II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

DECISIONS

COMMISSION

COMMISSION DECISION

of 5 August 2008

setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC

(Text with EEA relevance)

(2008/721/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) Three Scientific Committees were established by Commission Decision 2004/210/EC (1), as amended by Commission Decision 2007/263/EC (2): the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER), the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).

(2) Certain tasks of the SCHER have been transferred to the European Chemical Agency (ECHA) established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council (3), and therefore the fields of competence of that Committee should be revised.

(3) The experience with the functioning of the three Scientific Committees shows the need to introduce modifications and improvements in the structure and working procedures of the Committees.

(4) The terms of office of the members of three Scientific Committees established by Commission Decision 2004/210/EC was prolonged by Commission Decision 2007/708/EC (4) and come to an end on 31 December 2008. Members of those committees remain in office until they are replaced or their appointments are renewed.

(5) Therefore, and for the sake of clarity, it is necessary to replace Decision 2004/210/EC with a new Decision.

(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. A flexible advisory structure is necessary in that respect, in order to ensure easier access to highly qualified scientific expertise in a wide range of fields.

(7) The scientific advice 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 Commission: principles and guidelines. Improving the knowledge for better policies (5), and it must be organised in conformity with best practice principles of risk assessment.

It is essential that the Scientific Committees make best use of scientific expertise in the EU and beyond as may be necessary for a specific question. To that aim a pool of Scientific Advisors should be established adequately covering the fields of competence of the Committees.

The reorganisation of the advisory structure must provide increased 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, and must be able to provide rapid advice when needed, ensure full transparency and a high level of consistency and collaboration with other Community bodies and relevant scientific organisations.

The need for independent scientific advice both in established and new areas of Community responsibilities falling within the competence of the Scientific Committees is likely to continue to increase. The scientific advice structure on risk assessment needs therefore to be reinforced, in its composition as well as by more effective working practices.

Various Community bodies have been established which have among their tasks the assessment of risks in various domains. It is necessary to ensure consistency and promote coordination between the Scientific Committees and such bodies. The Scientific Committees need to reinforce their effectiveness also by appropriate exchanges of information and expertise and through collaboration with other scientific bodies and organisation at national and international level.

The working practices of the Scientific Committees should be improved by including, in addition to the internal work, the organisation of scientific meetings and workshops and the establishment of networks.

While preserving full independence, it is important to ensure openness and transparency of the work of the Scientific Committees by establishing appropriate stakeholder dialogue procedures.

The openness and transparency sought in the implementation of this Decision should be ensured while fully respecting the requirements laid down in the Community legislation with regard to the protection of personal data and to the access of the public to documents, including the protection of commercial confidentiality.

HAS DECIDED AS FOLLOWS:

CHAPTER 1
GENERAL PROVISIONS

Article 1
The advisory structure and its fields of competence

1. An advisory structure on scientific risk assessment in the areas of consumer safety, public health and the environment is hereby established. This structure includes:

(a) the Scientific Committee on Consumer Safety (hereinafter SCCS);

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

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

(d) a Pool of Scientific Advisors on Risk Assessment (hereinafter the Pool), which will support the activities of the Scientific Committees in accordance with the relevant provisions of this Decision.

2. The fields of competence of the advisory structure shall be as set out in Annex I, without prejudice to the competencies conferred by Community legislation to other Community bodies undertaking risk assessment, such as, in particular, the European Food Safety Authority, the European Medicines Agency, the European Chemical Agency and the European Centre for Disease Control.

Article 2
Mission

1. The Commission shall request a scientific opinion from the Scientific Committees in the cases laid down by Community law.

2. 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.

3. The Commission may also request the Scientific Committees to provide rapid advice on the state of scientific knowledge concerning specific risks in case of urgent needs.
4. The Commission may invite a Scientific Committee to identify research needs and assess research results in relation to the subject areas covered by its fields of competence.

