**This document is meant purely as a documentation tool and the institutions do not assume any liability for its contents**

►**B**

# COMMISSION DECISION

**of 3 March 2004**

**setting up Scientific Committees in the field of consumer safety, public health and the environment**

**(Text with EEA relevance)**

(2004/210/EC)

(OJ L 66, 4.3.2004, p. 45)

Amended by:

| | | Official Journal | | |
|---|---|---|---|---|
| | | No | page | date |
| ►**M1** | Commission Decision 2007/263/EC of 23 April 2007 | L 114 | 14 | 1.5.2007 |

▼B

# COMMISSION DECISION

## of 3 March 2004

## setting up Scientific Committees in the field of consumer safety, public health and the environment

**(Text with EEA relevance)**

(2004/210/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Articles 152 and 153 thereof,

Whereas:

(1) The Scientific Committees were established by Commission Decision 97/404/EC of 10 June 1997 setting up a Scientific Steering Committee ([1]) and by Commission Decision 97/579/EC of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety ([2]).

(2) The responsibilities of the Scientific Steering Committee (SSC) in relation to scientific advice on bovine spongiform encephalophathy and transmissible spongiform encephalopathies have been transferred to the European Food Safety Authority (EFSA) established by 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 the procedures in matters of food safety ([3]).

(3) Also the responsibilities of five of the eight Scientific Committees established by Decision 97/579/EC have been transferred to EFSA namely the responsibilities of the Scientific Committee on Food, the Scientific Committee on Animal Nutrition, the Scientific Committee on Animal Health and Animal Welfare the Scientific Committee on Veterinary Measures relating to Public Health, and of the Scientific Committee on Plants.

(4) The terms of office of the members of the remaining three Scientific Committees established by Commission Decision 97/579/EC, namely the Scientific Committees on Cosmetic Products and Non-food Products intended for Consumers, the Scientific Committee on Medicinal Products and Medical Devices and the Scientific Committee on Toxicity, Ecotoxicity and the Environment have come to an end. Members of those committees remain in office until they are replaced or their appointments are renewed.

(5) It is therefore necessary to replace Decision 97/404/EC and Decision 97/579/EC and to repeal these acts.

(6) Sound and timely scientific advice is an essential requirement for Commission proposals, decisions and policy relating to consumer safety, public health and the environment.

(7) The advice of the Scientific Committees on matters relating to consumer safety, public health and the environment must be based on the principles of excellence, independence and impartiality, and transparency, as developed in the Commission Communication on ‘The collection and use of expertise by the

([1]) OJ L 169, 27.6.1997, p. 85; Decision as amended by Decision 2000/443/EC (OJ L 179, 18.7.2000, p. 13).
([2]) OJ L 237, 28.8.1997, p. 18; Decision as amended by Decision 2000/443/EC.
([3]) OJ L 31, 1.2.2002, p. 1; Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

▼B

Commission: principles and guidelines. Improving the knowledge for better policies' ([1]).

(8) It is essential that the Scientific Committees make best use of external expertise in the EU and beyond as may be necessary for a specific question.

(9) It is timely to reorganise the Scientific Committee advisory structure in the light of operational experience, the establishment of the EFSA and the Commission's future needs for independent scientific advice. Such a structure must provide the flexibility to allow it to advise the Commission on matters falling under established areas of competence as well as on emerging and newly identified health risks and matters not within the competence of other Community risk assessment bodies.

(10) The need for independent scientific advice both in established and new areas of Community responsibilities falling within the competence of the Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers and the Scientific Committee on Toxicity, Ecotoxicity and the Environment is likely to continue to increase.

(11) The number of requests for scientific advice from the Scientific Committee on Medicinal Products and Medical Devices are too few to justify its continuation as a separate Committee. However, in view of the potential importance of this area and in particular of medical devices, it is necessary to retain the capacity to provide scientific advice through an appropriate Scientific Committee.

(12) In order to strengthen their scientific coherence, synergisms and a multi-disciplinary approach and at the same time minimise overlapping responsibility, it is necessary to redefine the fields of competence of the Scientific Committees and to ensure systematic and structured coordination.

(13) It is important that the Commission can take a proactive approach to the early assessment of emerging and other newly identified risks,

HAS DECIDED AS FOLLOWS:

*Article 1*

**Scientific Committee advisory structure and fields of competence**

1. The following Scientific Committees are hereby established:

(a) the Scientific Committee on Consumer Products (hereinafter SCCP);

(b) the Scientific Committee on Health and Environmental Risks (hereinafter SCHER);

(c) the Scientific Committee on Emerging and Newly Identified Health Risks (hereinafter SCENIHR).

