



Brussels, 7.8.2015
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COMMISSION DECISION

of 7.8.2015

**on establishing Scientific Committees in the field of public health, consumer safety and
the environment**

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Whereas:

- (1) Commission Decision 2008/721/EC¹ established an advisory structure on scientific risk assessment in the areas of consumer safety, public health and the environment consisting of the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER), the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and the Pool of Advisors.
- (2) The experience shows the need to introduce modifications and improvements in the current structure and working procedures of the Scientific Committees. In particular, in order to achieve efficiency, consistency, and to avoid duplication of efforts, SCHER and SCENIHR should be merged.
- (3) The Scientific Committees should be allowed to invite external experts with the relevant scientific knowledge and expertise to contribute to their work. As a consequence of this option, the existing Pool of Scientific Advisors on Risk Assessment will no longer be necessary.
- (4) The experience further shows that in order to ensure continuity of the membership in the Committees, replacements in the membership should be made from a reserve list drawn for that purpose.
- (5) A second intermediate evaluation on the functioning of the Scientific Committees is being carried out in 2015 and its results are expected by beginning of 2016. As a follow-up, a possible further reorganisation of the Scientific Committees may be undertaken.
- (6) The work of the Committees effectively contributes to improving public health, and protecting citizens and the environment. This is achieved by evaluating the latest available scientific data to provide the Commission with sound and timely evidence-based risk assessment and scientific advice for the development and monitoring of Union policies and legislation relating to public health, consumer safety and environmental risks. The activities carried out by the Committees are essential in order for the Commission to attain the relevant Union policy objectives. Therefore, it is appropriate to provide adequate financial support to the Scientific Committees, in the

¹ Commission Decision 2008/721/EC of 5 September 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 (OJ L 241, 10.9.2008, p. 21).

form of a special allowance for their members and external experts, beyond reimbursement of expenses. The financing of the activities of the Scientific Committees should be provided by the relevant budget line that is dedicated to support initiatives in the area of public health, consumer safety and environment, as relevant.

- (7) The work of the Scientific Committees should be based on the principles of high level of expertise, independence, and transparency. It must be organised in conformity with best practice and principles of risk assessment that is independent from risk management and decision making.
- (8) The Committees' members should be highly qualified, specialised and independent experts, working in the public interest. They should be selected on the basis of objective criteria and through a public call for expression of interest and should be appointed in their personal capacity. The expertise of the members should adequately cover the fields of competence of the Committees, reflecting the diversity of the scientific problems and approaches. As far as possible, geographical origin and gender balance should be achieved.
- (9) The organisation of the Scientific Committees should provide flexibility to enable them to advise the Commission on matters falling under the established areas of competence as well as on emerging and newly identified health risks and matters not within the competence of other Union bodies, and to provide rapid advice when needed.
- (10) Various Union bodies have been established that are responsible for risk assessment in various domains, among other tasks. It is necessary to ensure consistency of the risk assessment performed by those Union bodies and promote coordination between the Scientific Committees and such other 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 organisations at national and international level.
- (11) 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 Union legislation on the access of the public to documents, including the protection of personal data and commercial confidentiality.
- (12) Personal data should be collected, processed and published in accordance with Regulation (EC) No 45/2001 of the European Parliament and the Council².
- (13) Therefore, and for the sake of clarity and rationality, Decision 2008/721/EC should be repealed and replaced by a new Decision.

² 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 (OJ L 8, 12.1.2001, p1)

HAS DECIDED AS FOLLOWS:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scientific Committees

The following Scientific Committees are established:

- (a) the Scientific Committee on Consumer Safety (hereinafter SCCS); and
- (b) the Scientific Committee on Health, Environmental and Emerging Risks (hereinafter SCHEER).

Article 2

Mission

- (1) The mission of the Scientific Committees shall be to provide the Commission with scientific advice and risk assessment in the areas of public health, consumer safety, environmental risks, including, when relevant, identification of research needs to address critical information gaps, assessment of proposed future research actions and of research results.
- (2) The fields of competence of the Scientific Committees are set out in Annex I.
- (3) Paragraphs 1 and 2 shall be without prejudice to the competencies conferred by Union acts to other Union bodies undertaking risk assessment, in particular, the European Food Safety Authority, the European Medicines Agency, the European Chemical Agency and the European Centre for Disease Prevention and Control.

Article 3

Scientific advice

- (1) The Scientific Committees shall provide the Commission with scientific opinions on risk assessment in the cases laid down by Union law.
- (2) Furthermore, the Scientific Committees shall provide the Commission services, on request, with scientific advice on questions of particular relevance to public health, consumer safety and environmental risks.
- (3) The Commission services may invite Scientific Committees to identify research needs to address critical information gaps, to assess proposed future research and to assess research results in relation to the subject areas covered by their fields of competence.
- (4) The Commission services may also request the Committees to provide rapid risk advice on the state of scientific knowledge concerning specific risks in case of urgent risks.