5. At the request of the Commission, or acting on their own initiative and in agreement with the Commission, the Scientific Committees may decide to set up thematic workshops in order to review data and scientific knowledge on particular risks or on broad risk assessment issues. At the request of the Commission, they shall produce reports, position papers or conclusions resulting from these workshops.

These workshops may involve, in addition to members of the Committees, scientific advisors from the Pool and external experts, including experts from Community, national or international bodies carrying out similar tasks, as appropriate.

These workshops shall be organised by the Secretariat of the Scientific Committees. The Secretariat shall define and ensure, where appropriate, the dissemination of the reports, position papers or conclusions resulting from the workshops.

6. The Commission may invite the Scientific Committees to be part of thematic networks with other Community bodies or scientific organisations, in order to monitor and contribute to the development of scientific knowledge on risks in the fields of competence defined in Annex I.

7. 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, by adopting and addressing to the Commission memoranda or position statements. The Commission may decide to publish such memoranda and statements and shall determine the action to be taken including, if appropriate, a request for a scientific opinion on the matter.

CHAPTER 2
CONSTITUTION OF THE SCIENTIFIC COMMITTEES AND OF THE POOL

Article 3
Appointment of the members of the Scientific Committees

1. The SCCS, the SCHER and the SCENIHR shall each consist of a maximum of 17 members and may associate, at their own initiative, up to 5 scientific advisors from the Pool to contribute to the Committee work on specific issues or disciplines.

2. The members of the Scientific Committees shall be appointed by the Commission on the basis of their expertise and consistent with this a geographical distribution that reflects the diversity of scientific problems and approaches, notably in Europe. The Commission shall determine the number of members of each Committee in accordance with the requisite needs.

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

3. The Commission shall appoint the members of the Scientific Committees from a list of suitable candidates established following publication in the Official Journal of the European Union and on the Commission website of a call for expressions of interest.

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

Article 4
Establishment of the Pool

1. The Pool shall consist of scientific advisors who are experts in one or more of the fields of competence defined in Annex I or on related subjects, covering collectively the widest possible range of disciplines.

2. The Commission shall appoint scientific advisors to the Pool from a list of suitable candidates established following publication in the Official Journal of the European Union and on the Commission website of a call for expressions of interest.

3. The number of scientific advisors in the Pool at any time shall be decided by the Commission based on its needs for scientific advice.

Article 5
Terms of office

1. Members of the Scientific Committees shall be appointed for a term of three years, and may not serve for more than three consecutive terms in the same Committee. They shall remain in office until they are replaced or their appointments are renewed.

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 who have just completed three consecutive terms of office in a Scientific Committee shall be eligible for membership of another Scientific Committee.
2. When a member does not comply with the participation criteria which shall be laid down in the rules of procedures referred to in Article 12, or wishes to resign, the Commission may terminate the member’s membership and appoint a replacement from the Pool.

3. Scientific advisors shall be appointed to the Pool for a period of five years and their appointment may be renewed.

CHAPTER 3
FUNCTIONING OF THE ADVISORY STRUCTURE

Article 6
Resort to the support of the Pool

1. Each Scientific Committee may decide to associate up to five scientific advisors from the Pool to the preparation of a scientific opinion. These associated members shall participate in the activities and deliberations concerning the subject considered with the same functions, responsibilities and rights as the members of the Committee concerned.

2. In addition, each Scientific Committee may decide to invite other scientific advisors from the Pool to the preparation of a scientific opinion. Those advisors shall participate in the activities concerning the subject considered, but their functions and responsibility are restricted to the preparation of the opinion.

3. Scientific advisors from the Pool may also be invited by the Scientific Committees to assist them in the provision of a rapid advice requested by the Commission in accordance with Article 2(3), or to participate in thematic workshops referred to in Article 2(5).

4. Scientific advisors from the Pool may be invited by the Commission to participate in scientific meetings or to provide the Commission services with ad hoc information on specific issues.