2. The fields of competence of the Scientific Committees shall be as set out in Annex I, without prejudice to the competence conferred by Community legislation to other Community bodies undertaking risk assessment, such as the European Food Safety Authority and the European Agency for the Evaluation of Medicinal Products.

([1]) COM (2002) 713 final of 11 December 2002 on 'The collection and use of expertise by the Commission: principles and guidelines. Improving the knowledge for better policies'.

▼B

*Article 2*

**Mission**

1. The Commission shall request a scientific opinion from the Scientific Committees in the cases laid down by Community law. The Commission may also request an opinion from the Committees on questions:

(a) of particular relevance to consumer safety, public health and the environment; and

(b) not falling within the mandate of other Community bodies.

2. Requests for a scientific opinion on questions which do not fall within the fields of competence of a single scientific committee or which need to be considered by more than one Committee, shall be addressed in accordance with the rules of procedures set out in Article 10(2)(c). The same shall apply to needs for clarification of requests for scientific opinions in accordance with the rules of procedure set out in Article 10(2)(b).

3. The Commission may require the adoption of a scientific opinion from a Scientific Committee within a specified period.

4. The Scientific Committees shall draw the Commission's attention to a specific or emerging problem falling within their remit, which they consider may pose an actual or potential risk to consumer safety, public health or the environment. The Commission shall determine the action to be taken including, if appropriate, a request for a scientific opinion on the matter.

5. Subject to paragraph 3, a Scientific Committee may require additional information from stakeholders for the completion of a scientific opinion.

A Scientific Committee may give a deadline for submitting the required information to it. If the required information has not been submitted within that deadline, the Committee may adopt its opinion on the basis of the available information.

*Article 3*

**Appointment of the members of the Scientific Committees and associated members**

1. The SCCP and the SCHER shall each consist of a maximum of 19 members. They shall be appointed on the basis of their expertise and consistent with this a geographical distribution that reflects the diversity of scientific problems and approaches in the Community. The Commission shall determine the number of members in each committee in accordance with the requisite needs.

2. ►M1 The SCENIHR shall consist of a maximum of 17 members. ◄ They shall be appointed on the basis of their broad expertise in the application of risk assessment and, consistent with this, a geographical distribution that reflects the diversity of scientific problems and approaches in the Community.

For any specific question, the SCENIHR may enlist the support of up to six associated members selected on the basis of their expertise. Associated members shall have the same rights to participate in the discussions and responsibilities as members.

3. The members of each Scientific Committee shall be scientific experts in one or more of the fields of competence of that Committee and shall collectively cover the widest possible range of disciplines.

4. The Commission shall appoint the members of the Scientific Committees from a list of suitable candidates established following

▼B

publication in the *Official Journal of the European Union* and on the Commission website of a call for expressions of interest.

5. No member of a Scientific Committee may be appointed to more than one of the Committees set out in Article 1(1).

*Article 4*

**Constitution of a reserve list**

1. Candidates found suitable for the position in a Scientific Committee but not appointed shall be invited to be included on a reserve list. The reserve list may be used by:

(a) the Commission to identify suitable candidates to replace members in accordance with Article 7(2);

(b) the SCENIHR to identify associated members having the required expertise for specific questions;

(c) the Scientific Committees to identify external experts in working groups.

2. Associated members shall be selected from the reserve list or from lists established by other Community bodies following open selection procedures designed to fulfil the requirements for excellence and independence.

*Article 5*

**Election of the Chairs and Vice-chairs**

1. Each Scientific Committee shall elect a Chair and two Vice-Chairs from among their members. The election shall take place by simple majority of the members which make up the Committee. The term of office of the Chair and Vice-Chair shall be three years, renewable.

2. The procedure for the election of the Chair and Vice-Chairs of the Scientific Committees shall be laid down in the rules of procedures.

*Article 6*

**Coordination of the Scientific Committees**

The Chairs shall assist the Commission on matters relating to the coordination of the three Scientific Committees in accordance with the rules of procedures referred to in Article 10(2)(d).

▼M1

*Article 7*

**Terms of office**

1. Members shall be appointed to the Scientific Committees for a term of three years, and may not serve for more than three consecutive terms. In order to safeguard the continuity of the expertise, the Commission may, in exceptional circumstances, prolong the terms of office of the members of a Scientific Committee for a period not exceeding 18 months.

Members shall remain in office until they are replaced or their appointments are renewed.

Members who have just completed three consecutive terms of office in a Scientific Committee shall be eligible for membership of another Scientific Committee.

