Board on 16 December 2004)

INTRODUCTION

1. Regulation 178/2002 establishing the European Food Safety Authority (EFSA) highlights the importance of ensuring the confidence of the Community institutions, the general public and interested parties in the Authority. To that effect it is essential to ensure its independence, high scientific quality, transparency and efficiency.

2. Integrity and high standards of professional conduct by all those involved in the activities of the European Food Safety Authority - members of the Management Board, Advisory Forum, Scientific Committee, Scientific Panels, Expert Working Groups, *ad hoc* external experts and staff - are therefore crucial for its independence and for its reputation.

3. One aspect of integrity is to demonstrate that those involved in the work of EFSA act independently of any external influence related to the subject of the activity. Therefore, professionals involved in the activities of EFSA must reveal on a regular basis the interests they may have in the outcome of EFSA's assessments and other outputs. To that end, the Management Board endorsed in March 2004 the "Code of Conduct on Declarations of Interests" (MB-10.03.2004-5). In using the "Code of Conduct" it appeared that there was a misunderstanding with respect to the nature and level of detail of what should be considered an interest that needed to be declared. Therefore it was considered appropriate to amend document MB-10.03.2004-5 to:

- clarify that an "interest" is not automatically considered as a negative and undesirable element;
- further elaborate on what constitutes an "interest"; and
- harmonise the level of detail of material and intellectual interests.

4. It should be noted that according to Regulation 178/2002 the primary responsibility for assessing whether an interest might impede independence and for declaring any possible conflict of interest is placed on the individuals. This guidance aims at supporting experts in complying with their obligations.

5. 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 as mentioned in Article 24 of Regulation 178/2002, i.e. the Management Board, the Advisory Forum, the Scientific Committee, any of the Scientific Expert Panels and EFSA staff members, as well as any Expert Working Group or who are *ad hoc* external experts of any of these groups, all have a

professional interest in the work they are undertaking and in the outcome of these activities. In the work of EFSA these interests are usually of an intellectual nature and are even

considered as indispensable to safeguard the quality and overall balanced objectivity of the scientific work.

6. It should therefore be highlighted that the intention of this guidance is not to ban or sanction the holding of interests by individuals operating in the sphere of EFSA. 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 however necessary to facilitate throughout the spectrum of EFSA activities, in a clear and consistent manner, understanding and handling of situations where potential conflicts may arise.

LEGAL BASIS

7. Article 37 of Regulation (EC) No 178/2002 as amended lays down provisions which require that:

i. The members of the Management Board, the Members of the Advisory Forum and the Executive Director shall undertake to act independently in the public interest.

   For this purpose, they shall make a declaration of commitment and a 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. Those declarations shall be made annually in writing.

ii. The members of the Scientific Committee and the Scientific Panels and members of Expert Working Groups shall undertake to act independently of any external influence.

   For this purpose, they shall make a declaration of commitment and a 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. Those declarations shall be made annually in writing.

iii. The members of the Management Board, the Executive Director, the members of the Advisory Forum, the members of the Scientific Committee, the Scientific Panels, Expert Working Groups as well as *ad hoc* 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.

WHO SHOULD DECLARE INTERESTS?

8. The Executive Director has decided that the requirement to declare interests should apply to the Executive Director, the Deputy Executive Director/Director of Science and all A-grade staff in the Authority's Science, Communications, International and Institutional Affairs and Legal Departments.

9. In summary, taking into account this Guidance, declarations of interest are requested from:

- All members of the Management Board, the Advisory Forum, the Scientific Committee, the Scientific Panels and to all *ad hoc* external experts on EFSA committees;
- The Executive Director, the Deputy Executive Director and all A-grade staff in the Science, Communications, International/Institutional Affairs and Legal Departments

10. The EFSA Guidance on Declarations of Interest will apply by analogy to all visiting staff, including national experts on secondment (ENDs), trainees and visiting experts.

11. Each individual is responsible for the declaration of his interests. Interests may include interests held by first-line members of his family/household (i.e. spouse or partner and dependent children living in the same household), membership of interest groups etc. In order to maintain privacy, the names of family/household members do not need to be declared.

12. The forms for the declaration of commitment and annual declaration of interests are annexed to the respective implementation instruments[1] and are set out in the Annex.

WHAT TO DECLARE?

What is an interest?

13. There are essentially four categories of interests: (a) financial interests, (b) work carried out for food, feed and animal production-related business, (c) other links with the food, feed and animal production-related business, and (d) intellectual interests. Any interest stemming from prior experience or affiliation of the individual with food, feed and animal production related business should be declared only insofar as they relate directly to the specific area of expertise or field of activity of the individual within EFSA. As a clarifying illustration the following examples may be useful (for examples of intellectual interest see paragraphs 16 and 17):

- Previous affiliation of an individual with an animal feed producing company is not considered a declarable interest in the context of this individual's involvement in activities related to the work on human health/risk assessment of dietetic products, nutrition and allergies.
- Previous affiliation of an individual with the development/production of genetically modified plant organisms is not considered a declarable interest in the context of this individual's involvement in activities related to the work on animal health and welfare.
- Previous affiliation of an individual with the development/production of genetically modified micro-organisms is considered a declarable interest in the context of this individual's involvement in activities related to the work of the GMO Panel and the BIOHAZ Panel.

[1] Decision concerning the establishment and operations of the Scientific Committee and Panels, (adopted by the Management Board on 17.10.2002); Rules of procedure of the Management Board (as last amended on 22.06.2004); Rules of Procedure of the Advisory Forum (as last amended on 18.6.2003)

(a) ***Financial interests***

14. Any financial interests in a company operating in the food or feed business[2], including holding of stocks and shares, equity, bonds, partnership interests[3] in the capital of a company, one of its subsidiaries or a company in the capital of which it has a holding.

Note: The holding of financial interests connected with a pension scheme previously contracted prior to the nomination or appointment at EFSA and/or interests in non-nominal unit trusts or similar arrangements would not, in principle, have particular consequences providing the individual has no influence on financial management and, therefore, are not considered a financial interest.

(b) ***Work carried out for a company operating in the food, feed or animal production related business***

15. During the preceding five years, all activities performed for or on behalf of a company operating in the food, feed or animal production related business[4], whether or not these activities have been subject to regular or occasional remuneration in cash or kind, directly or indirectly, including:

- Participation in the internal decision-making of a company (e.g. board membership, executive or non executive directorship).
- Permanent or temporary member of the personnel of a company. Other activities performed within a company (e.g. traineeship) are also subject to declaration.
- Work contracted out by companies, through consultancy or otherwise.

(c) ***Other links with the food, feed or animal production related business***

16. During the preceding five years, all assistance and support received from the food, feed or animal production related business, whether associated with direct or indirect pecuniary or material benefits, including:

- grants for travel, study or research;
- fellowships or sponsorships endowed by a company operating in the food or feed business.

(d) ***Intellectual interests***

17. During the preceding five years, interests of non-pecuniary or material benefit to the individual, arising from professional activities or affiliation with national or international organisations or bodies with tasks mirroring those of EFSA. Intellectual interests also include participation in public interest groups, professional/scientific societies, religious

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[2] By reference to the definitions set out in Article 3 of Regulation (EC) 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. For the purpose of the declarations of interests the involvement in public bodies shall fall under intellectual interests.

[3] When declaring financial interests e.g. stocks and shares, only the kind, number and company name need be stated.

[4] Company name, position held and activities performed should be set out clearly and precisely. Where activities relate to (a) specific product(s) or substance(s), declarations must indicate product or substance name and nature of the work.

organisations, communication media, clubs or organisations which have an agenda or an interest or involvement in the Authority's work.

18. Examples of intellectual interests include the participation of the individual in scientific projects and the (co)authorship of scientific documents or literature. As explained in paragraph 4 intellectual interest is often a prerequisite for the scientific excellence of the work and is not necessarily considered an undesirable bias as long as the interest is known to all individuals involved in the activity. The various interests of individuals in a group (e.g., a panel) once put together may well result in a balanced interest of the group as a whole.

What are direct and indirect interests?

19. Interests can be direct or indirect depending on their likely or potential impact on the individual's behaviour at a given point in time.

- Direct interests: Interests of personal benefit to the individual at the time of declaration, likely to influence or give the appearance of influencing his behaviour (e.g. employment with a company operating in the food, feed or animal production related business, financial interests of a certain magnitude)

- Indirect interests: Other interests that may have some influence over the individual's behaviour and therefore have to be neutralised.

20. The holding of direct interests of a certain breadth could be incompatible with membership or affiliation to EFSA. Regulation (EC) 178/2002 does not prohibit the holding of indirect interests, which are subject to public declaration. Indirect interests should be scrutinised so that precautions can be taken in order to ensure impartiality of decision making. Appropriate actions could include precluding the individual from certain functions or tasks (e.g. rapporteur) or requiring abstention from part of the relevant proceedings or voting in a meeting.

WHEN TO DECLARE?

Initial declaration

21. Upon nomination or appointment, each individual concerned is required to fill out a commitment of independence and the declaration of interests form.

Appointment as rapporteur

22. Members of the Scientific Committee, a Panel or Working Group should not accept appointment as rapporteur for an opinion if it becomes apparent that their declaration of interests could lead to a conflict of interest e.g. because that person has personal involvement in the studies contained in the dossier.

Spontaneous declarations

23. If during assessment or advisory work or any other activity in EFSA, an individual becomes aware that he has an interest that may be in conflict with the current activity he is involved in, then this must be declared immediately to the chairperson of the group he is member of who will notify the Secretariat to consider appropriate action. This in particular

would include a situation where an expert is asked to assess data of his own research or his own expert report in a dossier.

Updates

24. Declarations of interests must be updated at least annually or as soon as an update is required for any new situation arising.

OPERATIONAL ASPECTS

Tasks of EFSA staff

25. The EFSA Scientific staff, under the direct responsibility of the Director of Science, undertakes the following:

- To remind all parties concerned of their obligation to declare the interests;
- To monitor regularly declarations and preliminary appraisal of compatibility of interests declared with general or specific office or duties of the individuals concerned;
- To initiate and facilitate handling of issues in close liaison with the meeting chairperson (e.g. scientific committee, panel or working group);
- To declare their interests as needed but at least annually.

26. EFSA A-level staff in the Communications, International/Institutional Affairs and Legal Departments, under the direct responsibility of the Executive Director undertake to declare their interest as needed but at least annually.

27. In accordance with Article 38 of Regulation (EC) 178/2002, the Authority will also ensure the public availability of annual declarations of interests. Declarations made at meetings and the outcome of discussions related to declarations of interest shall be duly recorded in meeting minutes.

Obligations of individuals concerned

28. Members of the Management Board, Advisory Forum, Scientific Committee, Panels and other experts have a primary obligation to disclose at any time the existence of possible conflict of interests that may place the impartiality of EFSA at risk. The individual should state in particular the type and nature of interests, specifying whether they are general or relate to a specific product or substance. If the conflict is product- or substance-related, prior involvement in relation to competing products and past and current links with companies should also be declared.

Meeting proceedings

29. Individuals have the primary responsibility for spontaneously declaring any conflict of interest at all times.

30. In accordance with Article 38 (d) of Regulation (EC) 178/2002, meeting chairpersons should at each meeting request whether interests with specific items on the agenda exist. The outcome should be recorded in minutes of meetings together with statements on interests declared.

31. On the basis of the type and nature of interests noted, the Chairperson, in consultation with EFSA staff, could consider various options, including:

- Fundamental incompatibility with membership of the Group ;
- Temporary exclusion from the meeting;
- Passive participation in proceedings;
- Active participation in proceedings.

ANNEX 1: COMMITMENT OF INDEPENDENCE

Name: _____

Position :

[ ] Member of the Management Board
[ ] Member of the Advisory Forum
[ ] Member of the Scientific Committee
[ ] Member of the Panel on .....
[ ] Member of the Expert Working Group on.....
[ ] Member of EFSA staff

Pursuant to Article 37 of Regulation (EC) 178/2002 establishing the Authority, I hereby undertake to act independently of any external influence. In particular I know that I am obliged to make an annual written declaration of interests and to declare at each meeting of the Management Board, Advisory Forum, Scientific Committee, Scientific Expert Group or the Scientific Panels or of their Working Groups any interest which might be considered prejudicial to my independence in relation to the items on the agenda.

DONE AT _____ ON _____

SIGNATURE: _____

ANNEX 2: ANNUAL DECLARATION OF INTERESTS

Name: _____

Position :

[ ] Member of the Management Board
[ ] Member of the Advisory Forum
[ ] Member of the Scientific Committee
[ ] Member of the Panel on :.....
[ ] Member of the Expert Working Group on.....
[ ] Member of EFSA staff

Information on direct or indirect interests of relevance to the mission of the Authority

(1) Direct interest (financial benefits arising from, for example, employment, contracted work, investments, fees etc.):

(2) Indirect interests (indirect financial, e.g. grants, sponsorships, or other kind of benefits):

(3) Interests deriving from the professional activities of the member or his/her close family Members:

(4) Any Membership role or affiliation that you have in organisations/bodies/club with an interest in the work of the Authority:

(5) Other interests or facts that the undersigned considers pertinent:

Declaration:
I declare on my word of honour that the information provided above is true and complete.

Done at_____ on _____

Signature: _____

efsa
European Food Safety Authority

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 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

- o the importance of providing declarations of interests and
- o 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.

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[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

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[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).

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[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.

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[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: _____

(9)

efsa
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.

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[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)

(10)

MB 16.09.2003 – 11 – Adopted

European Food Safety Authority

EFSA CODE OF GOOD ADMINISTRATIVE BEHAVIOUR

THE MANAGEMENT BOARD,

Having regard to the Treaty of the European Union, and in particular Articles 21 and 195 thereof,

Having regard to Article 41 of the Charter of Fundamental Rights,

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[1],

Having regard to the own-initiative inquiry of the European Ombudsman into the existence and the public accessibility, in the different Community institutions and bodies, of a Code of good administrative behaviour for agents or other servants in their relations with the public,

Having regard to the proposal from the Executive Director,

WHEREAS the Amsterdam Treaty has explicitly introduced the concept of openness into the Treaty on European Union by stating that it marks a new stage in the process of creating an ever closer union in which decisions are taken as openly as possible and as closely as possible to the citizen,

WHEREAS the Charter of fundamental rights proclaimed at the Nice Summit in December 2000 includes as fundamental rights of citizenship the right to good administration and the right to complain to the European Ombudsman against maladministration,

WHEREAS, in order to bring the administration closer to the citizens and to guarantee a better quality of administration, a Code should be adopted which contains the basic principles of good administrative behaviour for agents and other servants of the Authority when dealing with the public,

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[1] OJ L 31 of 1.2.2002, p. 1

MB 16.09.2003 – 11 - Adopted

Considering it therefore desirable to establish a Code governing the principles of good administrative behaviour which the agents and other servants of the Authority should respect in their relations with the public, and to make this Code publicly available,

HAS DECIDED AS FOLLOWS:

Article 1 - General provision

In their relations with the public, any agent and other servant of the Authority shall respect the principles which are laid down in this Decision and which constitute the Code of good administrative behaviour, hereafter referred to as 'the Code'.

Article 2 - Personal scope of application

The Code shall apply to all agents and other servants to whom the Staff Regulations and the Conditions of employment of other servants apply, in their relations with the public.