Article 7
Working groups

1. The Scientific Committees may create specific working groups the task of which shall consist of preparing and drafting their scientific opinions. These working groups shall be established in particular when there is a need for external expertise on a particular subject.

2. In agreement with the Commission, the Scientific Committees may invite associated members, other scientific advisors from the Pool, specialised external experts, as well as experts from other Community bodies that they consider to have the relevant scientific knowledge and expertise, to contribute to their work.

3. The working groups shall be chaired by a member of the Scientific Committee that convenes them and shall report to it, and may appoint a Rapporteur from among their participants. For particularly complex questions of a multidisciplinary nature, more than one Rapporteur may be appointed.

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

Article 8
Participation of trainees

In agreement with the Commission and in accordance with the rules of procedure referred to in Article 12, the Scientific Committees may admit trainees to attend their meetings, with a view to contribute to capacity building in the area of risk assessment.

Article 9
Special requirements

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

2. The Commission may require the adoption of a joint 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. A joint opinion, following a request for an opinion from the Commission, may also be adopted by Scientific Committees at the initiative of the Inter-Committee Coordination Group referred to in Article 11.

3. The Commission may define in the request for a scientific opinion the consultations, hearings or collaboration with other scientific bodies it deems necessary for the preparation of this opinion. Consultations and hearings may also be decided by a Committee, in agreement with the Commission, if considered necessary for completing an opinion.

4. 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. In such a case, the Scientific Committee may decide to suspend its work on the scientific opinion in question. 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 10

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 of 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 referred to in Article 12.

Article 11

Coordination of the Scientific Committees

An Inter-Committee Coordination Group (ICCG) composed of the Chairs and Vice-Chairs of the Scientific Committees shall ensure the coordination of the three Scientific Committees in accordance with the rules of procedures referred to in Article 12.

Article 12

Rules of procedures

1. On proposal by and in agreement with the Commission, the Scientific Committees shall adopt common rules of procedures.

2. The rules of procedures 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 as well as to the risk assessment principles which may be established by the Commission in light of the experience and in view of its policy in this area.

3. The rules of procedures shall cover in particular the subjects listed in Annex II.

Article 13

Voting rules

1. The Scientific Committees shall adopt their opinions, rapid advice, memoranda and/or position statements by a majority of the total number of members of the Committee concerned combined with the number of associated members.

2. Each Scientific Committee shall act by a majority of its members on all other issues.

3. Those members of a Committee who have resigned or whose membership has been terminated in accordance with Article 5(2) shall not be taken into account for the calculation of the majority for the implementation of paragraphs 1 and 2.

Article 14

Diverging opinions, coordination and collaboration with other Community, national or international bodies

1. The Scientific Committees shall assist the Commission and contribute to identifying at an early stage:

(a) needs and possibilities for coordination of work and collaboration;

(b) potential or actual divergences in scientific opinions with other relevant Community, national or international bodies carrying out similar tasks, on general or specific risk assessment issues.

They shall assist the Commission in avoiding, resolving or clarifying divergent opinions and in establishing and maintaining collaboration relationships with such bodies.

2. The Commission may take the initiative to request and organise joint work of the Scientific Committees with Community, national or international bodies carrying out similar tasks. It may in particular request the Scientific Committees to produce joint opinions with other Community bodies, upon agreement with such bodies.

3. 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.

CHAPTER 4

PRINCIPLES

Article 15

Independence

1. The Members of the Scientific Committees, associated members, other scientific advisors of the Pool and the external experts shall be nominated in a personal capacity. They shall not delegate their responsibilities to any other person.

2. Members of the Scientific Committees and, scientific advisors of the Pool, and the external experts participating in working groups 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 absence or existence of any direct or indirect interest which might be considered prejudicial to their independence.
These declarations shall be made in writing. Members of the Scientific Committees and scientific advisors from the Pool shall make annual declarations.