- (5) The Commission services may invite the Scientific Committees to be part of thematic networks or events with other Union bodies or scientific organisations, in order to monitor and contribute to the development of scientific knowledge in the fields of competence defined in Annex I.
- (6) The Scientific Committees shall draw the attention of the Commission and its services to a specific or emerging problem falling within their fields of competence, 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 services memoranda or position statements. The Commission services 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.
- (7) The Committees, after consulting the Secretariat provided for in Article 14, shall adopt their methodology for performing and providing risk assessment and keep it under review to reflect all relevant scientific factors. They shall ensure that the methodology reflect current risk assessment practice.

CHAPTER 2

COMPOSITION OF THE SCIENTIFIC COMMITTEES

Article 4

Appointment of the members of the Scientific Committees

- (1) The SCCS and the SCHEER shall each consist of a maximum of 19 members. The Director General of the Directorate General for Health and Food Safety shall determine the number of members of each Committee in accordance with the requisite needs.
- (2) The members of the Scientific Committees shall be appointed by the Director General of the Directorate General for Health and Food Safety on the basis of the proven scientific expertise and of experience demonstrated by the candidates for the defined range of disciplines, having regard to the need to ensure:
 - (a) balanced representation of expertise in one or more of the fields of competence of the relevant Committee, in order to collectively cover the widest possible range of disciplines relevant for that Committee to fulfil its mission and to reflect the diversity of scientific problems and approaches;
 - (b) independence and absence of conflict of interest;
 - (c) balanced geographical origin representation;
 - (d) balanced gender representation.
- (3) The members of the Scientific Committees shall be appointed from a list of suitable candidates established following publication on the Commission website of a call for expression of interest; a link from the Register of Commission Expert Groups and Other Similar Entities (hereinafter 'the Register of expert groups') to this website will also be provided.

- (4) Suitable candidates who have been included in the list referred to in paragraph 3, but who have not been appointed, shall be included on a reserve list. The reserve list may be used to find suitable candidates to replace members whose membership in the Committee has been terminated in accordance with Article 5(2) or due to death.
- (5) The list of members of the Scientific Committees shall be published in the Register of Expert Groups and be also made available on the relevant Commission's website.

Article 5

Terms of office

- (1) The members of the Scientific Committees shall be appointed for a term of five years. They shall remain in office until they are replaced or their appointment is renewed.
- (2) When a member no longer complies with the condition under Articles 16 to 18 of this Decision or Article 339 of the Treaty on the Functioning of the European Union, wishes to resign or is no longer capable of contributing effectively to the Committee's deliberations, the Commission services may terminate the membership of that member.
- (3) When the membership of a member has been terminated in accordance with paragraph 2 or due to death, the Director General of the Directorate General for Health and Food Safety shall appoint a replacement for the remainder of the five year term.

CHAPTER 3

FUNCTIONING OF THE SCIENTIFIC COMMITTEES

Article 6

Election of the Chairs and Vice-Chairs

- (1) At the beginning of each term, each Scientific Committee shall elect a Chair and two Vice-Chairs from among their members. The election shall take place by a simple majority of the total number of members of the Committee.
- (2) The term of office of the Chair and Vice-Chair shall be five years, and shall be renewable. Any replacement of the Chair or Vice-Chair during the five year term shall be for the remainder of that term.
- (3) 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 7

Voting rules

- (1) Each Scientific Committee shall take decision by a majority of the total number of its members.

- (2) Those members of a Committee who have resigned or whose membership has been terminated in accordance with Article 5(2) or due to death shall not be taken into account for the calculation of the majority referred to in paragraph 1.

Article 8

Preparation of scientific opinions

- (1) The Commission services may require the adoption of a scientific opinion from a Scientific Committee within a specified period.
- (2) The Commission services may require the adoption of a joint opinion on questions which need to be considered by both Committees.
- (3) The Commission services may organise consultations, hearings or collaboration with other scientific bodies it deems necessary for the preparation of the Committees' opinions.

Article 9

External experts

- (1) The Commission services may invite external experts, as well as experts from other Union bodies with specific and relevant scientific knowledge and expertise to contribute to the work of the Scientific Committees, including working groups referred to in Article 10.
- (2) The selection of the external experts shall comply with the rules of procedures referred to in Article 12.

Article 10

Working groups

- (1) In agreement with the Commission services, the Scientific Committees may establish specific working groups whose task shall consist of preparing and drafting the Committees' scientific opinions. These working groups shall be established in particular when there is a need for external expertise on a particular subject.
- (2) The working groups shall be composed of members of the relevant Committee, and may also include external experts. The working groups shall be chaired by a member of the Scientific Committee. The chair of the working group shall be responsible for convening the working group and reporting to the Committee, and may appoint a rapporteur from among participants to the working group. For particularly complex questions of a multidisciplinary nature, more than one rapporteur may be appointed.
- (3) When a question is common to more than one Scientific Committee, a joint working group including members from both Committees, as well as external experts, as necessary, shall be set up.

