

# **European Food Safety Authority**

# DECISION CONCERNING THE ESTABLISHMENT AND OPERATIONS OF THE SCIENTIFIC COMMITTEE AND PANELS

Having regard to Regulation N° 178/2002/EC¹ (hereinafter referred to as 'the Regulation') of the European Parliament and the Council of 28<sup>th</sup> 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,

Whereas, in order not to delay the launch of the call for expression of interests, the Management Board has agreed on the general orientations on the establishment and operations of the Scientific Committee and Scientific Panels, on the understanding that details of the call and the procedure be developed in close consultation with the Board's appointee for the post of Executive Director.

- In order to ensure the start of the European Food Safety Authority, hereinafter referred to as 'the Authority', and, in particular, the process to establish the Scientific Committee and Panels, in line with the requirements of the Regulation, and in particular Article 28-9, 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. These procedures shall relate in particular to:
  - (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;
  - (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;
- Article 29-7 requiring that the Authority's internal rules shall specify requirements in regard to format, explanatory background and publication of a scientific opinion.

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

<sup>&</sup>lt;sup>1</sup> Official Journal L 31, 1. 2. 2002, p1

## **Article 1: Confidentiality**

- 1. Members of Scientific Committee or Panels as well as experts shall not divulge to third parties information specifically identified by the Authority as "restricted or confidential".
- 2. Members of the Scientific Committee or Panels shall sign a written declaration that they will comply with the rules of confidentiality set out in paragraph 1. (Annex 1)
- 3. Members of the Scientific Committee or Panels as well as 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 2: Independence**

Members of the Scientific Committee and Panels shall undertake to act independently of any external influence. For this purpose, they shall make a declaration of commitment (Annex 2) and a declaration of interests (Annex 3). The declaration of interests shall indicate any direct or indirect interests which may be considered prejudicial to their independence or the absence of any such interests.

These declarations shall be made annually in writing and shall be published on the Authority's web page.

- 1. Members and external experts participating in 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. This declaration shall be made in writing or verbally, following a request of the chair. The extent of the member's participation in the work of the Committee shall be laid down by the Chair in agreement with the respective Members and shall be recorded.
- 2. Any Member or external expert who, in accordance with his/her declaration or in the opinion of the Scientific Committee, Scientific Panel or the Working Group is not able to act independently, may not act as Rapporteur or as Chair in relation to the specific matter and may not participate in decision-making.
- 3. Members or external experts who receive documents or pertinent information of relevance to their work for the Scientific Committee or Panels directly from a third party shall ensure that the information is made available to the Secretariat.

#### **Article 3: Delegation of responsibilities**

- 1. The Members of the Scientific Committee and Scientific Panels are nominated 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 function, he may be replaced by one of the vice-Chairs or, failing that, in common accord of the Members.

# Article 4: Appointment of Members of the Scientific Committee and Panels and their Terms of Office

- 1. Members of the Scientific Committee or Panels shall be appointed by the Management Board, acting upon a proposal from the Executive Director, following publication in the OJEC, in relevant leading scientific publications and on the Authority's web site 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.
- 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 Panels, and, consistent with this, a geographical distribution that reflects the diversity of scientific problems and approaches in the EU.
- 3. Members of the Scientific Committee and of the Panels shall be appointed for a three-year term of office that may be renewable twice.
- 4. Members who have just completed three consecutive terms of office in the Scientific Committee shall be eligible for membership of a Panel. Likewise, Members who have just completed three consecutive terms of office in a Panel shall be eligible for membership of the Scientific Committee or a different Panel.

### Article 5: Members who do not contribute effectively to the work

When it is found that a Member does not contribute effectively to the work of the Scientific Committee or Panel or wishes to resign, the Management Board, acting on a proposal of the Executive Director, may appoint a replacement from the reserve list mentioned in paragraph 1, Article 4.

#### **Article 6: Number of Members in the Panels**

- 1. The number of Members of a 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 7: Election of the Chairs and vice-Chairs of the Scientific Committee and Scientific Panels

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.