3. Members of the Scientific Committees, associated members and other scientific advisors, 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 16

Transparency

1. The activities of the Scientific Committees shall be carried out with a high level of transparency. The Commission shall in particular make available to the public on its website, without undue delay:

(a) the request for opinions addressed to the Scientific Committees;

(b) agendas and minutes of the meetings of the Scientific Committees, Inter-Committee Coordination Group and working groups;

(c) the scientific opinions, and rapid advice adopted by the Scientific Committees, including the minority opinions and the names of the participants in the working groups that contributed to the opinion concerned; minority opinions shall be attributed to the members or advisors concerned;

(d) the common rules of procedures of the Scientific Committees;

(e) the names of the members of the Scientific Committees as well as of the scientific advisors from the Pool, together with a brief curriculum vitae of each member and advisor;

(f) the declarations of interests of the members of the Scientific Committees, of the scientific advisors from the Pool and of the external experts that participated in a working group.

2. The transparency rules referred to in paragraph 1 shall be applied in accordance with the requirements of Regulation (EC) No 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 (1), and of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (2), especially with regard to commercial confidentiality.

Article 17

Confidentiality

The members of the Scientific Committees, scientific advisors, external experts and trainees shall not divulge information acquired as a result of the work of the Scientific Committees, thematic workshops, working groups or other activities related to the application of this Decision, when they are informed that it is confidential.

CHAPTER 5

FINAL PROVISIONS

Article 18

Secretariat of the Commission’s Scientific Committees

1. The Scientific Committees and their working groups, the ICCG as well as other meetings, workshops or events related to the application of this Decision shall be convened by the Commission.

2. The Commission shall provide the scientific and administrative secretariat for the Scientific Committees and their working groups as well as for all other activities related to the application of this Decision.

3. The secretariat shall be responsible for providing scientific and administrative support necessary to facilitate the efficient functioning of the Scientific Committees, to monitor compliance with the rules of procedure, particularly in relation to the requirements for excellence, independence and transparency, to ensure communication on the Committees’ activities and the appropriate stakeholder dialogue, including in particular organisation of hearings on the activities of the Committees, and publication of the opinions and other public documents. Moreover, the secretariat shall provide support to the Committees and organise and apply quality control of the opinions, as provided for in the rules of procedure, as far as completeness, consistency, clarity, correspondence with requests and with editorial standards are concerned.

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, national and international bodies, as well as the application of the stakeholder dialogue procedure set up in the rules of procedure and the communication on the activities of the Committees.

Article 19

Reimbursements and indemnities

Members of the Scientific Committees, scientific advisors from the Pool and external experts shall be entitled to an indemnity for their participation in the meetings of the Committees, thematic workshops, working groups and other meetings and events organised by the Commission, and for serving as Rapporteur on a specific question, as provided for in Annex III.

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

Article 20

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 2004/210/EC as follows:

(a) the Scientific Committee on Consumer Safety shall replace the Scientific Committee on Consumer Products;

(b) the Scientific Committee on the Health and Environmental Risks shall replace the Committee of the same name;

(c) the Scientific Committee on Emerging and Newly Identified Health Risks shall replace the Scientific Committee of the same name.

Article 21

Repeals

1. Decision 2004/210/EC is repealed.

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

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

Done at Brussels, 5 August 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission
ANNEX I

FIELD OF COMPETENCE

1. Scientific Committee on Consumer Safety

It shall provide opinions on questions concerning all types of health and safety risks (notably chemical, biological, mechanical and other physical risks) of non-food consumer products (for example: cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products such as detergents, etc.) and services (for example: tattooing, artificial sun tanning, etc.).

2. Scientific Committee on Health and Environmental Risks

It shall provide opinions on health and environmental risks related to pollutants in the environmental media and other biological and physical factors or changing physical conditions which may have a negative impact on health and the environment, for example in relation to air quality, waters, waste and soils, as well as on life cycle environmental assessment. It shall also address health and safety issues related to the toxicity and eco-toxicity of biocides.