2. When it is found that a member does not participate in the work of a Scientific Committee or wishes to resign, the Commission may terminate the member's membership and appoint a replacement either

▼M1

from the reverse list provided for in Article 4 or, for justified reasons, following a call for expressions of interest.

▼B

*Article 8*

**Working groups and participation of external experts**

1. In agreement with the Commission, the Scientific Committees may invite specialised external experts that they consider to have the relevant scientific knowledge and expertise to contribute to their work.

2. The Scientific Committees may create specific working groups with clearly defined tasks. These working groups shall be established in particular when there is a need for external expertise to fulfil the mandate of the Committee. In such cases, it shall draw on the expertise of those working groups when adopting scientific opinions.

3. The working groups shall be chaired by a member of the Scientific Committee that convened them and shall report to it.

4. When a question is common to more than one Scientific Committee, a common working group including members from the Committees, associated members concerned and external experts as necessary shall be set up.

*Article 9*

**Reimbursements and indemnities**

Members of the Scientific Committees, Associated Members and the external experts shall be entitled to an indemnity for their participation in the meetings of the Committees and for serving as Rapporteur on a specific question, as provided for in Annex II.

Reimbursement of travel and subsistence costs shall be paid by the Commission.

*Article 10*

**Rules of procedures**

1. The Scientific Committees shall adopt common rules of procedure in consultation with the Commission. The rules of procedure shall ensure that the Scientific Committees perform their tasks in compliance with the principles of excellence, independence and transparency, whilst having regard to legitimate requests for commercial confidentiality.

2. The rules of procedure shall cover in particular:

(a) the election of the Chair and Vice-Chairs of the Scientific Committee;

(b) the procedures for:

  (i) the coordination and allocation of questions,

  (ii) the adoption of opinions under normal conditions, and

  (iii) the adoption of opinions under an accelerated, written procedure if the urgency of the matter requires such a procedure;

(c) the designation of the Scientific Committee responsible for dealing with questions common to more than one Scientific Committee;

(d) the procedures for ensuring coordination between the Scientific Committees including matters relating to harmonisation of risk assessment;

(e) the creation and organisation of the working groups of the Scientific Committees;

▼B

(f) the involvement of external experts and, for the SCENIHR, of associated members;

(g) the appointment of Rapporteurs and the description of their tasks in relation to the preparation of draft opinions for the Scientific Committees;

(h) the format and content of scientific opinions and procedures for ensuring and improving their coherence;

(i) procedures for identifying, resolving or clarifying diverging opinions with Community and international bodies carrying out similar tasks, including information exchange and the organisation of joint meetings;

(j) the organisation of hearings with industry or other special interest groups;

(k) the responsibilities and obligations of members, associated members and external experts in relation to their contacts with petitioners, special interest groups and other stakeholders;

(l) representation of a Scientific Committee in external activities, notably in relation to other Community or international bodies engaged in overlapping activities.

*Article 11*

**Voting rules**

Each Scientific Committees shall act by a majority of its members.

*Article 12*

**Adoption of scientific opinions**

The Scientific Committees shall adopt their opinions by a majority of the Members which make up the Committee.

*Article 13*

**Diverging opinions**

1. The Scientific Committees shall assist the Commission in identifying at an early stage potential or actual divergence between their scientific opinions and the scientific opinions of Community and International bodies carrying out similar tasks. They shall assist the Commission in avoiding, resolving or clarifying divergent opinions.

2. Where a substantive divergence over scientific issues has been identified and the body in question is a Community body, the Scientific Committee concerned shall, on the request of the Commission, cooperate with the body concerned with a view to either resolving the divergence or presenting a joint document to the Commission clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

*Article 14*

**Independence**

1. The Members of the Scientific Committees and associated members shall be nominated in a personal capacity. They shall not delegate their responsibilities to another member or to a third person.

2. Members of the Scientific Committees and associated members shall undertake to act independently of any external influence.

For that purpose they shall make a declaration of commitment to act in the public interest and a declaration of interests indicating either the

▼B

absence or existence of any interest which might be considered prejudicial to their independence.

These declarations shall be made in writing and be publicly available. Members of the Scientific Committees shall make annual declarations.

3. Members of the Scientific Committees, associated members and the external experts participating in working groups shall declare at each meeting any specific interest which might be considered as prejudicial to their independence in relation to the items on the agenda.

*Article 15*

**Transparency**

1. Request for opinions, agendas, minutes and opinions of the Scientific Committees shall be published without undue delay and with regard to the need for commercial confidentiality.

2. Minority opinions shall always be included in the opinions of the Scientific Committees and shall be attributed to the members or associated members concerned.