The Code shall also apply to Members of the Authority's constitutive bodies when acting for or on behalf of the Authority in their relations with the public.

The Authority will take the necessary measures to ensure that the provisions set out in this Code also apply to other persons working for it, such as persons employed under private law contracts, experts on secondment from national civil services and trainees.

The public refers to natural and legal persons, whether they reside or have their registered office in a Member State or not.

Article 3 - Material scope of application

This Code contains the general principles of good administrative behaviour, which apply to all relations of the Authority's agents and other servants with the public, unless they are governed by specific provisions.

The principles set out in this Code do not apply to the relations between the Authority and its agents and other servants. Those relations are governed by the Staff Regulations.

Article 4 - Lawfulness

The agents or other servants of the Authority shall act according to law and apply the rules and procedures laid down in Community legislation. The agents or other servants of the Authority shall in particular take care that decisions which affect the rights or interests of individuals have a basis in law and that their content complies with the law.

Article 5 - Absence of discrimination

In dealing with requests from the public and in taking decisions, the agents or other servants of the Authority shall ensure that the principle of equality of treatment is

respected. Members of the public who are in the same situation shall be treated in a similar manner.

If any difference in treatment is made, the agents or other servants of the Authority shall ensure that it is justified by the objective relevant features of the particular case.

The agents or other servants of the Authority shall in particular avoid any unjustified discrimination between members of the public based on nationality, sex, racial or ethnic origin, religion or belief, disability, age, or sexual orientation.

Article 6 – Proportionality

When taking decisions, the agents or other servants of the Authority shall ensure that the measures taken are proportional to the aim pursued. The agents or other servants shall in particular avoid restricting the rights of the citizens or imposing charges on them, when those restrictions or charges are not in a reasonable relation with the purpose of the action pursued.

When taking decisions, the agents or other servants of the Authority shall strike a fair balance between the interests of private persons and the general public interest.

Article 7 - Absence of abuse of power

Powers shall be exercised solely for the purposes for which they have been conferred by the relevant provisions. The agents or other servants of the Authority shall in particular avoid using those powers for purposes which have no basis in the law or which are not motivated by any public interest.

Article 8- Impartiality and independence

The agents or other servants of the Authority shall be impartial and independent. They shall abstain from any arbitrary action adversely affecting members of the public, as well as from any preferential treatment on any grounds whatsoever.

The agents or other servants of the Authority shall not be guided by any outside influences of whatever kind, including political influences, or by personal interests.

The agents or other servants shall abstain from being involved in the taking of a decision on a matter concerning their own interests, or those of their family, relatives, friends and acquaintances.

Article 9 - Objectivity

When taking decisions, the agents or other servants shall take into consideration the relevant factors and give each of them its proper weight in the decision, whilst excluding any irrelevant element from consideration.

MB 16.09.2003 – 11 - Adopted

Article 10 - Legitimate expectations and consistency

The agents or other servants of the Authority shall be consistent in their own administrative behaviour as well as with the administrative action of the Authority. The agents or other servants shall follow the Authority's normal administrative practices, unless there are legitimate grounds for departing from those practices in an individual case.

The agents or other servants shall respect the legitimate and reasonable expectations that members of the public have in the light of how the Authority has acted in the past.

Article 11 - Fairness

The agents or other servants of the Authority shall act fairly and reasonably.

Article 12 - Courtesy

The agents or other servants of the Authority shall be service-minded, correct, courteous and accessible in relations with the public. When answering correspondence, telephone calls and e-mails, the agents or other servants shall try as much as possible to be helpful and to reply to the questions which are asked.

If an agent or other servant is not responsible for the matter concerned, he or she shall direct the citizen to the appropriate agent or other servant.

If an error occurs which negatively affects the rights or interests of a member of the public, the agents or other servants shall apologise for it.

Article 13 - Reply to letters in the language of the citizen

The agents or other servants shall ensure that every citizen of the Union or any member of the public who writes to the Authority in one of the Treaty languages receives an answer in the same language.

Article 14 - Acknowledgement of receipt and indication of the competent agent or other servant

Every letter or complaint to the Authority shall receive an acknowledgement of receipt within a period of two weeks, except if a substantive reply can be sent within that period.

The reply or acknowledgement of receipt shall indicate the name and the telephone number of the agent or other servant who is dealing with the matter, as well as the service to which he or she belongs.

No acknowledgement of receipt and no reply need be sent in cases where letters or complaints are abusive because of their excessive number or because of their repetitive or pointless character.

Article 15 - Obligation to transfer to the competent service of the Authority

If a letter or a complaint to the Authority is addressed or transmitted to a department which has no competence to deal with it, its staff shall ensure that the file is transferred without delay to the competent department of the Authority.

The department which originally received the letter or complaint shall notify the author of this transfer and shall indicate the name and the telephone number of the agent or other servant to whom the file has been passed.

Article 16 - Right to be heard and to make statements

In cases where the rights or interests of individuals are involved, the agents or other servants shall ensure that, at every stage in the decision-making procedure, the rights of defence are respected.

Every member of the public shall have the right, in cases where a decision affecting his rights or interests has to be taken, to submit written comments and, when needed, to present oral observations before the decision is taken.

Article 17 - Reasonable time-limit for taking decisions

The agents or other servants shall ensure that a decision on every request or complaint to the Authority is taken within a reasonable time limit, without delay, and in any case no later than two months from the date of receipt. The same rule shall apply for answering letters from members of the public.

If a request or a complaint to the Authority cannot, because of the complexity of the matters which it raises, be decided upon within the above-mentioned time-limit, the agents or other servants shall inform the author thereof as soon as possible. In that case, a definitive decision should be notified to the author in the shortest time.

Article 18 - Duty to state the grounds of decisions

Every decision, opinion or recommendation of the Authority which may adversely affect the rights or interests of a private person shall state the grounds on which it is based by indicating clearly the relevant facts and the legal basis of the decision.

The agents or other servants shall avoid making decisions which are based on brief or vague grounds or which do not contain individual reasoning.

If it is not possible, because of the large number of persons concerned by similar decisions, to communicate in detail the grounds of the decision and where standard replies are therefore made, the agents or other servants shall guarantee that he subsequently provides the citizen who expressly requests it with an individual reasoning.

Article 19 - Indication of the possibilities of appeal

A decision, opinion or recommendation of the Authority which may adversely affect the rights or interests of a private person shall as appropriate contain an indication of the appeal possibilities available for challenging the decision, opinion or recommendation. It shall in particular indicate the nature of the remedies, the bodies before which they can be exercised, as well as the time limits for exercising them.

Article 20 - Notification of the decision or recommendation

The agents or other servants shall ensure that decisions or recommendations which affect the rights or interests of individual persons are notified in writing, as soon as the decision has been taken, to the person or persons concerned.

The agents or other servants shall abstain from communicating the decision to other sources until the persons or persons concerned have been informed.

Article 21- Data protection

The agents or other servants who deal with personal data concerning a citizen shall respect the principles laid down in the Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and the free movement of such data.

The agents or other servants shall in particular avoid processing personal data for non-legitimate purposes or the transmission of such data to non-authorised persons.

Article 22 - Requests for information

The agents or other servants shall, when they have responsibility for the matter concerned, provide members of the public with the information that they request. They shall ensure that the information communicated is clear and understandable.

If an oral request for information is too complicated or too comprehensive to be dealt with, the agents or other servants shall advise the person concerned to formulate his demand in writing.

If, because of its confidentiality, an agent or other servant may not disclose the information requested, he or she shall, in accordance with Article 18 of this Code, indicate to the person concerned the reasons why he or she cannot communicate the information.

Further to requests for information on matters for which he or she has no responsibility, the agent or other servant shall direct the requester to the competent person and indicate his or her name and telephone number. Further to requests for information concerning another Community institution or body, the agent or other servant shall direct the requester to that institution or body.

Where appropriate, the agent or other servant shall, depending on the subject of the request, direct the person seeking information to the unit or sector responsible for providing information to the public.

Article 23 - Requests for public access to documents

Further to requests for access to documents of the Authority, the agents or other servants shall give access to these documents in accordance with the Decision on access to EFSA documents.

If the agents or other servants cannot comply with an oral request for access to documents, the citizen shall be advised to formulate it in writing.

Article 24 - Keeping of adequate records

The Authority's departments shall keep adequate records of their incoming and outgoing mail, of the documents they receive, and of the measures they take.

Article 25 - Public access to the Code

The Authority will take the necessary measures in order to ensure that this Code enjoys the widest possible publicity amongst the citizens. It will in particular make it available on its Internet site and will provide a copy of this Code to any citizen who requests it.

Article 26 - Right to complain to the European Ombudsman

Any failure of an agent or other servant to comply with the principles set out in this Code may be the subject of a complaint to the European Ombudsman in accordance with Article 195 of the Treaty establishing the European Community and the Statute of the European Ombudsman.

Article 27 - Revision

Within two years of entry into force of this Decision, the Executive Director shall submit to the European Ombudsman a report on the implementation of this Decision.

Article 28 - Entry into force

This Decision will take effect from 1 October 2003 and will be published on the Authority's Internet site.

Done at Brussels on 16 September 2003

Dr Stuart Slorach
The Chair

(11)

European Food Safety Authority

Brussels, 28.4.2004
C(2004) 1597 85-2004

EFSA DECISION

on outside activities and assignments

EFSA DECISION

on outside activities and assignments

THE EXECUTIVE DIRECTOR,

Having regard to the Staff Regulations of Officials of the European Communities, and in particular Article 1c, the second paragraph of Article 11, Article 11a, Article 12, Article 12b, the second paragraph of Article 15, Article 16, Article 17, Article 17a, Article 19, the first paragraph of Article 55 and article 13 and 40 of Annex VIII thereof, and to the Conditions of Employment of Other Servants of the Communities, and in particular Articles 11, 16, 54, 57, 81 and 91 thereof;

Whereas in the interest of transparency the provisions governing permission to engage in an outside activity and assignment should be incorporated in a single measure indicating in detail which factors have to be taken into account when taking a decision on such permission;

Whereas the Commission, in the context of the reform process, has decided to encourage external mobility to enable officials to acquire new skills and knowledge which are of benefit both to the officials themselves and to the institution;

Whereas the present rules are intended to prevent conflicts of interest from arising, without imposing unreasonable restrictions on officials' outside activities,

HAS DECIDED AS FOLLOWS:

Article 1
Definition

For the purposes of the present decision

1. "Public office" means any public office, paid or unpaid, that is filled following an election or otherwise;

2. "Assignment" means the taking-on of a defined, time-limited task;

3. "Outside activity" means any other activity, paid or unpaid, that is of an occupational character or goes otherwise beyond what can be reasonably considered a leisure activity.

Chapter 1
Officials in active employment
(Article 35(a) of the Staff Regulations)

Article 2
Assignments and outside activities

Officials in active employment or secondment wishing to engage in an assignment or outside activity within the meaning of Article 1 of this Decision must request permission from the appointing authority pursuant to Article 12b of the Staff Regulations. Applications, accompanied by the necessary supporting documents, must be submitted through their immediate superiors, where possible, 2 months before the beginning of the activity or assignment. The appointing authority shall respond to this request within 1 month of receipt of the application.

Article 3
Exercise of a public office

1. Officials that are elected or appointed to public office and who continue working are subject to the obligations that normally apply to officials. By way of exception, any payment made to an official in that connection shall not count towards the ceiling for net remuneration set out in Article 9 of this Decision.

2. Officials who are elected or appointed to public office and who take leave on personal grounds in order to fill it shall require prior authorisation for assignments or outside activities that are not related to the performance of the duties that it entails. This provision shall not apply where an elective office is covered by legal immunity.

Article 4
Activities carried out in the framework of a mission

An official may not accept any remuneration that is offered in exchange for any work done - and in particular participation in a conference or a presentation - in the course of a mission ordered by the appointing authority. The official should however ask for the costs of the mission to be reimbursed by the body to which he renders such services. Any such reimbursement shall be declared to the appointing authority and deducted from the official's mission costs.

Article 5
Voluntary work

Without prejudice to Article 8, permission shall in principle be granted for work not giving rise to remuneration or the like, whether charitable or not, provided that it is not so onerous as to be likely to impair the official's ability to work for the Commission, and in particular his obligations under Article 55 first indent of the Staff Regulations.

Article 6
Educational activities

Subject to Article 5 and 8 of this decision, teaching and other educational activities, whether gainful or not, shall in principle be authorised for one year provided that their duration does not exceed 100 hours per academic year.

In exceptional circumstances, where the activity is clearly in the interest of the institution, the educational activities may be extended to academic activities, including research. In those cases no decision may be taken without prior consultation of the Director-General for Personnel and Administration.

Article 7
Professional activities

Without prejudice to Articles 5, 6 and 8 of this Decision, permission shall not be granted for assignments or outside activities which are pursued in a professional or similar capacity (e.g. architect, lawyer, economist, accountant, computer expert, engineer, interpreter, doctor, translator, consultant etc.).

Article 8
Commercial activities

Permission shall not be granted for assignments or activities for firms and companies, whose objects are commercial, even if the official's relationship with the company or firm in question entails no remuneration or purely nominal remuneration.

Article 9
Maximum net remuneration

The maximum annual ceiling for net remuneration, including any fees received, which an official may receive in connection with all his assignments or outside activities combined, shall be € 4500. The reimbursement of costs (e.g. transportation etc.) shall not be taken into account for this purpose. The official shall hand over to the appointing authority amounts exceeding the sum of € 4500.

Royalties received for publications shall be excluded from the calculation of net remuneration.

Article 10
Prizes and awards

Officials given a prize or award for an assignment or outside activity are required to apply to the appointing authority for permission to accept it. Such permission shall be granted or withheld by the appointing authority depending on the circumstances of each case, regardless of the value of the prize or award. Permission shall only be refused if the acceptance of the prize or award is incompatible with the interests of the institution or could impair the independence of the official.

Article 11
Special leave

Where unpaid activities are of benefit to the Communities, the appointing authority may grant special leave amounting to half the number of working days involved, up to a maximum of twelve days per year.

Article 12
Period of validity

Permission granted pursuant to Article 12b of the Staff Regulations shall be valid for the period set out in the authorisation but in principle not more than one year. A new application must be submitted for any prolongation or renewal at least two months before expiration of the period.

Article 13
Officials working part time

1. Officials who have been authorised to work part time may take on unpaid outside assignments and activities if such outside assignments and activities are not incompatible with the reasons for which part-time work has been authorised.

2. Officials elected or appointed to public office who have been authorised to work part time may take on paid outside assignments and activities directly related to the reasons for which part-time work has been authorised.

Chapter 2
specific provisions for officials on leave on personal grounds (Articles 35(c) and 40 of the Staff Regulations)

GENERAL PROVISIONS

Article 14
Permission for outside activities or assignments for officials on leave on personal grounds (Article 12b of the Staff Regulations)

1. Officials on leave on personal grounds must seek permission pursuant to Article 12b of the Staff Regulations to undertake an assignment or an outside activity at any time during the period of leave in accordance with the present decision.

2. Such permission shall in principle be granted except where the assignment or the activity could give rise to a conflict of interest or be detrimental to the interest of the Communities. A conflict of interest shall be deemed to exist where the assignment or the activity would reflect on the official's status as an official and would be detrimental to the loyalty she owes to the institution and its authorities but also where it would be incompatible with her duty to conduct herself in a manner that is beyond

suspicion in order that the relationship of trust between that institution and herself may at all times be maintained.