#### 1. Election of the Chair

The Chair shall be elected by secret ballot. Subject to a unanimous decision by the Scientific Committee or Panel, the secrecy requirement for the ballot may be waived. The Executive Director or his 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.
- 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/she receives the majority of votes cast.
- c) Where there are several candidates, election shall take place in accordance with the following procedure. However, if there are only two candidates, the first ballot will not be held.
- In the first ballot, the candidate who receives at least a two-thirds majority of the votes of all members is elected.
- If none of the candidates receive a two-thirds majority of the votes of all Members, the two candidates who obtained the highest number of votes go forward to the second ballot. When it is not possible to determine who are the two candidates with the highest number of votes due to equality, there shall be a special ballot in order to obtain the two candidates for the next round.
- In the second ballot, the candidate who receives at least a two-thirds majority of the votes of all Members is elected. If none of the candidates receive a two-thirds majority of the votes of all members, there will be a third round.
- In the third round, the candidate who receives at least a two-thirds majority of the votes of all members is elected. If none of the candidates receive a two-thirds majority of the votes of all Members, the candidate who receives the majority of the votes of all members is elected.
- If the two candidates receive an equal number of votes after the third ballot, the name of the successful candidate will be drawn by lot.
- d) Candidates may withdraw their candidature at any time during the procedure.

#### 2. Election of Vice-Chairs

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.

## **Article 8: Working Groups and external experts**

- 1. The Scientific Committee and Panels may create Working Groups whenever they deem it necessary for reasons related to the need for external expertise or their capacity to fulfil their mandates. Creation of Working Groups shall be consistent with the Authority's work programme.
- 2. The Scientific Committee and Panels shall entrust the Working Groups with tasks which are clearly defined. In particular, the Working Group may be asked to undertake all necessary preparatory tasks in relation to a draft opinion. The Scientific Committee or Panel can require that these tasks be completed within a set period.
- 3. Working Groups shall report to the Scientific Committee or Panel that convened them and shall be chaired by a member of the corresponding Scientific Committee or Panel.
- 4. External experts possessing particular and relevant scientific knowledge may be invited to contribute to the work of the Scientific Committee or the Working Group.
- 5. The Members and external experts of a Working Group shall be designated by its Chair in consultation with the Scientific Committee or corresponding Panel. They shall be invited by the Secretariat. If an expert is invited but is not available, the Secretariat may, in agreement with the Chair, invite another suitable expert.
- 6. External experts are subject to the rules covering independence and confidentiality. In particular, they shall be required to make declaration of interest in relation to specific matters on the agenda at each meeting.
- 7. The names of participants of Working Groups shall be made public.
- 8. External experts contacted by third parties in connection with their participation in a Working Group may refer the third party to the Secretariat.

# Article 9: Planning of meetings, invitations, agenda, documentation, time limits

- 1. The Scientific Committee and Panels shall establish a schedule of its meetings for the forthcoming calendar year.
- 2. As a general rule, the Secretariat will confirm a meeting of the Scientific Committee, Panels or Working Group 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, Panel or Working Group 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 Panels shall be drawn up by the Secretariat. The draft agenda shall be circulated to Members, generally within two weeks of the meeting. They shall be published on the Authority's web site 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 external expert shall be available to the Members and external experts one week before that meeting.
- 6. Where Community legislation does not already specify a time-limit for the delivery of a scientific opinion, the Authority shall issue scientific opinions within the time-limit specified in the requests for opinions, except in duly justified circumstances. The Scientific Committee and Panels shall prioritise their work to ensure that time limits are respected.

#### Article 10: Quorum and majority

A quorum of at least two thirds of the Members of the Scientific Committee or of a Panel shall have to be physically present in order for the meeting to be valid.

The Scientific Committee and Panels shall adopt opinions by a majority of their members.

#### **Article 11: Accelerated Procedure**

In urgent cases and if requested by the Secretariat and sanctioned by the Chair of the Scientific Committee or Panel, an accelerated procedure may be applied as follows:

1. The Secretariat shall, and whenever possible in collaboration with the Chair of the Scientific Committee or Panel, determine whether the Authority's personnel, a Working Group or Rapporteur shall prepare a draft opinion for submission to the Secretariat within a specified period.

- 2. If the Chair and Secretariat determine that the nature and urgency of the question requires an emergency meeting, the Secretariat shall endeavour to organise a meeting at short notice. The Secretariat shall place the draft opinion on the agenda of the next meeting of the Scientific Committee or Panel.
- 3. In the event that the nature, urgency and circumstances do not necessitate or allow discussion at a meeting, a draft opinion may be adopted by written procedure. In this case, the Secretariat shall send the draft opinion to the Members of the Scientific Committee or 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 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 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.

#### Article 12: Risk-related issues raised by the Scientific Committee or Panels

The Scientific Committee or a 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 Panel.