Without prejudice to the competences conferred on the European Chemical Agency (ECHA), Scientific Committee on Consumer Safety (SCCS) and other European risk assessment agencies, it may also be invited by the Commission to address, notably in collaboration with other European agencies and in particular ECHA, questions relating to examination of the toxicity and eco-toxicity of chemical, biochemical and biological compounds whose use may have harmful consequences for human health and the environment. In addition, the Committee will address questions relating to methodological aspect of the assessment of health and environmental risks of chemicals, including mixtures of chemicals, as necessary for providing sound and consistent advice in its own areas of competence as well as in order to contribute to the relevant issues in close cooperation with other European agencies.

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

It shall provide opinions on questions concerning emerging or newly identified health and environmental 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. It may also be invited to address risks related to public health determinants and non-transmissible diseases.
ANNEX II

RULES OF PROCEDURES

The common rules of procedures to be adopted by the Scientific Committees in accordance with Article 12 shall cover in particular the following subjects:

1. coordination between the Scientific Committees
   (a) the designation of the Scientific Committee responsible on request for scientific opinions 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;
   (b) the adoption of joint opinions, rapid advice, memoranda and/or position statements;
   (c) the procedures for ensuring coordination between the Scientific Committees including matters relating to harmonisation of risk assessment and the functioning of the Inter-Committee Coordination Group;

2. decision procedures within the Committees
   (a) the election of the Chair and Vice-Chairs of the Scientific Committees;
   (b) the procedures for the adoption of opinions:
      — under normal conditions,
      — under written procedure under normal conditions, and
      — under an accelerated, written procedure if the urgency of the matter requires such a procedure;
   (c) the procedure for the provision of rapid advice when so requested by the Commission in accordance with Article 2(3); this procedure shall ensure the quality and appropriate endorsement by the Committee of the advice;
   (d) the adoption of memoranda and position papers to draw the attention of the Commission to specific or emerging problems;

3. organisation of the scientific works
   (a) the creation and organisation of the working groups of the Scientific Committees, including joint working groups;
   (b) the association of scientific advisors from the Pool to the activities of the Committees and the involvement of external experts;
   (c) the appointment of Rapporteurs and the description of their tasks in relation to the preparation of draft opinions for the Scientific Committees;
   (d) the format and content of scientific opinions and procedures for ensuring and improving their coherence as well as the editing standards;
   (e) the organisation of, and participation in, meetings, thematic workshops, and networks;
   (f) the association of trainees;

4. obligations of the members of the Committee, the associated and other scientific advisors from the Pool, external experts and for the trainees
   (a) the participation criteria and the conditions under which membership of the Committee shall expire;
   (b) the implementation of the confidentiality requirements laid down in Article 17;
   (c) the responsibilities and obligations of members, associated and other scientific advisors from the Pool and external experts in relation to their contacts with petitioners, special interest groups and other stakeholders;
   (d) the conditions and the procedure under which a member of a Committee, an associated or other scientific advisor or an external expert should be excluded from the deliberations and/or the vote on a particular subject in the Committee or in a working group, where there are reasonable doubts on his independence;
5. relations with third parties

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

(b) representation of a Scientific Committee in external activities, notably in relation to other Community or international bodies engaged in similar activities;

(c) the organisation of the stakeholder dialogue procedure, in particular the organisation of hearings with industry or other special interest groups or other stakeholders;

(d) the publication of scientific opinions and other documents.

ANNEX III

INDEMNITIES

Members of the Scientific Committees, scientific advisors from the Pool 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 increased to EUR 600 for questions which are particularly demanding in terms of work load.

The Commission will regularly assess the need to adapt these indemnities in light of prices indexes, the evaluation of indemnities paid to experts in other European bodies and the experience on the workload for members, associated members, other scientific advisors and external experts. The first assessment will take place in 2009.