3. An official requesting permission pursuant to Article 12b of the Staff Regulations in order to take up an assignment or outside activity shall in particular provide to the appointing authority:

   - a description of her activity during her last three years of active service at the Commission;
   - a description of the activity that she wishes to take up including information on the position the official is to occupy and the expected duration of the activity;
   - the name, address and telephone number of the potential employer;
   - the employer's fields of activity;
   - the links with the official's functions exercised in the Commission, if any;
   - any other information that could reasonably be considered relevant by the appointing authority in deciding on the request.

   To this end the official will fill in and file with the Commission an application form provided by the appointing authority. Applications, accompanied by the necessary supporting documents, must be submitted through her immediate superiors, at least two months before the beginning of the activity or assignment. Authorisation shall only be refused if the work referred to above is incompatible with the interests of the institution or could impair the independence of the official.

4. In addition, the official shall sign a declaration confirming that she has full knowledge of her obligations in the sense of the present decision.

5. The appointing authority shall make permission to undertake an activity whilst on leave on personal grounds conditional upon the official's consent to the Commission making her name, position in the undertaking, and the name of the undertaking for which she intends to work, publicly available. To this end the official will sign a declaration provided by the appointing authority.

6. Any permission granted pursuant to an application under paragraph 3 of this article shall be limited to employment with the named employer, and any person with whom the employer merges or transfers the undertaking by which the official is employed.

7. An official on leave on personal grounds who wishes to transfer to a different employer shall seek a revised authorisation pursuant to Article 12b of the Staff Regulations. Obligations of the present decision shall apply.

8. An official shall inform the appointing authority without delay where any other change in one or more of the circumstances set out in paragraph 3 of this article arises after permission pursuant to Article 12b, second paragraph, of the Staff Regulations has been granted. The appointing authority shall examine whether to modify the conditions of or to withdraw its permission in the light of such a change.

Such withdrawal shall take effect after the official has had a reasonable time to take the necessary measures.

Article 15
Consultation of the Director-General for Administration and Personnel

A decision on a request for permission to engage in an outside activity or assignment which is made in connection with:

(a) a request for leave on personal grounds,

(b) a request by an official who is already on leave on personal grounds to engage in an outside activity or assignment,

shall be taken after consultation of the Director-General for Personnel and Administration.

SPECIFIC PROVISIONS

Article 16
Work dealing with active service in the Commission

1. If the official intends to undertake work that requires her to deal directly or indirectly with subjects that fall within a policy area in which she was or has been working during the three years of active service immediately preceding the probable or actual date of commencement of her leave on personal grounds, she shall provide full details thereof to the appointing authority. Such work may not be undertaken unless and until she has received the written authorisation of the appointing authority.

2. The official may not deal with individual cases that she had worked on in the course of the three years of active service in the Commission immediately preceding the probable or actual date of commencement of her leave on personal grounds. When officials have worked on individual cases prior to the said period of three years, they are not thereby automatically authorised to deal with those individual cases.

3. The official may not participate in meetings or have contacts of a professional nature with her former Directorate General or service for a period of :

   - 1 year where the official occupied a management function in this Directorate General or Service,

   - 6 months in all other cases.

4. The appointing authority may make any authorisation it grants subject to such conditions as it reasonably sees fit, in the light of the particular characteristics of a policy area or of the circumstances of the case. The appointing authority may in particular increase the restrictions laid down in paragraph 3

Article 17
Contracts with the Commission

1. No official on leave on personal grounds may be given an assignment of any kind that carries remuneration other than a daily allowance and / or a reimbursement of expenses unless an exemption has been granted under paragraphs 2 to 4 of this article.

   For the purposes of this Article, « assignment » includes in particular:

   (a) any direct contractual relationship between the Commission and an official on leave on personal grounds as an individual; and

   (b) any contractual relationship between the Commission and an undertaking in which an official on leave on personal grounds has directly or indirectly a significant financial interest.

2. The Director-General for Personnel and Administration may grant exemptions in cases which fall under paragraph 1 of this article, where an official has been granted leave on personal grounds in accordance with Article 40 paragraph 2 2nd indent, of the Staff Regulations (accompanying a spouse who is also an official) except for assignment mentioned in paragraph 1 (b).

3. The Director-General for Personnel and Administration may grant an exemption from paragraph 1 of this Article in a case of an urgent need by the Commission of the official's services except for assignment mentioned in paragraph 1 (b). However, in the case of a direct contract between the official and the Commission, the remuneration may not exceed the salary (on a pro-rata basis) the official would have obtained if she had carried out the task when in active service, plus any reasonable professional expenses.

4. In cases other than those referred to in paragraph 1 of this Article, where the official on leave on personal grounds is asked by a third party to work on the performance of contracts with or for the Commission, whether directly or by way of sub-contracting, and where she intends to give a positive answer, she shall immediately inform the appointing authority about this request and give all the necessary information allowing the appointing authority to assess the request and take a decision.

Chapter 3
officials having left the service of the European Commission

Article 18

1. An official leaving the service of the Commission shall sign a declaration following a form provided by the Appointing authority so as to acknowledge that he is aware of his continuing obligations to the Commission, in particular under Articles 16, 17b and 19 of the Staff Regulations.

2. For a period of 2 years after leaving the Commission, a former official wishing to take up an assignment or outside activity shall inform the appointing authority. The former official shall in particular provide:

- a description of his activity during his last three years of active service at the Commission;
- a description of the activity that he wishes to take up including information on the position he is to occupy and the expected duration of the activity;
- the name, address and telephone number of the potential employer;
- the employer's fields of activity;
- the links with his former functions in the Commission, if any.

To this end the former official will fill in and file with the Commission the application form provided by the Appointing Authority.

3. Any permission granted pursuant to the application form under paragraph 2 of this Article shall be limited to employment with the named employer, and any person with whom the employer merges or transfers the undertaking by which the official is employed.

4. A former official shall inform the appointing authority without delay where any other change in one or more of the circumstances set out in paragraph 2 of this Article arises after permission has been granted. The appointing authority shall examine whether to modify the conditions of or, in exceptional circumstances, to withdraw its permission in the light of such a change.

SPECIFIC PROVISIONS FOR CERTAIN GROUPS OF FORMER OFFICIALS

Article 19
Former officials receiving a retirement pension or on non-active status or retired in the interests of the service

1. Former officials in receipt of a retirement pension may be requested by the Commission to undertake assignments or carry out activities provided that such assignments or activities are unpaid and do not give rise to remuneration of any kind. However costs reasonably incurred in connection with such assignments or activities may be reimbursed. The above restriction shall not apply to assignments and activities which, although not directly paid by the Commission, give rise to payments that are financed from Community funds.

2. The Director-General of Personnel and Administration may authorise a former official who is receiving a retirement pension to provide services to the Commission.

(a) such permission will only be given when it is in the general interests of the institutions and to fulfil a specific need demanding a knowledge that is difficult to find other than with the official in question;

(b) the former official can receive ad hoc payments for his services, which when cumulated with his retirement pension or allowance for the then current year, do not exceed his last total annual remuneration whilst in activity; the

reimbursement of costs shall not be taken into account for this purpose. The annual remuneration is established on the basis of the salary table in force on the first day of the month for which the pension is paid;

(c) an official may render services described in this paragraph until a date of 3 years after his day of retirement.

3. The provisions of this Article shall apply by analogy to officials on non-active status or who have been retired in the interest of the service.

Article 20
Former officials receiving an invalidity allowance or invalidity pension

1. Former officials receiving an invalidity allowance or invalidity pension may not be given an assignment of any kind, paid or unpaid, by the Commission.

2. In addition, the official shall sign a declaration confirming that he has full knowledge of his obligations in the sense of the present decision.

3. When deciding whether to grant the permission to undertake an activity or assignment on the basis of Article 13 of annexe VIII paragraph 2 of the staff regulation, the appointing authority must consider whether such an assignment or activity is consistent with the original reasons for granting an invalidity allowance or pension.

Chapter 4
Temporary staff

Article 21

1. The present decision shall apply by analogy to members of the temporary staff, of the auxiliary staff and of the contract staff.

Only those contract staff who have had access to sensitive information shall be subject to the obligations laid down in Article 18 (2). Contract staff shall be informed by their service whether Article 18 (2) is applicable on leaving the service.

2. Former temporary, auxiliary and contract staff in receipt of an unemployment allowance may not be given an assignment of any kind, paid or unpaid, by the Commission for as long as the allowance is paid.

Chapter 5
Final provisions

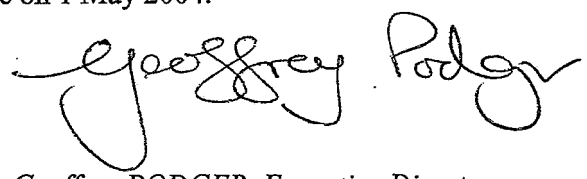
Article 22
Former decisions

The Decisions of 21 July 1976[1] and of 14 May 1992[2] are repealed.

Article 23

Article The present Decision shall enter into force on 1 May 2004.

Done at Brussels, 28.4.2004.



Geoffrey PODGER, Executive Director

[1] Administrative Notice No 117 – 1976
2 Administrative Notice No 745 – 1992

(12)

efsa
European Food Safety Authority

EXECUTIVE DIRECTORATE

Decision of the Executive Director of the European Food Safety Authority on the adoption of implementing provisions of the Staff Regulations by analogy

The Executive Director of the European Food Safety Authority,

HAVING REGARD to the Treaty establishing the European Community,

HAVING REGARD to the Regulation (EC) No. 178/2002/EC of the European Parliament and the Council of 28 January 2002 laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in relation to food safety, as amended by Regulation (EC) No. 1642/2003,

HAVING REGARD to the Staff Regulations of Officials of the European Communities and the Conditions of Employment of other servants of the European Communities[1], and in particular Article 110 of the Staff Regulations,

HAVING REGARD to the decisions of the Commission setting up implementing provisions for the application of the Staff Regulations of Officials of the European Communities and the Conditions of Employment of other servants of the European Communities,

In agreement with the Commission pursuant to Article 110 of the Staff Regulations,

Whereas it is necessary, following Article 110 of the Staff Regulations for agencies to adopt the appropriate implementing provisions for giving effect to these Staff Regulations, after consultation of the relevant Staff Committee and in agreement with the Commission,

Has adopted the following general implementing provisions:

Article 1

The general implementing provisions of the Staff Regulations, as adopted by the Commission and listed in Annex I, shall apply by analogy to the staff of the European Food Safety Authority.

Article 2

This decision shall enter into force on the day following its adoption and shall replace the decision of the Executive Director of 24 February 2005.

Done at Parma on 1/9/09

Catherine Geslain-Lanéelle
Executive Director

[1] Council Regulation (EEC, Euratom, ECSC) No. 259/68 (OJ L 56, 4.3.1968, p.1), as last amended by Regulation (EC, Euratom) No. 31/2005 (OJ L 8, 12.1.2005, p.1), which entered into force on 1 May 2004.

Annex I

1. Commission Decision C(2004)1318 69-2004 implementing Article 1d(4) of the Staff Regulations.
2. Commission Decision C(2004)1364 54-2004 on general implementing provisions for Article 42a of the Staff Regulations concerning parental leave.
3. Commission Decision C(2004)1314 64-2004 on Article 42b of the Staff Regulations concerning family leave.
4. Commission Decision C(2004)1364 51-2004 on general implementing provisions on granting the household allowance by special decision.
5. Commission Decision C(2004)1364 52-2004 on general implementing provisions for giving effect to Articles 67 and 68 of the Staff Regulations and Articles 1, 2 and 3 of Annex VII thereto.
6. Commission Decision C(2007)3195 dated 2 July 2007 laying down general implementing provisions for the reimbursement of medical expenses.
7. Commission Decision of 15 April 2004 COM(2004)1364 50-2004 on general implementing provisions concerning persons to be treated as dependent children (Article 2(4) of Annex VII to the Staff Regulations).
8. Commission Decision C(2004)1313 53-2004 on general implementing provisions for the grant of education allowance (Article 3 of Annex VII to the Staff Regulations).
9. Commission Decision C(2004)1364 57-2004 on general implementing provisions for giving effect to Article 7(3) of Annex VII to the Staff Regulations on determining the place of origin.
10. Commission Decision C(2004)1588 56-2004 on general provisions giving effect to Article 8 of Annex VII to the Staff Regulations.
11. Commission Decision C(2004)1364 61-2004 on general implementing provisions for Article 4 of Annex VIII to the Staff Regulations concerning the taking into account, for purposes of calculating pension rights, of periods of activity previously completed by staff before they resume active employment.
12. Commission Decision C(2004)1588 60-2004 on general implementing provisions for Articles 11 and 12 of Annex VIII to the Staff Regulations on transferring pension rights.
13. Commission Decision C(2004)1588 63-2004 on general implementing provisions on the early retirement of officials and temporary agents without reduction of pension rights.
14. Commission Decision C(2004)1314 67-2004 dated 14 April 2004 on Article 55b of the Staff Regulations concerning job-sharing.
15. Commission Decision C(2004)1597 85-2004 on outside activities and assignments.

16. Commission Decision C(2004)1597 102-2004 on introducing implementing provisions on leave.

17. Commission Decision C(2004)1588 62-2004 on general implementing provisions for Article 26 of Annex XIII to the Staff Regulations on transferring pension rights.

18. Commission Decision C(2004)1588 59-2004 on general implementing provisions for Article 22(4) of Annex XIII to the Staff Regulations.

19. Commission Decision C(2004) 1613 88-2004 on transitional measures required by the revision of the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Communities.