The Authority 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 Secretariat shall inform the Scientific Committee and the Panel of the Authority's decision.

#### Article 13: Co-ordination of the work of the Scientific Panels

- 1. The Scientific Secretariat shall seek to ensure:
- that the Panels work in close co-operation with each other and the Scientific Committee where this is necessary,
- the avoidance of overlapping or inconsistent opinions.
- 2. The Chairs of the Panels shall keep the Scientific Committee informed of their activities through regular reports at meetings of the Scientific Committee.
- 3. The Scientific Committee shall assure consistency in the approach to risk assessment and the presentation of scientific opinions.

## **Article 14: Rapporteurs**

- 1. The Scientific Committee, a Panel or Working Group may designate one or more Rapporteurs from among its Members or external experts who shall ensure that draft reports or opinions are prepared, if necessary within a set time period. The Rapporteur(s) shall work in close co-operation with the Secretariat.
- 2. The work of a Rapporteur is terminated when the Scientific Committee or Panel adopts the report or opinion.

# Article 15: 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. With the exception of minority opinions referred to in Article 19, individual views, whether expressed orally or in writing by Members or external experts during deliberations within the Scientific Committee, Panels or a Working Group shall be confidential.
- 3. Rules relating to public access to the meetings of the Scientific Committee and Panels will be established in separate internal rules of the Authority.

#### **Article 16: Technical Hearings**

The Scientific Committee, a Panel or Working Group may organise scientific hearings with individuals, petitioners of other stakeholder representatives if it considers it necessary for the completion of a scientific opinion.

- 1. Hearings shall be indicated clearly in the draft agenda of the meeting during which it is to take place.
- 2. The Scientific Committee, Panel or Working Group shall not take any decisions during hearings.

## **Article 17: Adoption of scientific opinions**

- 1. The Scientific Committee and individual Panels shall adopt their scientific opinions at their plenary meetings or, exceptionally, by the written procedure set out in Article 11, Paragraph 3.
- 2. The Scientific Committee or a Panel may adopt a preliminary opinion which will be published on the Authority's Web site with an invitation to provide scientific comment before a specified deadline. The Scientific Committee or Panel will take account of the comments received when adopting its final opinion.

## **Article 18: Requests for Scientific opinions**

1. The Executive Director shall assign requests for scientific opinion to either:

One of the Scientific Panels in accordance with their mandate as set out below;

- the Panel on food additives, flavourings, processing aids and materials in contact with food: safety in use of food additives, flavourings, processing aids and materials in contact with food; associated subjects concerning the safety of other deliberately added substances to food and questions related to the safety of processes.
- 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 health, plant protection products and their residues: safety of plant protection products for the user/worker, the consumer of treated products and the environment and plant health.
- for the Panel on genetically modified organisms: genetically modified organisms as defined in Directive 2001/18/EC, such as micro-organisms, plants and animals, relating to deliberate release into the environment and genetically modified food and feed including their derived products.
- 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 Panel.
- for the Panel on animal health and welfare: all aspects of animal health and animal welfare, primarily relating to food producing animals including fish.

<u>Or</u>, to the Scientific Committee for questions on multi-sectorial issues falling within the competence of more than one Panel, and on issues which do not fall within the competence of any of the Panels.

- 2. Requests for scientific opinions shall be presented by the Secretariat. They will consist of the question, the scientific background and the Community interest. Where necessary they shall specify the deadline for response.
- 3. The Scientific Committee or Panel may ask the Secretariat to clarify a question and/or to supply additional information.
- 4. A scientific opinion shall comprise the question posed by the Commission, the Parliament, a Member State or the Authority itself, the background to the request, the information considered, the scientific reasoning and the opinion of the Scientific Committee or Panel.
- 5. The full scientific opinion shall be published without delay on the Authority's Web site.

### **Article 19: Minority Opinions**

The opinions of the Scientific Committee and Panels within the meaning of Article 29 of the Regulation, shall include any minority opinions. Minority opinions shall be attributed to their authors and shall include supporting argumentation.

#### **Article 20: Minutes**

- 1. The Secretariat of the Scientific Committee and Panels shall prepare draft minutes of plenary meetings. These shall contain, inter alia:
  - the list of participants,
  - declaration of interests by participants concerning their independence and the action taken
  - a summary of discussions, including important minority stand points and agreed actions,
  - a record of decisions taken and opinions adopted.
- 2. The draft minutes shall be circulated to Members for comments and adopted not later than the next meeting.
- 3. The minutes shall be made placed on the Authority's Web site after their adoption.