3. The rules of procedures shall be published on the Commission's website.

4. The names of the members of the Scientific Committees shall be published in the *Official Journal of the European Union*. They shall also be made available on the Commission's website together with a brief Curriculum vitae of each member.

The names of participants in the working groups shall be given with the opinion to which they have contributed.

5. The reserve list resulting from the call for expressions of interest shall be published in the *Official Journal of the European Union*. It shall also be made available on the Commission's website.

*Article 16*

**Confidentiality**

The members of the Scientific Committees, associated members and external experts shall not divulge information acquired as a result of the work of the Scientific Committees, or one of the working groups, when they are informed that it is confidential.

*Article 17*

**Secretariat of the Commission's Scientific Committees**

1. The Scientific Committees and their working groups shall be convened by the Commission.

2. The Commission shall provide the scientific and administrative secretariat of the Scientific Committees and their working groups.

3. The secretariat shall be responsible for providing scientific and administrative support necessary to facilitate the efficient functioning of the Scientific Committees in compliance with the rules of procedure, particularly in relation to the requirements for excellence, independence and transparency.

4. The secretariat shall ensure the scientific and technical coordination of the activities of the Scientific Committees and where necessary coordination of their activities with those of other Community and international bodies.

▼B

*Article 18*

**Replacement of the Scientific Committees**

The Scientific Committees established by Article 1(1) of this Decision shall replace the existing Scientific Committees established by Decision 97/579/EC as follows:

(a) the Scientific Committee on Consumer Products shall replace the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers;

(b) the Scientific Committee on the Health and Environmental Risks shall replace the Scientific Committee on Toxicity, Ecotoxicity and the Environment;

(c) the Scientific Committee on Emerging and Newly Identified Health Risks shall replace the Scientific Committee on Medicinal Products and Medical Devices.

*Article 19*

**Repeals**

1. Decisions 97/404/EC and 97/579/EC are repealed.

However, the three Committees established by those decisions shall remain in office until the Scientific Committees established by this Decision take office.

2. References to the repealed decisions shall be understood as applicable to this Decision; references to the Committees and sections established by the repealed decisions shall be understood as applicable to the Committees established by this Decision.

▼B

*ANNEX I*

**FIELD OF COMPETENCE**

1. **Scientific Committee on Consumer Products**

   It shall provide opinions on questions concerning the safety of consumer products (non-food products intended for the consumer). In particular, it shall address questions in relation to the safety and allergenic properties of cosmetic products and ingredients with respect to their impact on consumer health, toys, textiles, clothing, personal care products, domestic products such as detergents and consumer services such as tattooing.

2. **Scientific Committee on Health and Environmental Risks**

   It shall provide opinions on questions relating to examinations of the toxicity and ecotoxicity of chemical, biochemical and biological compounds whose use may have a harmful consequences for human health and the environment. In particular, it shall address questions in relation to new and existing chemicals, the restriction and marketing of dangerous substances, biocides, waste, environmental contaminants, plastic and other materials used for water pipework (e.g. new organics substances), drinking water, indoor and ambient air quality.

   It shall address questions relating to human exposure to mixtures of chemicals, sensitisation and identification of endocrine disrupters.

3. **The Scientific Committee on Emerging and Newly Identified Health Risks**

   It shall provide opinions on questions concerning emerging or newly identified risks and on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Community risk assessment bodies.

   Examples of potential areas of activity include potential risks associated with interaction of risk factors, synergic effects, cumulative effects, antimicrobial resistance, new technologies such as nanotechnologies, medical devices including those incorporating substances of animal and/or human origin, tissue engineering, blood products, fertility reduction, cancer of endocrine organs, physical hazards such as noise and electromagnetic fields (from mobile phones, transmitters and electronically controlled home environments), and methodologies for assessing new risks.

▼B

*ANNEX II*

**INDEMNITIES**

Members of the Scientific Committees, Associated Members and the external experts shall be entitled to indemnities related to their participation in the activities of the scientific committees as follows:

For participation at meetings:

— EUR 300 for each full day participation or EUR 150 for participation in a morning or afternoon meeting of a Scientific Committee, a working group or at an external meeting attended in connection with the work of a Scientific Committee.

For acting as Rapporteur for a question requiring not less than one day of preparation of a draft opinion and with the prior written agreement of the Commission:

— EUR 300.

— Where fully justified and subject to budget availability, this sum may be exceptionally increased to EUR 600 for questions which are particularly demanding in terms of work load.

For particularly complex questions of a multidisciplinary nature, more than one Rapporteur may be appointed.