ANNEX III

Enclosures No 13 (BBA event programme & list of participants),

&

Enclosures (meeting/event reports) concerning meetings/events

No 17, No 23, No 25, No 31 and No 45

13

Programme

Cel - PMER = joint effort /b/ CAs/MS and applicants
- broad, involving ≠ areas
- too large diversity of inconsistent data

Thursday, 26 April

10:00	**Registration**
13:00 - 13:10	**Opening remarks** *J. Schiemann (BBA) Germany*

Session 1: Review of the different MS situations, efforts and necessities for harmonization at the European level

Chair: J. Schiemann (BBA) Germany
Co-Chair: L. Beißner (KWS SAAT AG) Germany

13:10 – 13:40	Concepts for the post market environmental monitoring of genetically modified plants *K. Lheureux (EFSA) Italy*
13:40 – 14:10	Concepts for the coordination and harmonization of monitoring data exchange *A. Andre (DG Environment) Belgium*
14:10 – 14:40	Implementation of monitoring in the EU in accordance with the present regulatory framework *B. Tinland (Monsanto) Belgium*

Session 2: Tools and methodologies for a harmonized data management and an effective and purposeful data analysis

Chair: O. Sanvido (ART) Switzerland
Co-Chair: M. Finck (VDI) Germany

14:40 – 15:10	European-wide GMO monitoring data management and analysis *K. Schmidt (BioMath GmbH) Germany*
15:10 – 15:40	**Coffee Break**
15:40 – 16:10	Biological surveillance programmes for the monitoring of crop pests and indicators – a European approach *M. Delos (SRPF-DRAF) France*
16:10 – 16:40	General Surveillance: roles and responsibilities - the industry view *E. Lecoq (EuropaBio) Belgium*

Session 3: Harmonization of decision making and GMO management at the European level

Chair: G. Neemann (BlaU-Umweltstudien) Germany
Co-Chair: K. Lheureux (EFSA) Italy

16:40 – 17:10	Coordination of GMO monitoring in the agro-ecosystem – a concept for Germany *R. Wilhelm (BBA) Germany*
17:10 – 17:40	Agrobiodiversity monitoring – documentation on the European level *S. Schröder (BLE-IBV) Germany*

17:40 – 18:10	First EFSA experiences with monitoring plans *D. Bartsch (BVL) Germany*
18:10 – 18:40	Challenges and perspectives in environmental decision-making of genetically modified crops *O. Sanvido, (Agroscope, ART) Switzerland*
18:40 – 20:30	**Dinner**
20:30 – 21:30	Spotlight Discussion: Harmonization and Standardization *- Statements by selected participants -* *Chair: J. Sweet*

Friday, 27 April

08:00 – 08:30	**Coffee**
08:30 – 10:50	**Working Group 1: Data acquisition and analysis** *Chair: J. Schiemann (BBA),* *Rapporteur: D. Bartsch (BVL)*
08:30 – 08:50	Insect Resistance Monitoring for Bt maize in the EU, the Industry IRM working group programs *E. Alcalde (Syngenta) Spain*
08:50 – 09:10	Practical experience of the herbicide resistant GM soybean monitoring in the Center of the Origin and Diversity of Russian Far East *D.B. Dorokhov (Russian Academy of Science) Russia*
09:10 – 09:30	Monitoring of Plant Pests as a Base of the Germany-wide online decision support system ISIP *C. von Kröcher (Pflanzenschutzamt Niedersachsen) Germany*
09:30 – 09:50	Data acquisition by farm questionnaires - progress, problems and prospects *P. Böttinger (BBA) Germany*
09:50 – 10:10	„Good Monitoring Practice" - Quality control measures for farm questionnaires *A. Berensmeier (BioMath) Germany*
10:10 – 10:30	Analysis of Neighbourhood relations: Steps from Small Scale to the Regional Scale *B. Breckling (University of Bremen) Germany*
10:30 – 10:50	WebGIS-Technologies for GMO monitoring purposes in Europe *W. Schröder (University of Vechta) Germany*
08:30 – 10:50	**Working Group 2: Data management and decision making** *Chair: M. Finck (VDI),* *Rapporteur: K. Schmidt (BioMath)*
08:30 – 08:50	Principles and Methods for General Surveillance Sites Selection *G. Neemann (BLaU Umweltstudien) Germany*
08:50 – 09:10	Implementation of general surveillance for Amflora potato cultivation - Data management *C. Wandelt (BASF) Germany*
09:10 – 09:30	Monitoring genetically modified plants (GMPs): Harmonization and coordination on multiple levels to ensure data quality and comparibility *F. Graef (BfN) Germany*

09:30 – 09:50	Standardization of methods for a GMO-Monitoring on a European level *H. Beismann (VDI) Germany*
09:50 – 10:10	Use of existing networks for the General Surveillance of GMPs? – Proposal for a reporting system and a Central Reporting Office *J. Schmidtke (BioMath) Germany*
10:10 – 10:30	Public GMO locations register in Germany – Harmonization in Europe? *A. Vaasen (BVL) Germany*
10:50 – 11:45	**Coffee break and Poster session** Using an oilseed rape - wild/weedy relative gene flow index for the monitoring of transgenic oilseed rape *Y. Devos (Ghent University) Belgium* A tool for efficient data collection based on controlled vocabulary and the entity-value model *K. Köhl (MPI Molekulare Pflanzenphysiologie) Germany*
11:45 – 12:15	**Rapporteurs' reports** *Chair: J. Sweet* *D. Bartsch, J. Schiemann* *K. Schmidt, M. Finck*
12:15 – 12:45	**Final discussion** *Chair: J. Sweet*
12:45 – 13:00	**Take home messages / Key statements** *J. Schiemann*

Participants

Surname	First name	Institution	Country	Zip	City	Street	Email
Alcalde	Esteban	Syngenta	Spain	28042	Madrid	Ribera del Loira, 8-10	esteban.alcalde@syngenta.com
Andre	Aurelie	European Commission DG Environment	Belgium		Brussels		Aurelie.ANDRE@ec.europa.eu
Ball	Louise	DEFRA	UK	SW1P 3JE	London	Nobel House, Smith Square	louise.ball@defra.gsl.gov.uk
Bartsch	Detlef	BVL	Germany	D-10117	Berlin	Mauerstr. 39-42	detlef.bartsch@bvl.bund.de
Beismann	Heike	VDI	Germany	D-40002	Düsseldorf	POBox 10 11 39	beismann@vdi.de
Beissner	Lutz	KWS Saat AG	Germany	D-37555	Einbeck	Grimsehlstr. 31	l.beissner@kws.com
Berensmeier	Anja	BioMath GmbH	Germany	D-18055	Rostock	Schnickmannstr. 4	anja.berensmaier@biomath.de
Böttinger	Petra	BBA, RS	Germany	D-38106	Braunschweig	Messeweg 11/14	p.boettinger@bba.de
Breckling	Broder	Universität Bremen	Germany	D-28334	Bremen	Leobener Str.	broder@uni-bremen.de
Bubl	Walter	Bayer CropScience Deutschland	Germany	D-65926	Frankfurt / Main	Industriepark Hoechst K607	walter.buebl@bayercropscience.com
De Schrijver	Adinda	Scientific Institute of Public Health, Sect. Biosafety and Biotechology	Belgium	B-1050	Brussels	J. Wytsmanstraat 14	ads@sbb.ihe.be
Degenhardt	Heinz	Pioneer Hi Bred Northern Europe Sales Division	Germany	D-21614	Buxtehude	Apensener Str. 198	heinz.degenhardt@pioneer.com
Delos	Marc	French Ministry of Agriculture- Plant Protection	France	F 31074	Toulouse cedex	Cité Admin. -Bat E-Bd Armand Duportal	marc.delos@agriculture.gouv.fr
Devos	Yann	University of Ghent, Bioscience Engineering, Dep. of Plant Production	Belgium	B-9000	Ghent	Coupure Links, 653	Yann.Devos@UGent.be
DeWolf	Marie-Christine	Provincial Institute of Hygiene and Bacteriology of the Hainaut (IPHB)	Belgium	B-7000	Mons	Bd. Sainctelette, 55	marie_christine.dewolf@hainaut.be
Dobbelaere	Dirk	Vetsuisse Faculty Bern, Molecular Pathology	Switzerland	CH-3012	Bern	Langgassstrasse 122	dirk.dobbelaere@mopa.unibe.ch
Dorokhov	Dmitry	Centre Bioengineering of Russ. Acad. Science; Plant Genome Laboratory	Russian Fed.	117312	Moscow	Pr. 60-letya Oktyabrya 7, korp .1	dorokhov@biengi.ac.ru
Fagan	John	Genetic ID NA	USA	52556	Fairfield	Dimick Drive 501	info@genetic-id.com
Finck	Markus	VDI	Germany	D-40239	Düsseldorf	Graf-Recke-Str. 84	finck@vdi.de
Gathmann	Achim	BVL	Germany	D-10117	Berlin	Mauerstr. 39-42	achim.gathmann@bvl.bund.de
Gielkens	Marco	National Institute for Public Health and the Environment / GMO office	The Netherlands	3720BA	Bilthoven	P.O.Box 1	marco.gielkens@rivm.nl
Graef	Frieder	BfN	Germany	D-53179	Bonn	Konstantinstr. 110	graefl@bfn.de
Hoffmann	Torsten	Landesamt f. Verbraucherschutz, Landwirtschaft und Flurordnung	Germany	D-14469	Potsdam	Pappelallee 20	torsten.hoffmann@lvlf.brandenburg.de
Janssens	Jan	Bayer BioScience N.V. Regulatory Affairs	Belgium	B-9052	Gent	Technologiepark 38	janjanssens@bayercropscience.com
Jung	Simone	Robert Koch-Institut	Germany	D-13353	Berlin	Seestr. 10	jungs@rki.de
Karwasz	Michael	BLaU Umweltstudien	Germany	D-37073	Göttingen	Wiesenstr. 8	karwasz@blau-umweltstudien.de
Köhl	Karin	Max-Planck-Institut für Molekulare Pflanzenphysiologie	Germany	D-14476	Golm	Am Mühlenberg 1	koehl@mpimp-golm.mpg.de
Koziolek	Christiane	BVL	Germany	D-10117	Berlin	Mauerstr. 39-42	christiane.koziolek@bvl.bund.de
Krug	Manfred	Landesamt für Umweltschutz Sachsen Anhalt	Germany	D-06116	Halle	Reideburger Str. 47	grug@lau.mlu.lsa-net.de
Ladewig	Erwin	IFZ Institut für Zuckerrübenforschung	Germany	D-37079	Göttingen	Holtenser Landstraße	ladewig@ifz-goettingen.de
Lecoq	Eveline	Pioneer Overseas Corp.	Belgium	B-1040	Brussels	Avenue des Artes 44	eveline.lecoq@pioneer.com
Lheureux	Karine	EFSA, European Food Safety Authority	Italy	43100	Parma	Largo N.Palli 5/A	karine.lheureux@efsa.europa.eu
Linnestad	Caspar	Norwegian Biotechnology Advisory Board	Norway	NO-1540	Oslo	Rosenkrantz' gt. 11	casper.linnestad@blon.no
Matzk	Anja	KWS Saat AG	Germany	D-37555	Einbeck	Grimsehlstr. 31	a.matzk@kws.com
Meissner	Annett	BLaU Umweltstudien	Germany	D-37130	Göttingen	Wiesenstr. 8	kontakt@BLaU-umweltstudien.de
Mesdagh	Sylvie	EFSA, European Food Safety Authority	Italy	43100	Parma	Largo N.Palli 5/A	sylvie.mesdagh@efsa.europa.eu
Müller	Elke	Genetic ID (Europe) AG	Germany	D-86167	Augsburg	Am Mittleren Moos 48	emueller@genetic-id.de
Neemann	Gerd	BLaU Umweltstudien	Germany	D-37073	Göttingen	Wiesenstr. 8	gneemann@blau-umweltstudien.de
Ophoff	Holger	Monsanto Agrar Deutschland GmbH	Germany	D-40470	Düsseldorf	Vogelsanger Weg 91	holger.ophoff@monsanto.com

Surname	FirstName	Institution	Country	Zip	City	Street	Email
Pignard	Annie	Syngenta Seeds SAS	France	F-31790	Saint Saveur	12 Chemin de l'Hobit -BP 27	annie.pignard@syngenta.com
Pleysier	Annick	Monsanto Europe S.A., Regulatory Affairs	Belgium	1040	Brussels	Av. De Tervueren 270-272	annick.pleysier@monsanto.com
Pohl	Matthias	BASF Plant Science Holding Gmbh	Germany	D-67117	Limburgerhof	Carl-Bosch-Str.64	matthias.pohl@basf.com
Povolný	Marek	ÚKZÚZ, National Plant Variety Office	Czech Republic	656 06	Brno	Hroznová 2	marek.povolny@ukzuz.cz
Rees	Ulrich	BLaU Umweltstudien	Germany	D-37130	Göttingen	Wiesenstr. 8	urees@blau-umweltstudien.de
Salovuori	Irma	Ministry of Social Affairs and Health, Board for Gene Technology	Finland	00017	Helsinki	Kirrkokatu 14	irma.salovuori@stm.fi
Sanvido	Olivier	ART, Agroscope Reckenholz Taenikon Research Station	Switzerland	CH-8046	Zürich	Reckenholzstrasse 191	olivier.sanvido@art.admin.ch
Sarvas	Matti	Ministry of Social Affairs and Health, Board for Gene Technology	Finland	00330	Helsinki	Kirrkokatu 14	matti.sarvas@ktl.fi
Schauzu	Marianna	BfR	Germany	D-14195	Berlin	Thielallee 88-92	m.schauzu@bfr.bund.de
Schiemann	Joachim	BBA, PS	Germany	D-38104	Braunschweig	Messeweg 11/12	j.schiemann@bba.de
Schlotter	Peter	DowAgroSciences GmbH	Germany	D-83666	München	Tüderinger Strasse 16	pschlotter@dow.com
Schmidt	Kerstin	BioMath GmbH	Germany	D-18055	Rostock	Schnickmannstr. 4	kerstin.schmidt@biomath.de
Schmidtke	Jörg	BioMath GmbH	Germany	D-18055	Rostock	Schnickmannstr.4	joerg.schmidtke@biomath.de
Schröder	Winfried	Chair of Landscape Ecology, Univ. Vechta	Germany	D-49377	Vechta	POBox 1553	wschroeder@luw.uni-vechta.de
Schroeder	Stefan	BLE	Germany	D-53179	Bonn	Deichmanns Aue 29	STEFAN.SCHROEDER@ble.de
Schulte	Elisabeth	Genius GmbH	Germany	D-64293	Darmstadt	Robert-Bosch-Str. 7	elisabeth.schulte@genius.de
Smit	Eric	RIVM	Netherlands	3813 BT	Bilthoven	PO Box 11	eric.smit@rivm.nl
Storer	Nick	DowAgroSciences LLC	USA	48674	Midland, MI	1803 Building	nstorer@dow.com
Sweet	Jeremy	Consultant	UK	CB4 5JA	Cambridge	The Green, Willingham	jeremysweet303@aol.com
Thieme	Thomas	BTL Bio-Test labor GmbH Sagerheide	Germany	D-18184	Thulendorf	Birkenallee 19	tt@biotestlab.de
Tinland	Bruno	Monsanto Europe S.A.	Belgium	1040	Brussels	Av. De Tervueren 270-272	bruno.tinland@monsanto.com
Toppan	Alain	Limagrain	France	F-63720	Chappes	BP 1	alain.toppan@limagrain.com
Vaasen	Anja	BVL	Germany	D-10117	Berlin	Mauerstr. 39/42	anja.vaasen@bvl.bund.de
von Kröcher	Carolin	Pflanzenschutzamt LWK Niedersachsen	Germany	D-30453	Hannover	Wunstorfer Landstrasse 9	carolin.vonkroecher@lwk-niedersachsen.de
Wandelt	Christine	BASF Plant Science Holding GmbH	Germany	D-67117	Limburgerhof	Agricultural Center	christine.wandelt@basf.com
Wilhelm	Ralf	BBA, PS	Germany	D-38105	Braunschweig	Messeweg 11/13	r.wilhelm@bba.de
Wüst Saucy	Anne-Gabrielle	BAFU Bundesamt für Umwelt Schweiz	Switzerland	CH-3063	Ittingen	Worblentalstr. 68	anne-gabrielle.wust-saucy@bafu.admin.ch

(17)

European Food Safety Authority

MINUTES OF THE 33RD PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 16 MAY 2007 IN LJUBLJANA, SLOVENIA (ADOPTED ON 4 JULY 2007)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Detlef Bartsch, Josep Casacuberta, Marc De Loose, Niels Bohse Hendriksen, Lieve Herman, Jozsef Kiss, Ilona Kryspin-Sorensen, Nickolas Panopoulos, Joe Perry, Joachim Schiemann, Willem Seinen, Jeremy Sweet (Chair).

EFSA:
GMO Unit: Zoltan Diveki, Karine Lheureux, Sylvie Mestdagh, Claudia Paoletti, Suzy Renckens, Ellen Van Haver.