## Article 21: Mission expenses of Members, external experts and indemnities

1. Travel and subsistence expenses incurred by Members or external experts in connection with meetings relating to the Scientific Committee or Panel shall be reimbursed by the Authority in accordance with the scales laid down by the Staff Regulations of Officials of the European Communities for officials in grades A4 to B.

- 2. Members and external experts shall be entitled to an indemnity of 300 € 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 Panel.
- 3. Rapporteurs shall be entitled to an indemnity of 600 € to defray costs linked to the co-ordination of preparatory work for draft opinions.

## Article 22: Secretariat of the Scientific Committee and the Panels

The Scientific Secretariat shall be responsible for providing support necessary to facilitate the efficient functioning of the Scientific Committee and Panels and compliance with the rules of the Authority, particularly in relation to the requirements for excellence, independence and transparency and with any rules established by the Scientific Committee or Panels. Specific duties include:

- Ensuring best use of the Authority's resources and the planning to meet priorities and time-limits;
- Providing information on the legislative/policy aspects of questions;
- Preparing the work of the Committee and Panels and their respective Working Groups, in consultation with their chairs;
- Drafting agendas and minutes of meetings;
- Co-ordinating the work carried out within and between the Scientific Committee or Panels and their respective Working Groups;
- Ensuring that the relevant background information is made available to the Scientific Committee, Panel or Working Group;
- Assisting the Chairs of the Scientific Committee, the Panels and their Working Groups in the preparation of draft opinions before adoption.

#### **Article 23: Entry into force**

- 1. The present Decision shall enter into force on the date of its adoption.
- 2. The Management Board may return to these rules whenever deemed necessary and adopt any modifications needed.

Done at Brussels, 6 November 2002

Dr Stuart Slorach The Chair

# ANNEX 1: DECLARATION CONCERNING CONFIDENTIALITY

| Name:  |                                     |  |
|--|-------------------------------------|--|
| Position :   | [ ]<br>[ ]<br>[ ]                   | Member of the Scientific Committee  Member of a Panel on :   |
| that I am of<br>the [<br>confidential<br>by Member | oliged no<br>ity. I sha<br>s of the | I am aware of my obligation to respect confidentiality. I know of to divulge information acquired as a result of my position on] if this information is subject to a request for all also respect the confidential nature of the opinions expressed [] or the external experts during discussions ded in written form. |
| Done at  |                                     | on   |
| Signature:   |                                     |  |

# **ANNEX 2: COMMITMENT OF INDEPENDENCE**

| Name:                                    |                       |   |
|--|-----------------------|---|
| Position :                               | []<br>[]<br>[]        | Member of the SC Member of a Panel on : Member of a Working Group   |
| know that I declare at eat their Working | am oblach meeing Grou | to act independently of any external influence. In particular liged to make an annual written declaration of interests and to tring of the Scientific Committee or the Scientific Panels or of aps any interest which might be considered prejudicial to my ation to the items on the agenda. |
| Done at _                                |                       | on  |

# **ANNEX 3: ANNUAL DECLARATION OF MEMBER'S INTERESTS**

| Name:                              |   |
|------------------------------------|---|
| Position :                         | <ul><li>[ ] Member of the SC</li><li>[ ] Member of a Panel on :</li><li>[ ] Member of a Working Group</li></ul> |
| Information on                     | direct or indirect interests of relevance to the mission of the Authority                                       |
|                                    | erest (financial benefits arising from, for example, employment, contracted estments, fees etc.):               |
|                                    |   |
|                                    |   |
| (2) In direct into                 | marks (indicate financial a compute an angular an athentical of homefits).                                      |
| (2) indirect inte                  | erests (indirect financial, e.g. grants, sponsorships, or other kind of benefits):                              |
|                                    |   |
|                                    |   |
| (3) Interests der<br>family Member | riving from the professional activities of the applicant or his/her close rs:                                   |
|                                    |   |
|                                    |   |
|                                    |   |
|                                    | ership role or affiliation that you have in organisations/bodies/club with an work of the Authority:            |
|                                    |   |
|                                    |   |
|                                    |   |
| (5) Other interes                  | ests or facts that the undersigned considers pertinent:   |
|                                    |   |
|                                    |   |
| Declaration:                       |   |
|                                    | word of honour that the information provided above is true and complete.  |
| Done at                            | on  |
| Signature:                         |   |