European Commission:
Bernadette Murray (DG ENV), Sébastien Goux and Michael Walsh (DG SANCO).

APOLOGIES

GMO Panel:
Salvatore Arpaia, Howard Davies, Sirpa Kärenlampi, Harry Kuiper, Ingolf Nes, Annette Pöting and Jean-Michel Wal.

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. Apologies for absence were received from some Panel members as mentioned above.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3. DECLARATION OF INTERESTS

Panel members were invited to declare possible interests on topics included on the agenda. Declarations of interests with regard to applications already announced during previous Plenary meetings are noted in the corresponding minutes.

As regards the new application (see item 8.2), one member[1] indicated that they in the future may be to some extent involved in the safety assessment process of this application at national level and provided a written declaration. It was decided from these declarations that there was no conflict of interest and that involvement in the national safety assessment process did not compromise the assessment of applications by EFSA.

[1] Detlef Bartsch

4. ADOPTION OF THE MINUTES OF THE 32ND PLENARY MEETING HELD ON 22-23 MARCH 2007

The minutes of the 32nd plenary meeting (22-23 March 2007) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_32nd_meeting.html.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Guidance document for the risk assessment of GM plants containing stacked transformation events

Introduction

This guidance has the objective to outline the requirements for the risk assessment, under Regulation (EC) 1829/2003 and Directive 2001/18/EC, of GM plants containing stacked transformation events when the single events have already been assessed by the GMO Panel. The document will be used by the Panel when reviewing and updating its current guidance document for risk assessment of GM plants and derived food and feed[2].

Discussion

The draft document has been published on the EFSA website (from 6 July to 10 September 2006) for public consultation. The members of the working groups of the GMO Panel on molecular characterisation, food/feed safety and environmental risk assessment have carefully considered all comments received during this consultation and revised the document accordingly.

The Panel is aware that whilst current applications involve the stacking of two or three individual events, there is likely to be a move towards further increases in the numbers of events in GM stacks. As long as each event in the highest number of stacked events has been risk assessed, the risk assessment of the stacked events might also be applicable to GM stacks containing fewer of these events. Thus a single risk assessment of such a stack could cover all combinations with fewer of these events. However, applicants need to take into account the potential impact of any reduction in the number of events involved and should provide scientific argumentation for the absence of specific data on the stacked events with a lower combination of events.

EFSA is consulting the Commission on the practical implications of this approach.

Adoption

The guidance document was adopted unanimously by the Panel. It will be published on the EFSA website at:

http://www.efsa.europa.eu/en/science/gmo/gmo_guidance/gmo_guidance_ej512.html.

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[2] http://www.efsa.europa.eu/en/science/gmo/gmo_guidance/660.html

6. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC, REGULATION (EC) NO 1829/2003 AND REGULATION (EC) NO 1831/2003

Ongoing applications

- LLRice62 rice (application UK/2004/04): the applicant sent a reply to the request for additional information with respect to the molecular characterization, food/feed safety and environmental risk assessment. This additional information will be considered by the Panel at its next working group meetings on molecular characterisation, food/feed safety and environmental risk assessment.

- MIR604 maize (application UK-2005-11): following a request from the Panel for additional information, the applicant provided further compositional data which were assessed by the working group in charge of food/feed safety assessment and the additional data was considered satisfactory to proceed with the risk assessment.

- A2704-12 soybean (application NL-2005-18): the Panel requested further information from the applicant as regards the food/feed safety part of the application. The clock therefore was stopped as the Panel cannot proceed with the risk assessment.

- GA21 maize (application UK-2005-19): the applicant provided additional information on the molecular characterization of GA21 maize following a request from the Panel. The additional information will be considered in the next molecular characterization working group.

Renewals

The Commission representative informed the Panel that the Commission has received 20 applications for renewal of authorization for an existing (notified) product according to Articles 11 and 23 of Regulation (EC) No 1829/2003. These applications will be forwarded to EFSA once they have been checked to fulfill the requirements of the Regulation.

7. UPDATE ON MON 863 PUBLICATION

Following the request from the European Commission to examine the recently published CRIIGEN study on the statistical analysis of the GM maize MON 863 toxicology data and the Member States' consultation via the EFSA Advisory Forum (see item 10 of the minutes of the 32nd plenary meeting[3]), EFSA has received responses from nine Member States. These responses and the outcome of the ongoing evaluation by EFSA staff and *Ad Hoc* experts of the statistical methodology used in the CRIIGEN publication will be considered in the EFSA's response to the Commission.

8. NEW REQUESTS TO EFSA: DISCUSSION AND ADOPTION OF MANDATES

8.1. Guidance on environmental and human health risk assessment of GM animals

[3] http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_32nd_meeting.html

EFSA has received a request from the European Commission in the context of Article 29 of Regulation (EC) No 178/2002 to develop, building on the work done in the context of Codex Alimentarius, a guideline on the safety evaluation of GM animals that would address both food/feed safety and environmental safety of this technology. A specific annex on GM fishes is also requested, as these would be the first GM animals to be expected on the EU market (for ornamental and not for food/feed purposes). The Commission would like this guidance to be delivered by the end of 2007.

EFSA and the GMO Panel are monitoring the ongoing work within the Codex Alimentarius Task Force on foods derived from biotechnology, and more specifically the draft guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals and the report of the FAO/WHO Expert Consultation on the safety assessment of foods derived from GM animals, including fish[4]. The Panel considers it adequate to await the outcome of this activity at international level.

The Panel suggested that in first instance information needs to be gathered on GM animals' applications in the pipeline in the EU in order to decide on priorities with respect to the choice of the animals for which an in depth study might be most needed. Special attention is to be paid to the environmental aspects of the release of GM animals as these aspects are not covered by the Codex Alimentarius and the FAO/WHO Expert Consultation.

Given the high workload of the Panel, EFSA will consider to outsource (part of) this work within the framework of Article 36 of Regulation (EC) No 178/2002 enhancing cooperation and networking in Europe. The timeframe as proposed by the Commission is however too short and EFSA will propose a new timeframe.

8.2. Applications under Regulation (EC) No 1829/2003

EFSA received, via France, one new application (FR-2007-44 dried killed bacterial biomass PT73 Escherichia coli (THR)) within the framework of Regulation (EC) No 1829/2003 for an overall opinion including the scientific opinion on the GMO for import and processing, food and feed use.

Nominated risk assessment bodies of the Member States and national competent authorities within the meaning of Directive 2001/18/EC as foreseen by Articles 6 (4) and 18 (4) of Regulation (EC) No 1829/2003 will be consulted by EFSA once the above mentioned application is valid. These comments will be considered during the scientific risk assessment of the application by the EFSA GMO Panel.

The summary of this application, as well as the information on their current status can be found on the following website:
http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.

9. OUTCOME OF JOINT SESSION WITH EUROPEAN ADVISORY COMMITTEES ON BIOSAFETY HELD ON 15 MAY

[4] ftp://ftp.fao.org/docrep/fao/006/y5316E/y5316E00.pdf

A joint session of the GMO Panel and members of national Advisory Committees on Biosafety took place on 15 May pm, back to back to the 2nd meeting of the European Biosafety Advisory Committees in the field of the deliberate release of GMOs.

Panel members of the Environmental risk assessment working group briefly presented issues to be considered for the environmental risk assessment of GMOs and EFSA staff presented the procedure of delegating the environmental risk assessment to national competent authorities in the field of Directive 2001/18/EC for applications that concern GMOs to be used as seeds or other plant-propagating material. The presentations were followed by a discussion, and main discussion points included the issue of regional specificities within the environmental risk assessment, principles of evaluating non-target effects of GM plants, the risk assessment of GM plants containing stacked transformation events, the feasibility of general surveillance and how to assess long term effects. The members of the national Advisory Committees on Biosafety were also informed about and invited to the EFSA Scientific Colloquium on the environmental risk assessment of GM plants that will take place on 20-21 June in Tabiano, Italy[5].

10. UPDATE ON SELF TASKING ACTIVITIES AND GUIDANCE ON GMO RISK ASSESSMENT

10.1. Allergenicity assessment of GM foods

A sub-working group meeting was held on 14 March 2007 to discuss clinical aspects of the allergenicity assessment of GM foods/feed. IgE and non-IgE mediated reactions as well as coeliac disease have been addressed and will be further discussed at the next working group meeting. Telephone-conference meetings have also been held to discuss bioinformatics and *in vitro* tests for novel/transgenic proteins and *in vitro* analysis for the potential allergenicity testing of the whole GM plant.

10.2. Animal feeding trials

A 11th working group meeting was held on 16 March 2007 to discuss the comments on the draft document on the role of animal feeding trials within the safety and nutritional assessment of GM plants derived foods/feed received via the public consultation (from 15 December 2006 until 15 February 2007). The working group has considered the comments in its revision of the document. The aim is to present the revised version of the document to the Member State experts during a consultation meeting before finalising the document.

10.3. Guidance for the assessment of GM plants used for non-food/feed purposes

A 5th working group meeting was held on 1-2 March 2007 during which further risk assessment criteria were discussed for specific case studies of GM plants used for non-food/feed purposes.

10.4. Statistical considerations in the safety evaluation of GMOs

A fourth working group meeting took place on 19 March 2007. The working group will establish more specific guidance on how data should be presented and will provide recommendations for the experimental study design.

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[5] http://www.efsa.europa.eu/en/science/colloquium_series/Colloquium_8_gmo.html

10.5. Working Groups of the Codex ad hoc Intergovernmental Task Force on Foods derived from Biotechnology

EFSA has provided scientific support to the European Commission in the Codex Working Group on Adventitious presence of rDNA material (Washington, 13-15 March) and the Codex Working Group on Foods derived from rDNA plants modified for nutritional or health benefits (Ottawa, 7-9 May).

11. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The 24th Plenary meeting of the Scientific Committee was held on 16-17 April 2007. The minutes of this meeting will be published at:
http://www.efsa.europa.eu/en/science/sc_commitee/sc_meetings/24th_sc_meeting.html.

12. DATES OF FUTURE MEETINGS

The November plenary meeting will be held on 22-23 November in Brussels, back to back to the Scientific Forum of EFSA's 5th Anniversary (20-21 November 2007). Consequently, the October and December Plenary meetings will need to be rescheduled.

13. ANY OTHER BUSINESS

The Panel discussed two proposals for outsourcing a task to a Member State institution within the framework of Article 36 of EFSA's founding Regulation (EC) 178/2002. The purpose of these assignments is to provide EFSA with a written scientific report on Cry proteins with a focus on their safety for human and animal health and the environment and with a report on the state-of-the-art on the impact of GM herbicide tolerant plants on non-target organisms. The final proposals will be published on the EFSA website.

EFSA has received a letter from the Dutch Competent Authority for Directive 2001/18/EC with comments on the EFSA guidance document for the risk assessment of GM microorganisms (GMMs) and their derived products intended for food and feed use[6]. The comments will be taken into account by the working group of the Panel on GMMs in the light of future revisions of the GMM guidance document.

The Panel was informed about the annual report, submitted to the Commission, on the implementation and the results of the monitoring activities for 1507 maize. This monitoring was carried out by Pioneer and Dow AgroSciences in accordance with Decision 2006/197/EC.

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[6] http://www.efsa.europa.eu/en/science/gmo/gmo_guidance/gmo_guidance_ej374_gmm.html

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8

EFSA SCIENTIFIC COLLOQUIUM
SUMMARY REPORT

ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY MODIFIED PLANTS - CHALLENGES AND APPROACHES

efsa

European Food Safety Authority

20-21 June 2007, Tabiano (Parma), Italy

European Food Safety Authority

MINUTES OF THE 34TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 4-5 JULY 2007 IN PARMA, ITALY (ADOPTED ON 12 SEPTEMBER 2007)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch[1], Howard Davies, Niels Bohse Hendriksen, Lieve Herman, Sirpa Kärenlampi, Jozsef Kiss, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Ingolf Nes, Joe Perry, Annette Pöting, Joachim Schiemann, Willem Seinen and Jeremy Sweet.

EFSA:
GMO Unit: Anna Christodoulidou, Zoltan Diveki, Ana Gomes, Karine Lheureux, Sylvie Mestdagh, Claudia Paoletti, Suzy Renckens, Reinhilde Schoonjans and Ellen Van Haver.

European Commission:
Bernadette Murray[2] (DG ENV), Sébastien Goux and Michael Walsh (DG SANCO).

APOLOGIES

GMO Panel:
Josep Casacuberta, Marc De Loose, Nickolas Panopoulos and Jean-Michel Wal.

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. Apologies for absence were received from some Panel members as mentioned above.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3. DECLARATION OF INTERESTS

Panel members were asked to update their annual declarations of interest that are published on the EFSA website[3], based on the new template as prepared by EFSA.

In addition, Panel members were invited to declare possible interests on topics included on the agenda. In the case Panel members have an interest to declare, they will be asked to fill in a specific declaration of interest, which will be reported in the minutes of the plenary meetings as has been done so far.

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[1] Present only on 4 July
[2] Present only on 5 July
[3] http://www.efsa.europa.eu/en/science/gmo/gmo_members.html

4. ADOPTION OF THE MINUTES OF THE 33RD PLENARY MEETING HELD ON 16 MAY 2007

The minutes of the 33rd plenary meeting (16 May 2007) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_33rd_meeting.html.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. A7204-12 Soybean (Application NL-2005-18 under Regulation (EC) 1829/2003)

Introduction

The Panel was requested in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003, to carry out a scientific assessment of the genetically modified soybean A7204-12 for food and feed uses, import and processing.

The opinion of the Panel corresponds to the safety assessment report as referred to in Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and will be part of the overall EFSA opinion as required by Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003.

Discussion

The assessment is based on the information provided in the application, including additional information from the applicant in reply to questions from Members States (MS) and from EFSA.

The comments from MS that were submitted during the three-month consultation period were addressed individually by the Panel in a separate annex.

The draft opinion and the table with comments from MS were presented to the Panel members during the plenary meeting followed by a discussion on outstanding issues.

The Panel is of the opinion that the molecular characterisation of the DNA insert and flanking regions of A2704-12 does not raise safety concerns, and sufficient evidence for the stability of the insert structure and of the newly introduced trait was provided. Comparative analysis has shown that soybean A2704-12 is compositionally and agronomically equivalent to conventional soybean lines, except for the introduced transgenic trait. The risk assessment included an analysis of data from analytical studies, bioinformatics, and *in vitro* and *in vivo* studies. The GMO Panel concluded that the soybean A2704-12 is as safe as its non GM counterpart and that the overall allergenicity of the whole plant is not changed.

The application is for food and feed uses, import and processing. There is therefore no requirement for scientific information on possible environmental effects associated with the cultivation of soybean A2704-12. Considering the scope of the application, not for cultivation, the Panel is of the opinion that the likelihood of the spread and establishment of soybean A2704-12 is very low and that unintended environmental effects due to this soybean will be no different from that of conventional soybean varieties. The scope of the monitoring plan provided by the applicant and the reporting intervals are in line with the intended uses of soybean A2704-12 since cultivation is excluded. In conclusion, taking into account issues raised by Member States, the Panel considers

that, on the basis of the information available for soybean A2704-12, it is unlikely that soybean A2704-12 will have any adverse effect on human and animal health or on the environment in the context of its proposed uses.

Adoption

The opinion was adopted unanimously by the Panel. The opinion and the table containing the responses of the Panel to MS comments can be found on the EFSA website at:

http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/ej524_soybean.html.

6. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC, REGULATION (EC) NO 1829/2003 AND REGULATION (EC) NO 1831/2003

Ongoing applications

- LLRice62 rice (application UK/2004/04): the Panel identified further questions to the applicant with respect to the molecular characterization of LLRice62.

- 59122 Maize (application NL-2005-23): EFSA met COGEM and the Dutch Competent Authority performing the initial environmental risk assessment of the 59122 maize application to discuss possible questions for additional information to be sent to the applicant.

- LY038 Maize (application NL-2006-31): questions to applicant for additional information on the food/feed safety of LY038 maize were identified by the Panel. In addition, the answer from the applicant to the request from the Panel for clarification of the molecular characterisation of LY038 was not considered satisfactory.

- T45 Oilseed rape (application UK-2005-25): the Panel identified questions to the applicant for further clarification of the molecular characterisation of T45 Oilseed rape.

- MON88017 maize (application CZ-2005-27): the Panel identified questions to the applicant with respect to the molecular characterisation of MON88017 maize.

- Dried killed bacterial biomass applications (applications FR-2007-40 and FR-2007-44) will be assessed in cooperation with the FEEDAP Panel. The GMO Panel will assess the genetic modification and environmental aspects of the applications, whereas the FEEDAP Panel will look at the nutritional and toxicity aspects of the feed.

In case additional information is requested to the applicant, the assessment procedure is kept on hold (the clock is stopped).

7. STATEMENT ON THE ANALYSIS OF DATA FROM A 90-DAY RAT FEEDING STUDY WITH MON 863 MAIZE

Following the request from the European Commission to examine the recently published CRIIGEN study on the statistical analysis of the GM maize MON 863 toxicology data (see items 10 and 7 of

the minutes of the 32nd plenary meeting[4] and of the 33rd plenary meeting[5] respectively), the Panel has adopted a statement on 25 June 2007 by written procedure.

The Panel has carefully considered the results of the statistical re-analysis of the 90-day rat feeding study with MON 863 maize in relation to the previous evaluations[6,7].

The Panel has considered the biological relevance of all statistically significant differences in test parameters. Observed differences in test parameters of exposed male and female rats were in general neither dose-related nor sex-dependent and were therefore considered as isolated phenomena occurring by chance. Furthermore the Panel has taken the natural variability of the test parameters into account. Given the fact that deviations in test parameters were relatively small and for the greatest part within natural variation ranges, the Panel did not consider these effects as biologically relevant.

In the absence of any indications that the observed differences in test parameters are indicative of adverse effects, the Panel does not consider that the publication by Séralini et al.[8] raises new issues which are toxicologically relevant. Therefore, the Panel sees no reason to revise its previous opinion that the MON 863 maize would not have an adverse effect on human and animal health or the environment in the context of its proposed use.

The Panel is aware of the fact that different approaches are applied in the statistical analysis of data obtained from animal experiments and has signaled the need for a harmonised approach in this area. A working group of the Panel is currently addressing this issue.

The full statement can be found at:
http://www.efsa.europa.eu/en/science/gmo/statements0/gmo_statement_mon863_ratfeeding.html

The EFSA report that was provided by an EFSA Task Force to advise the Panel on this matter and which provides a detailed statistical review is published on the following website:
http://www.efsa.europa.eu/en/science/scientific_reports/statistical_analyses_MON863.html

8. NEW REQUESTS TO EFSA: DISCUSSION AND ADOPTION OF MANDATES

8.1. Applications under Regulation (EC) No 1829/2003

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[4] http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_32nd_meeting.html

[5] http://www.efsa.europa.eu/en/science/gmo/gmo_meetings/gmo_33rd_meeting.html

[6] Opinions of the GMO Panel related to the placing on the market of insect-protected genetically modified maize MON 863 and MON 863 x MON 810.
http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_opinions/381.Par.0001.File.dat/opinion_gmo_06_en1.pdf &
http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_opinions/383.Par.0001.File.dat/opinion_gmo_07_en1.pdf

[7] Statement of the GMO Panel on the evaluation of the 13-week rat feeding study on MON 863 maize, submitted by the German authorities to the European Commission.
http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/statements/666.Par.0001.File.dat/sr_gmo01_statement_study_MON 863_en1.pdf

[8] Séralini, G.E., Cellier, D., de Vendomois, J.,S., 2007. New analysis of a rat feeding study with a genetically modified maize reveals signs of hepatorenal toxicity. Arch. Environ. Contam. Toxicol., 52, 596-602.

EFSA received, via the Netherlands, one new application (NL-2007-45: 305423 soybean) within the framework of Regulation (EC) No 1829/2003 for an overall opinion including the scientific opinion on the GMO for import and processing, food and feed use.

Nominated risk assessment bodies of the Member States and national competent authorities within the meaning of Directive 2001/18/EC as foreseen by Articles 6 (4) and 18 (4) of Regulation (EC) No 1829/2003 will be consulted by EFSA once the above mentioned application is valid. These comments will be considered during the scientific risk assessment of the application by the EFSA GMO Panel.

The summary of this application, as well as the information on its current status can be found on the following website:
http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.

8.2. Applications under Regulation (EC) No 1831/2003

EFSA received from the European Commission three requests for scientific opinions on GMO-derived feed enzymes (L-Valine for all species (EFSA-Q-2007-103), Econase XT L/P (beta-1,4-xylanase) for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding and piglets (EFSA-Q-2007-120) and Ronozyme NP (6-phytase) for chickens for fattening (EFSA-Q-2007-133)) within the framework of Regulation (EC) 1831/2003. For applications within the remit of two Panels (GMO and FEEDAP), the GMO Panel will perform the risk assessment of the genetic modification event and the FEEDAP Panel will perform the risk assessment of the feed additive.

9. OUTCOME OF EFSA SCIENTIFIC COLLOQUIUM ON THE ENVIRONMENTAL RISK ASSESSMENT OF GM PLANTS HELD ON 20-21 JUNE IN TABIANO, ITALY

On 20 and 21 June, EFSA held a two day Scientific Colloquium in Tabiano, Province of Parma on the Environmental Risk Assessment (ERA) of GM plants. Some 100 scientists and stakeholders from both EU and non-EU countries discussed approaches to environmental risk assessment in the light of current scientific thinking, focusing on issues such as environmental fitness, effects on non-target organisms, long-term and large scale environmental effects, broader environmental considerations and the assessment of risk versus environmental benefit.

Participants agreed on the current case-by-case approach to ERA, as outlined in EFSA's guidance, and that EFSA's risk assessment work on ERA was at the forefront of developments in this area. Experts at the colloquium argued that more specific guidance may be needed for the assessment of the potential impact on non-target organisms in terms of design and statistical power of testing. Modelling may be a useful tool to predict potential effects that GM plants might have over time and when cultivated on a larger scale in Europe. In addition, post-market environmental monitoring will play an important role for determining long-term effects of GM plants and for testing model predictions.

The presentations given and the summary report will be published on the EFSA website at:
http://www.efsa.europa.eu/en/science/colloquium_series/Colloquium_8_gmo.html.

10. UPDATE ON SELF TASKING ACTIVITIES AND GUIDANCE ON GMO RISK ASSESSMENT

10.1. Animal feeding trials

The working group on animal feeding trials aims at finalising its report in order to present it to the GMO Panel at their September plenary meeting for possible adoption.

10.2. Guidance for the assessment of GM plants used for non-food/feed purposes

A sixth working group meeting was held on 31 May 2007 during which the draft report was discussed and outstanding issues identified. Specific case studies of GM plants used for non-food/feed purposes will be further elaborated by a sub-working group meeting scheduled at 18 July 2007.

10.3. Statistical considerations in the safety evaluation of GMOs

A fifth working group meeting took place on 5 June 2007. A preliminary report of the working group will be presented at the next GMO Plenary meeting.

11. GMO CALLS FOR ARTICLE 36 PROPOSALS: CRY PROTEINS AND IMPACT OF GM HERBICIDE TOLERANT PLANTS ON NON-TARGET ORGANISMS

Two calls for proposals for outsourcing a task to a Member State institution within the framework of Article 36 of EFSA's founding Regulation (EC) 178/2002 have been published on the EFSA website (http://www.efsa.europa.eu/en/about_efsa/cooperation/call_for_proposal.html). The purpose of these assignments is to provide EFSA with a written scientific report on Cry proteins with a focus on their safety for human and animal health and the environment and with a report on the state-of-the-art on the impact of GM herbicide tolerant plants on non-target organisms. The deadline for submitting proposals is 20 August 2007.

12. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

A working group of the Scientific Committee has been established to assess the implications of animal cloning on food safety, animal health and welfare and environment.

13. FEEDBACK FROM THE COMMISSION

The Commission provided the Panel with the status of applications that have been presented to the Standing Committee on the Food Chain and Animal Health for possible authorisation, and for which no qualified majority was reached.

14. DATES OF FUTURE MEETINGS

The following GMO Panel plenary meetings have been scheduled in the fall of 2007: 12-13 September (Parma); 30 - 31 October (Parma); 22 - 23 November (Brussels, back to back to the EFSA's 5th anniversary Scientific Forum of 20-21 November); 18-19 December (Parma).

A proposal for plenary meetings in 2008 was also discussed.

15. ANY OTHER BUSINESS

The Commission has provisionally inquired EFSA about the view of the Panel on a letter provided by Germany in support of the invocation of a safeguard clause for cultivation of MON 810 maize according to Article 23 of Directive 2001/18/EC. The Panel is of the opinion that the letter provided by Germany does not comprise i) new or additional scientific information that will impact the previous scientific evaluation carried out on MON810 maize; ii) new scientific publication that the GMO Panel has not previously considered in its former scientific opinions/statements. The Panel will assess the monitoring plan of MON810 maize in the context of the submitted applications for renewal of MON810 maize for food, feed and cultivation purposes.

EFSA received via the Commission a letter from the Competent Authority of Austria with a statement from its national expert on antibiotic resistant marker (ARM) genes. This letter refers to the "Statement of the Scientific Panel on Genetically Modified Organisms on the safe use of the nptII antibiotic resistance marker gene in genetically modified plants[9]". The above mentioned Austrian statement agrees with the conclusion of the Panel that the probability of functional gene transfer from plants into microorganisms is extremely low. In its statement on the safe use of the *npt*II ARM gene in GM plants, the Panel also concluded that the therapeutic effect of the aminoglycoside group of antibiotics will not be compromised by the presence of the *npt*II gene in GM plants. In the Austrian statement concern was expressed that "a single successful transfer is enough to build up a founder generation, which is able to spread the newly acquired resistance vertically to an offspring generation via clonal expansion or horizontally via conjugation and transduction". The Panel discussed this issue and noted that the *npt*II gene is already present in environmental and clinical isolates. Therefore, the Panel confirms that is very unlikely that the presence of the *npt*II gene in GM plants will add to the existing prevalence of this antibiotic resistance gene in bacterial sources. This conclusion of the GMO panel has been previously supported by the Austrian Bundesministerium für Gesundheit und Frauen who recommended to the Austrian Competent Authorities in a document by Mag. Markus Wögerbauer entitled "Risikoabschätzung von Resistenzmarkergenen in transgenen Pflanzen" (English Summary) (2006, ISBN 3-900019-64-9) that "no indications in the recent literature can be found for a scientifically based argument in favour of a strict rejection of transgenic plants which contain group I antibiotic resistance marker genes" (The *npt*II gene is included in group I.). This document comprised a risk assessment of ARM genes on the basis of the relevant scientific literature available until November 2005. The Panel noticed that in the above mentioned Austrian statement other additional publications have been discussed as well. The Panel is of the opinion that the information provided does not change the conclusions of its earlier statement.

The Panel was informed by the Commission about a press statement from Greenpeace, based on a new study of CRIIGEN that presumes the possible toxicity of NK603 maize. The information that is being circulated via the internet is not providing any new scientific evidence with respect to the safety of NK603 maize. In addition, for this case, contrary to MON863 maize, there is no claim made through a peer reviewed scientific publication. From EFSA's extensive analysis on the MON863 data (see item 7 of these minutes) it can be concluded that statistical approaches are a tool to identify differences between a GMO and its comparator but that the most important issue is to assess the biological implications of any changes, as done in the assessment by the GMO Panel.

[9] Adopted on 22 March 2007 (http://www.efsa.europa.eu/EFSA/Statement/gmo_statement_nptII_.pdf)

The safety of a GMO is determined on the basis of the complete data package in accordance with the EFSA guidance. The detailed assessment of NK603 maize is described in the EFSA opinions on that maize[10].

The Panel was informed about an EFSA statement on the fate of recombinant DNA or protein in meat, milk or eggs of animals fed with GM feed, following a petition from Greenpeace to label food products (such as meat, milk and eggs) from animals that have been fed with genetically modified feed and a subsequent request from the Commission. The statement will be published at: http://www.efsa.europa.eu/EFSA/Statement/EFSA_statement_DNA_proteins_gastroint.pdf.

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[10] Opinions of the GMO Panel on GM maize NK603, 1507 x NK603, NK603 x MON810, MON863 x MON810 x NK603 and MON863 x NK603 (http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/176.html & http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/1482.html & http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/1284.html & http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/1033.html & http://www.efsa.europa.eu/en/science/gmo/gmo_opinions/1032.html).

(31)

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European Food Safety Authority

EXECUTIVE DIRECTORATE

Minutes of the
Management Board Meeting
11 September 2007
Hotel Howard Johnson, Bucharest

Members of the Management Board present

Diána Bánáti	Milan Pogačnik
Giorgio Calabrese	Pirkko Raunemaa
Marianne Elvander	Bart Sangster
Peter Gaemelke	Roland Vaxelaire
Matthias Horst	Patrick Wall
Deirdre Hutton	Konstantinos Yazitzoglou
Robert Madelin	

Observers and Invitees of the Executive Director

Professor Vittorio Silano, Chair Scientific Committee	Professor Harry Kuiper, Chair GMO Panel

Staff of the European Food Safety Authority present

Catherine Geslain - Lanéelle	Christine Majewski
Anne-Laure Gassin	Alexandrine Maviel-Sonet
Dirk Detken	Stefano Penati
Herman Koëter	Suzy Renckens
Djien Liem	Ingela Söderlund

Table of Contents

SUMMARY OF DECISIONS

The Management Board:

- Adopted the agenda without changes
- Adopted the minutes from the 19 June 2007 meeting without changes
- Agreed that following the incorporation of the comments from the Board, to adopt the documents on Declarations of Interest via written procedure
- Adopted the proposal to split the AFC Panel into 2
- Adopted the updated Rules of procedure for the Scientific Committee and Scientific Panels, subject to editorial comments
- Adopted the document on the Amending Budget for 2007

The Management Board also:

- Announced the nomination of a new Vice Chair, Bart Sangster, replacing Dame Deirdre Hutton
- Welcomed the new Member of the Board, Professor Milan Pogačnik
- Asked the Secretariat to circulate a new proposal for 2008 meeting dates
- Deleted the 16 October 2007 extra meeting date
- Asked the Executive Director to provide a presentation of the Advisory Forum
- Took note of the Executive Directors Progress Report and congratulated EFSA on the many activities undertaken since the last meeting
- Asked to be updated on the progress of the opinion on Nanotechnology
- Asked to be informed on the number of requests for opinions EFSA had received during the year
- Suggested that it could be useful to plan a meeting in conjunction with a meeting of the Advisory Forum
- Underlined the importance of EFSA's work on the opinion on food colours
- Noted the progress on the Declarations of Interest and suggested that the new Vice Chair could capture the views of the Board and liaise with EFSA.
- Noted the presentation of Dr Kuiper and offered to support it should there be any need in relation to its workload
- Took note of the update from the Chair of the Audit Committee, Mr Vaxelaire
- Took note of the transfers in the EFSA budget

PUBLIC SESSION

Preliminary Formalities

The Chair opened the meeting by welcoming the Board Members, Professor Silano, Dr Kuiper, the Authority's staff and the viewers on the web. Apologies had been received from Marion Guillou and João Machado. The Chair announced that Bart Sangster had been elected vice Chair for the Management Board. The Chair welcomed the new Member of the Board, Professor Milan Pogačnik, and invited him to introduce himself. Professor Pogačnik thanked the Board for its warm welcome and told the audience that he is a Professor at the Veterinary Faculty at the University of Ljubljana , Slovenia specialised in animal pathology.. The Chair introduced Liviu Rusu, the General Director of the General Division for Food Safety at the National Sanitary and Veterinary and Food Safety Authority of Romania. In his speech, Dr Rusu said that it was an honour for the Romanian Authority to host the Board meeting and wished the participants a successful meeting.

The Chair asked if members wished to make any declarations of interest. Marianne Elvander declared that she would be accompanying the Food and Veterinary Office (FVO) on a mission to Brazil in October-November, to carry out inspections on beef production. Diána Bánáti declared that she had received an honorary doctorate from the University of Szeged and served on the Agro-economic Judicial Expert Board.

No points suggested under any other business. The Chair raised the matter of the meeting dates for 2008 as there had been a suggestion to change the March date. The Secretariat would circulate a proposal for further discussion. The proposed extra date of 16 October 2007 would be deleted.

1. **Adoption of Agenda (Document MB 11.09.2007 -1)**
   - 1.1 The Chair asked the Members of the Management Board if there were any changes or additions they would like to make.
   - 1.2 No items were added to the agenda. The agenda was adopted.

2. **Adoption of draft minutes of the previous meeting and matter arising from the minutes (Document MB 11.09.2007 - 2)**

   - 2.1 The minutes 19 June 2007 were adopted and would be published on the Authority's website.
   - 2.2 Matters arising from the June Board meeting would be dealt with in agenda item 4, the update of the Internal Rules for the Scientific Committee and Panels and the split of the AFC Panel would be dealt with under agenda item 5. A Board member referred to point 3.5 from the June minutes and enquired when the Board would benefit from a presentation about the work of the Advisory Forum. The Executive Director suggested that a presentation could be made at the December meeting.

3. For information: Progress Report (Document MB 11.09.2007 – 3 and power point presentation)

3.1 The Chair invited the Executive Director to update the Board on progress made at EFSA since the last Board meeting. The Executive Director updated the Board on the progress of ongoing work in the relevant Panels. In particular EFSA had been informed by the UK Food Standards Agency (FSA) of a new study, commissioned by the FSA, on the possible impact of certain mixtures of colours on the behaviour of children. EFSA had received additional data from the FSA and the AFC Panel would consider the study and come back with a preliminary review on the study at the end of September. The Commission had sent a request for an opinion.

3.2 The Executive Director welcomed the Chair of the GMO Panel who would make a presentation later in the day and mentioned that the secretariat of the Panel had been very active in preparing two calls which would be launched under the Article 36 procedure, on proteins and the impact of herbicidal non-GM plants on non-target organisms.

3.3 The Scientific Committee had developed for a review system to assess the quality of EFSA's scientific work. In the proposed strategy, the quality of EFSA's scientific activities would be comprehensively reviewed, both by internal review and by independent, external review processes, together with additional consultations with institutional and non-institutional stakeholders.

3.4 EFSA had also received advice from the Scientific Committee on the responsiveness to urgent questions. The Scientific Committee's advice had been taken into account in the update of the internal rules of the Internal Rules for the Scientific Committee and Panels (discussed under item 5).

3.5 The Advisory Forum had met in Bratislava at the end of June. Member States discussed the issue of the establishment of focal points with the responsibility to support the representatives of the Advisory Forum to gathering data and transferring information between EFSA and relevant bodies in the respective Member State in the fields of risk assessments within EFSA's remit. The Advisory Forum had also agreed on mandates for projects related to the harmonisation of risk assessment approaches, the analysis of the risks and benefits of fortification of food with folic acid, on emerging risks and on the harmonisation of chemical occurrence data collection for food and feed.

3.6 In the area of external relations, EFSA had signed an agreement with the Food and Drug Administration (FDA) on confidentiality arrangements, EFSA had also met with the Japanese Food Safety Council to discuss a draft Memorandum of Understanding.

3.7 Representatives from EFSA had participated in meetings in the European Parliament on issues covering pesticides, fish meal and food improvement agents.

3.8 The Human Resources department had made progress with regard to recruitment and it was foreseen that by early 2008 EFSA would have some 300 temporary agents employed. The Executive Director presented the new head of EFSA's press office, Stephen Pagani, who was in the audience.

3.9 The Board thanked the Executive Director for her presentation and congratulated her on the many activities EFSA had been able to cover in such a brief period of time. The Board asked to be updated on the progress of the work on the opinion on nanotechnology, and she replied that EFSA would

probably be in the position to agree on the mandate with the Commission in September. The Board also asked to be informed about the high number of requests for opinions that EFSA had received, mentioned in the progress indicators report that had been sent to the Board at the end of July. The Executive Director replied that she would address the matter under agenda point 5.

3.10 Robert Madelin raised the matter of EFSA's possible cooperation with Japan and noted that this should of course be done within the normal legal framework for such collaboration. for such The Executive Director replied that EFSA was cooperating with colleagues in the Commission on that matter.

3.11 The Board suggested that it could be useful to plan a Board meeting in conjunction with an Advisory Forum meeting in the future, congratulated EFSA on the new website and underlined the importance of EFSA issuing an opinion on the food colours study as soon as possible.

3.12 The Executive Director thanked the Board for their encouraging words.

4. Declarations of Interest (MB 11.09.07 – 5.1, 5.2, 5.3, 5.4 and power point presentation)

4.1 The Executive Director introduced the draft proposals on a Policy on Declarations of Interest (DOI's) and Guidance and Procedures documents to implement the Policy. The approach was to have a general policy in which a set of DOI's would be described. An updated guidance document reflecting in detail the issues to be subject to a declaration and a set of procedures that would formalise the follow-up or the way EFSA would handle DOI's, were also presented to the Board.

4.2 Dirk Detken and Hubert Deluyker explained that the intention of EFSA was to make even clearer and transparent the way EFSA dealt with DOI's. The new policy includes a detailed procedure for screening these Declarations, identifying any potential conflicts of interest and taking appropriate action. It also contains full guidance on how to make a Declaration of Interests in order to harmonise the process across EFSA.

4.3 The Chair thanked Mr Detken and Mr Deluyker for their presentations and opened the floor for discussion. The Board pointed out that there was a need to clarify the consequences of not declaring interests, or only declaring some interests. The Board asked for the notion of family to be further clarified and also which interests of family members had to be declared and whether a declaration of the exact number of shares would be necessary. Other clarifications were asked in relation to the notion of employment and the scope of the DOI which should relate to Article 22 of the founding Regulation. It was also suggested that the person signing the DOI should sign a statement that he had read EFSA's policy on DOI's, and to add the possibility of experts to state themselves what they considered possible conflicts of interest and sign off that there were no interests that they had omitted to declare.

4.4 Professor Silano offered the possibility to present the new DOI policy also at the plenary meeting of the Scientific Committee of 18-19 September.

4.5 The Chair pointed out that it was fundamental to EFSA's philosophy of openness and transparency that the DOI's were comprehensive. He concluded that the document had received constructive comments but the present draft could not be adopted. He added that changes would be made in line with the comments received from the Board Members and the Scientific Committee before adoption.

4.6 The Executive Director thanked the Board for their input and stressed that DOI's would be evaluated on a case-by-case basis. The process would be applied to a context where the DOI's would be made and examined in the context in which they were given. There would be annual DOI's but also DOI's given in the context of meetings, and these would be recorded in the minutes of that meeting. She suggested that the documents should be amended taking into consideration the comments of the Board.

4.7 A Board member suggested that the new Vice Chair could coordinate the comments and consult with Board members. She suggested that this might be a practical way of handling the follow-up procedure.

4.8 The Chair agreed and suggested that the Vice Chair should capture the views of the Board, that the Scientific Committee would look at a document which incorporated the comments from the Board made at the meeting and that the documents would be circulated to the Board members and adopted via written procedure. The Vice Chair agreed, provided that he received an amended draft on which he could base further comments.

4.9 The Executive Director agreed to this procedure.

5. For adoption by the Board: Amendment of the Internal Rules of procedure for the Scientific Committee and Panels, split of the AFC Panel to create a new Panel (Document MB 11.09.2007 - 4)

5.1 The Executive Director introduced the point by explaining that the Board had made a series of recommendations relating to improving the work conditions for scientists and in particular to looking at greater support from EFSA staff to Panels looking at easing workloads, the reimbursements of experts and the location of the meetings. She explained that the tabled proposal addressed two points: the creation of new Panels and the change in the internal rules of the Scientific Committee and Panels. The proposed changes were made to enable EFSA to respond to the increasing workload and take into account the opinion of the Scientific Committee on urgent questions. She also explained that in 2008 some 90 per cent of recruitment would be made to the science department, compared with some 65 per cent in 2007. Resources would focus mainly on the areas where EFSA was expecting a large workload which mainly related to safety evaluations: GMO, nutrition, pesticides, food additives and feed additives. In order to reduce the burden on Panels, EFSA was also revisiting its draft 2008 work plan, together with Member States, and would seek to avoid duplication of work and assess how EFSA could benefit from work being done in the Member States.

5.2 The Director of Science introduced the documents. Given the workload of the AFC Panel it was suggested to create a new Panel. The current AFC Panel was able to adopt some 50 opinions per

year. However the number of requests for opinions was very high. This was the reasoning behind splitting the AFC Panel in two.

5.3 The proposed focus for the first Panel would be on food additives and have its main focus on toxicology. The other Panel would focus on food contact materials which also included aspects of toxicology but was an area strongly linked to chemistry. Therefore with toxicology and food additives in one panel and chemistry and food contact materials in another it was felt that there was a logical basis for the two proposed panels. The Chair recognised the need to split the Panel and said that he hoped that the existing scientists would be retained. He enquired about the process for fast-tracking the applications of the existing scientists for the new Panels.

5.4 The Director of Science explained that the proposal to split the Panel would have to go through a comitology procedure in the Commission and that a simplified procedure for the reappointment of the current experts of the AFC Panel could be examined. There would be an external call for experts with the objective of being able to start the work of the 2 new Panels as soon as possible.

5.5 The Chair supported the suggestion and asked Professor Silano for the view of the Scientific Committee on the proposal. Professor Silano explained that the Scientific Committee was supportive. The Chair asked the Board support the proposal to create a new Panel and the Board indicated its approval.

5.6 The Executive Director indicated her support for flexibility in the remits of the Panels however experts needed to know in which areas of work they would be expected to contribute. She suggested clear titles for the Panels, and that the mandates should be clearly defined. Flexibility would be ensured through maintaining a unique unit dedicated to the support of the two panels with two separate teams within this unit.

5.7 The Director of Administration introduced the proposal to amend the Internal Rules for the Scientific Committee and Panels. The proposed changes were reflected in Article 13 and 21 of the document.

5.8 The Board commented on the proposed changes and highlighted the need for a clear fast track procedure to be used in an emergency or a crisis which should reflect the existing available legal framework.

5.9 The Authority needed to be very clear on how external experts would be appointed to working groups set up in relation to fast track procedures in urgent situations.

5.10 The Chair asked the Board to agree to the proposal subject to the suggestions made. The Board supported the proposal.

6. Presentation of the GMO Panel by its Chair, Dr Harry Kuiper (Power point presentation)

6.1 The Chair of the GMO Panel introduced the work of the Panel and legal framework for the risk assessment of Genetically Modified Organisms (GMO's). There were 2 different procedures for the assessment of GMO's according to the legal bases i.e. one under Directive 2001/18 on the deliberate

release of a GMO into the environment for cultivation and a second one under Regulation 1829/2003 on GM food and feed. The Panel currently had 20 members with one vacancy, three standing working groups and ad hoc working groups on dossier evaluation; molecular characterisation, the food and feed evaluation and environmental risk assessment. He explained that to date, the Panel had adopted 23 opinions. The Panel had also produced guidance documents. Dr Kuiper informed the Board that an extensive report on the use of animals to assess the safety of GM foods and feeds would be available soon.

6.2 The Panel had received correspondence and enquiries from the European Commission, Member States authorities', European Parliament members, environmental NGOs, general public, applicants and other stakeholders. The Panel had also addressed the safeguard clauses invoked by some Member States. Petitions in countries could lead to statements such as the one the panel had made on the potential labelling of products from animals fed with GM feed. The challenge for the Panels was to look at these aspects seriously but the issue was to which extent the Panel should be involved in answering these questions. Such issues were growing and the Panel would be faced with resource problems if this demand continued.

6.3 The GMO Panel had liaised significantly with Member States, consulted on documents via the internet and held public consultations. Links had also been established with the FAO, the WHO and Codex Alimentarius. EFSA was planning a meeting with the Advisory Forum and with GMO experts on risk assessments involved at national level on the general principles of risk assessment.

6.4 Dr Kuiper suggested that EFSA could be more active in the area of new developments at the international level, where there were important issues concerning risk assessment and management. He added that the Panel should not be overburdened with recurring questions Prioritisation was important and EFSA staff, the Panel and the Commission should work together in that area more to find agreement on priorities.

6.5 The Chair thanked Dr Kuiper for his presentation and acknowledged the work of the scientists. He agreed that scientific panels could not be expected to deal with non scientific issues.

6.6 A Board member suggested that how concerns and uncertainties had been taken into consideration should be transparently presented in opinions as should minority views. He indicated that the perception of NGO's and consumers was that the Panel worked very hard to find the best scientific process but that it was important to indicate different views where these exist. Another Member of the Board asked whether assessments could be speeded up to enable risk managers to carry out their responsibilities.

6.7 Robert Madelin thanked Dr Kuiper and indicated that EFSA has the power specifically laid down in the founding regulation to reject requests. The work load would still be overwhelming because more and more GMO's were being put forward for the European market. The Board could decide that more members were needed on the Panel if there was a work load issue. He suggested that EFSA needed to provide more information on the issues linked to feeding studies and that EFSA could look at

feeding studies as a communication issue, go further into the technicalities and explaining in words for the general public to understand, and explain EFSA's risk assessment responsibilities.

6.8 The Chair noted the questions and comments from Board members related to the composition of the Panel, their increasing workload and the implications to risk managers.

6.9 The Board noted that the GMO Panel was the Panel for which there was probably the highest risk that risk assessment and risk management issues were mixed up. Some stakeholders were seeking very detailed answers about the methodology of the Panel whereas others only wanted to know of the GMO was safe or not. Dr Kuiper was asked if the Panel received any feedback on how the output of the Panel was perceived. The Board also asked whether the Panel was consulted when research programmes were agreed in the Commission and if the Panel was consulted when the priorities of research programmes were decided. The Board asked Dr Kuiper for his opinion about the future membership in the Panel and whether the Panel was able to attract and keep the most prominent independent scientists because of the work load.

6.10 Dr Kuiper thanked the Board for its questions. He noted the question about transparency in the Panel's opinions. The issue had been discussed in a meeting with NGO's some 18 months ago where the NGO's had expressed the view that uncertainties should be better than previously where there were uncertainties in the opinion. The Panel had made an effort to pay attention to noting uncertainties and stated that the Panel was constantly aware of the issue. He gave examples of where opinions had shown the differing views within a Panel and noted that uncertainties in risk assessment were vital to identify and communicate. The Panel was making all efforts to deal with the applications for GMO evaluations but with an increasing number of "additional" questions sometimes the part of the Panel's activities in relation to dossiers had to be prioritised. He agreed that there were communication issues but also noted that there was general agreement among risk assessors at Member State level. On setting priorities for research he suggested that this could be a topic also for the Scientific Committee and added that he was optimistic about being able to attract the best scientists to the Panel.

6.11 The Chair thanked Dr Kuiper again for presenting the work of the GMO Panel to the Board.

7. Amending Budget 2007

7.1 The Director of Administration introduced the document which concerned two technical amendments to the 2007 budget. She explained that the first one was related to the pre-accession programme for Turkey and Croatia. As follow up of the recommendation from the court of auditors EFSA had to reclassify specific funds under specific nomenclature, and call them internal signed revenue. The second point related to the signed revenue as the CDT, the Translation Centre of the European Commission, was returning funds back to EFSA and if the Authority want to obtain the money it had to be added to the budget. She asked the Board to adopt the amendments.

7.2 The Board adopted the document.

8. Update from the Audit Committee

8.1 Roland Vaxelaire updated the Board on the meeting of the Board's audit committee the previous day. The members had met with the new internal auditor, Stefano Penati, and been informed about the final conclusion of the Commission's internal audit service, which had audited EFSA one year ago and made 36 recommendations. Out of the 36 recommendations the audit committee was pleased that 26 had been closed, nine were currently being addressed, and one related to the corporate risk analysis will start to be implemented in September 2007. The members of the committee suggested to concentrate work on the risk analysis and to produce a progress report on all the other audits that were made for the last year. The last point of the meeting had been to review the process governing the preparation of EFSA scientific opinions.

8.2 The Chair thanked Roland Vaxelaire for his presentation.

9. For information: Transfers in the EFSA budget (Document 11.09.2007 - 6).

9.1 The Director for Administration introduced the point on transfers in the EFSA budget. The transfers made from title to title and chapter to chapter amounted to some 1,8 million €.

9.2 The Board took note of the transfer.

10. Concluding remarks

14.1 The Chair thanked the members of the Board, the audience, the Authority's staff, the interpreters, Professor Silano, Dr Kuiper and wished everyone a safe journey.

European Food Safety Authority

MINUTES OF THE 40TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS HELD ON 12-13 MARCH 2008 IN PARMA, ITALY
(ADOPTED ON 16 APRIL 2008)

AGENDA

PARTICIPANTS

GMO Panel:
Hans Christer Andersson, Salvatore Arpaia, Niels Bohse Hendriksen, Howard Davies, Lieve Herman, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Nickolas Panopoulos, Joe Perry, Willem Seinen, and Jean-Michel Wal.

EFSA:
GMO Unit: Elisa Bianco, Anna Christodoulidou, Yann Devos, Zoltan Diveki, Antonio Fernandez, Karine Lheureux, Sylvie Mestdagh, Claudia Paoletti, Suzy Renckens, Reinhilde Schoonjans and Ellen Van Haver.
IT Unit: Andre Malinowski[1].

European Commission:
Sabine Pelsser and Michael Walsh (DG SANCO), Chantal Bruetschy[2] and Bernadette Murray[1] (DG ENV).

APOLOGIES

GMO Panel:
Detlef Bartsch, Josep Casacuberta, Marc De Loose, Ingolf Nes, Annette Pöting, Joachim Schiemann and Jeremy Sweet.

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all. Apologies for absence were received from some Panel members as mentioned above.

Gijs Kleter was welcomed as new Panel member. Dr. Kleter, who was already actively involved in the work of the GMO Panel as *ad hoc* expert to several EFSA working groups, introduced himself. His biography and his annual declaration of interest can be found on the EFSA website at: http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_MembersAndWorkingGroup453.htm.

The Panel expressed its thanks and appreciation for the enthusiasm, commitment and professionalism shown by Dr. Suzy Renckens as Head of the EFSA GMO Unit. Dr. Renckens is leaving EFSA and this is a great loss for the GMO Panel. However, the Panel wished Dr. Renckens well in her future career, confident that her skills and experience will be used effectively by future employers.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3. DECLARATION OF INTERESTS

Panel members were invited to declare possible interests on topics included on the agenda. No specific declarations of interest were declared.

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[1] Only present for agenda item 9.
[2] 12 March only.

4. ADOPTION OF THE MINUTES OF THE 39TH PLENARY MEETING HELD ON 30-31 JANUARY 2008

The minutes of the 39th plenary meeting (30-31 January 2008) were adopted as proposed and will be published at:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178681574436.htm.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS ON:

5.1. Carnation Moonaqua 123.8.12 (notification C/NL/06/01) under Directive 2001/18/EC

Introduction

EFSA was requested, under Article 29(1) and in accordance with Article 22(5)(c) of Regulation (EC) No 178/2002, to provide a scientific opinion as to whether there is any scientific reason to believe that the placing on the market of the GM carnation Moonaqua 123.8.12 for import is likely to cause any adverse effects on human health and the environment within the scope of Directive 2001/18/EC. In particular, EFSA was requested to take account of the scientific objections raised by the Competent Authorities of the Member States in this context.

Discussion

The assessment is based on the information provided in the application, including additional information from the applicant in reply to questions from Member States (MS) and from EFSA.

The scope of notification C/NL/06/01 is restricted to the import of cut flowers of carnation Moonaqua 123.8.12 for ornamental use only.

As a main conclusion, the opinion states that:

The carnation Moonaqua 123.8.12 has a modified flower colour, a shade of light mauve, which is achieved by introducing into cream-white carnation two genes of the anthocyanin biosynthesis pathway, one from Petunia and the other from Viola sp. Carnation Moonaqua 123.8.12 also expresses sulfonylurea herbicide tolerance.
The Panel has evaluated the molecular analysis of the genetically modified carnation Moonaqua 123.8.12 and concludes that the molecular characterisation of carnation Moonaqua 123.8.12 does not raise any safety concern for humans, animals or the environment.
Given the intended use of carnation Moonaqua 123.8.12 (excluding cultivation and human or animal consumption), the Panel considers that a compositional analysis limited to the newly synthesized anthocyanins is sufficient for the risk assessment of the intended modification. In the case of accidental consumption of petals from carnation Moonaqua 123.8.12, the amount of delphinidin and cyanidin consumed will be negligible in comparison with the amount present in fruits containing high levels of delphinidin and cyanidin, such as blackcurrant or red grapes. An aqueous extract from petals did not induce adverse effects in an acute oral toxicity study in mice and was not mutagenic in bacterial gene mutation tests. Furthermore, based on the results of bioinformatic studies, there is no evidence that any of the three proteins expressed is toxic or allergenic. The Panel concludes that carnation Moonaqua 123.8.12 is unlikely to have adverse effects on human or animal health in the unlikely event that carnation Moonaqua 123.8.12 petals are consumed.

Considering the low environmental exposure due to the restricted scope of the notification, it is very unlikely that gene transfer and escape into the environment would occur. In the event that this did occur, the consequences of the escape of the three genes would be negligible with regard to environmental impact. The Panel agrees with the general methods and approaches of the general surveillance plan provided in the notification.

Adoption

The opinion was adopted unanimously by the Panel. The opinion can be found on the EFSA website at:
http://www.efsa.europa.eu/en/science/gmo/gmo_opinions.html.

6. UPDATE ON APPLICATIONS RECEIVED UNDER DIRECTIVE 2001/18/EC, REGULATION (EC) NO 1829/2003 AND REGULATION (EC) NO 1831/2003

Ongoing applications

- NK603 maize (Application NL-2005-22 for cultivation): the Spanish Competent Authority who carries out the environmental risk assessment of NK603 maize in accordance with Article 6.3(c) and 19.3(c) of Regulation (EC) No 1829/2003, has received additional information from the applicant following its request (see item 6.2 of the minutes of the 31st plenary meeting[3]). The Spanish Competent Authority will present its environmental risk assessment report at the next plenary meeting of the GMO Panel.

7. NEW REQUESTS TO EFSA: DISCUSSION AND ADOPTION OF MANDATES

7.1. Safeguard measure invoked by France in relation to MON 810 maize

France has adopted an Order which suspends the cultivation of seed varieties of MON 810 pending a decision on the application of the reauthorisation of the product. This Order was notified to the Commission as a safeguard measure under Article 23 of Directive 2001/18/EC. In the meantime, France also notified to the Commission a note titled "Emergency measure" under Article 34 of Regulation (EC) No 1829/2003.

EFSA received from the Commission a request, under Article 29(1) and in accordance with Articles 22(2) and 22(5)(c) of Regulation (EC) No 178/2002, to assess:

- The opinion of the 'Comité de préfiguration" of the High Authority for GMOs, dated 9 January 2008.
- The French position that the justifications presented by Monsanto on 30 January 2008 are not sufficient to invalidate the data of the French Order.
- The scientific evidence which is presented in the accompanying note of the Order.
- The scientific justification of the duration of the measure, which is linked to the ongoing procedure of the notification for the renewal of MON810.

[3] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775268.htm.

EFSA has sent an answer to the Commission following its request, indicating that the Panel will provide a scientific opinion on the measure taken by France by the end of April 2008, subject to the receipt of a comprehensive data package (literature references listed in the above mentioned opinion of the 'Comité de préfiguration", as well as the argumentation of the French position towards the justifications presented by Monsanto).

As regards the renewal of the market authorisation of maize MON 810 for cultivation (EFSA-GMO-RX-MON810) under Regulation (EC) No 1829/2003, the Panel will issue an opinion in accordance with the provisions of Regulation (EC) No 1829/2003. The evaluation of this renewal application will be performed in close collaboration with the Spanish Competent Authority, who will carry out the initial evaluation of the environmental risk assessment in accordance with Articles 6.3(c) and 18.3(c) of Regulation (EC) No 1829/2003.

7.2. Danisco Xylanase G/L (endo-1,4-beta-xylanase) – Request for an updated opinion (EFSA-Q-2008-021)

EFSA received a request from the Commission for an updated scientific opinion on the safety of the enzyme preparation of trade name "Danisco Xylanase G/L (endo-1-4-beta-xylanase)" as a feed additive for laying hens and chickens and ducks for fattening.

An opinion on "Danisco Xylanase" was adopted in September 2007[4] as a co-opinion of the FEEDAP and GMO Panels. In the opinion it was concluded that "fragments of recombinant DNA are present in the final concentrate only in trace amounts". This was considered by the Commission as not complying with Article 7(3)(i) of Regulation (EC) No 1831/2003. Therefore, the Commission has asked for further information from the company on this issue.

In view of the above, the Commission asks EFSA to deliver an opinion on the safety of this enzyme preparation as feed additive taking into account its earlier opinion of September 2007 and the new data submitted.

8. UPDATE ON SELF TASKING ACTIVITIES AND GUIDANCE ON GMO RISK ASSESSMENT

8.1. EC guidelines and update EFSA guidance document

Following the request from DG SANCO to establish EC guidelines for the risk assessment of GM plants (for which the EFSA guidance document[5] is used as a starting point; see also item 7.4 of the minutes of the 39th plenary meeting, item 7.2 of the minutes of the 38th plenary meeting and item 10 of the minutes of the 37th plenary meeting), the working group of the Panel on molecular characterisation met on 21-22 February and the working group on food/feed safety on 13 February 2008 to discuss issues in the EFSA guidance document that could be further elaborated and clarified, taking into account scientific progress and outcomes of self tasking activities. The ongoing self tasking activity on statistics will have its next meeting end of April during which issues of field trial design will be further discussed with the aim of updating the EFSA guidance document with regard to the statistical analysis.

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[4] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178654544327.htm.

[5] Guidance document of the GMO Panel for the risk assessment of genetically modified plants and derived food and feed (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775747.htm).

EFSA has sent a letter to the Commission (DG SANCO) indicating that the deadline for revising the guidance document by early March cannot be met given further discussions they require in the respective working groups, and the ongoing work on GMO applications that need to be assessed within the legal timeframe. The adoption of the revised guidance document at the Plenary meeting of 21-22 May 2008 has therefore been proposed as a new deadline.

With regard to the request from the Commission (DG ENV) for establishing guidelines in the area of environmental risk assessment (see item 9 of the minutes of the 39th plenary meeting), the working group on environmental risk assessment of the GMO Panel has discussed at its latest working group meeting a mandate with representatives of DG ENV. The EFSA guidance document with regard to the environmental risk assessment will be updated within a timeframe of 24 months, along the work of the self tasking activity for assessing the impacts of GM plants on non-target organisms.

8.2. Statistical considerations in the safety evaluation of GMOs

The next working group meeting is scheduled for 28th April 2008.

8.3. Allergenicity assessment of GM foods

The next working group meeting will take place on 7th April 2008, linked to a visit to the Joint Research Centre (JRC) of the European Commission on the 8th April 2008 to be informed about the GMO DNA sequence database integrated with bioinformatics tools for similarity searches (see item 9 of the minutes of the 39th plenary meeting) within the frame of the allergenicity assessment of GMO applications.

8.4. Guidance for the assessment of GM plants used for non-food/feed purposes

Comments were received from the European Commission and the European Medicines Agency (EMEA) on the draft opinion on 'the risk assessment of GM plants used for non-food or non-feed purposes' as adopted by the Panel at its 37th Plenary meeting of 22-23 November 2007 (see item 5.1 of the minutes of the 37th Plenary meeting). These comments will be considered before the report will be published on the EFSA website for public consultation.

8.5. Animal feeding trials

The report on the "Safety and nutritional assessment of GM plants and derived food and feed: The role of animal feeding trials" of the self tasking working group on animal feeding trials, and which was adopted by the Panel on 12 September 2007, has been published in Food and Chemical Toxicology 46 (2008) S1 – S70, and is accessible from the EFSA website at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178660555237.htm.

9. FEEDBACK FROM EFSA AND THE SCIENTIFIC COMMITTEE

The Panel was informed about the possibilities of Audio/Web and Telephone conferencing (Live Meeting), hosted by EFSA, which allows experts to participate in virtual meetings from their office, and at the same time allowing them to share and work on the same documents.

10. FEEDBACK FROM THE COMMISSION

A meeting of the OECD Task Force for the Safety of Novel Foods and Feeds is scheduled for 8-10 April 2008, for which the Commission has asked EFSA for assistance. Gijs Kleter will present the EFSA GMO activities as GMO Panel member on behalf of EFSA.

The Commission representative provided the Panel with the status of applications that have been presented to the Standing Committee on the Food Chain and Animal Health for possible authorisation, and for which no qualified majority was reached.

11. DATES OF FUTURE MEETINGS

Meeting dates were agreed at earlier plenary meetings.

12. ANY OTHER BUSINESS

No other business was discussed.