Article 11

Participation of trainees

In agreement with the Commission services 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 12

Rules of procedures

- (1) On a proposal by and in agreement with the Commission services, 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 as laid down in Chapter 4 and with the Commission rules on expert groups, whilst having regard to legitimate requests for commercial confidentiality as well as to the risk assessment principles which may be established by the Commission services in the light of the experience and in view of its policy in this area.
- (3) The rules of procedure shall provide in particular for:
 - (a) application of principles laid down in Chapter 4;
 - (b) a stakeholder dialogue procedure as referred to in Article 14(3);
 - (c) procedures for the adoption of a scientific opinion and provision of a rapid scientific advice as referred to in Article 3(4);
 - (d) relations with third parties including scientific bodies;
 - (e) other detailed rules on the functioning of the Scientific Committees including coordination between the Committees.

Article 13

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

- (1) With respect to the relations with other relevant Union, national or international bodies carrying out similar tasks, the Scientific Committees shall assist the Commission services in:
 - (a) identifying at an early stage needs and possibilities for coordination of work and collaboration, including sharing of data and information, and potential or actual divergences in scientific opinions;
 - (b) avoiding, resolving or clarifying divergent opinions and in establishing and maintaining collaboration relationships.
- (2) The Commission services may request and organise joint work, including joint opinions, of the Scientific Committees with Union, national or international bodies carrying out similar tasks.
- (3) Where a substantive divergence over scientific issues has been identified and the body in question is a Union body, the Scientific Committee concerned shall, on the request of the Commission services, cooperate with the body concerned with a view to either resolving the divergence or presenting a joint document to the Commission services clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

Article 14

Secretariat of the Scientific Committees

- (1) The Directorate General for Health and Food Safety shall provide a secretariat for the Scientific Committees and their working groups as well as for all other activities related to the application of this Decision.
- (2) 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.
- (3) The secretariat shall ensure the scientific and technical coordination of the activities of the Scientific Committees and, where necessary, timely coordination of their activities with those of other Union, national and international bodies to ensure consistency of the risk assessment performed on subjects of common concern, 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 15

Special allowance

- (1) The members of the Scientific Committees and external experts shall be entitled to a special allowance for their preparatory work and participation, in person or from a distance by electronic means, in the meetings of the Committees, working groups and other activities related to the application of this Decision and organised by the Commission services, and for serving as rapporteur on a specific question, as provided for in Annex II.
- (2) Travel and, where appropriate, subsistence expenses of members and external experts in connection with the Scientific Committees' activities shall be reimbursed in accordance with the provisions in force at the Commission. Those expenses shall be reimbursed within the limits of the annual budget allocated to the Scientific Committees by the responsible Commission services.

CHAPTER 4

PRINCIPLES

Article 16

Independence

- (1) The members of the Scientific Committees and external experts shall be nominated in a personal capacity. They shall not delegate their responsibilities to any other person.
- (2) The members of the Scientific Committees and external experts shall act independently and in the public interest. For this purpose they shall make a declaration of interests indicating any interest which may compromise or may reasonably be perceived to compromise their independence, including any relevant circumstances relating to their close family members.
- (3) Declarations of interests shall be made in writing, prior to the appointment as a member of the Scientific Committee or as an external expert, and annually. These declarations shall be updated whenever a change of circumstances so requires.
- (4) The members of the Scientific Committees and external experts shall declare at each meeting any specific interest which may compromise or may reasonably be perceived to compromise their independence in relation to the items on the agenda. The same obligation shall apply, *mutatis mutandis*, when a written procedure is launched in any of the Scientific Committees.

Article 17

Confidentiality

- (1) The members of the Scientific Committees and external experts shall not divulge information acquired as a result of the work of the Scientific Committees, or working groups or as a result of other activities related to the application of this Decision. For this purpose, they shall sign a declaration of confidentiality.
- (2) The members of the Scientific Committees and external experts shall comply with Commission's security rules for protecting European Union Classified Information (EUCI) and sensitive non-classified information, as set out in Commission Decisions (EU, Euratom) 2015/443³ and 2015/444⁴. If these obligations are not met, the Commission services may take all appropriate measures.

Article 18

Commitment

The members of the Scientific Committees and external experts shall commit themselves to act independently, in the public interest and to contribute actively to the work of the Scientific Committees. For this purpose, they shall sign a declaration of commitment.

Article 19

Transparency

- (1) The activities of the Scientific Committees shall be carried out with a high level of transparency. The Commission services shall publish all relevant documents, such as agendas, minutes and participants' submissions, on a dedicated website; a link from the Register of expert groups to this website will also be provided. The Commission

³ Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

⁴ Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

services 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 and minutes of the working groups;
 - (c) the scientific opinions 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 concerned;
 - (d) the rules of procedures of the Scientific Committees;
 - (e) the names of the members of the Scientific Committees, together with a brief curriculum vitae of each member;
 - (f) the declarations of interests, of confidentiality and of commitment of the members of the Scientific Committees and external experts.
- (2) The names and declarations of interest of working group members shall be made publicly available on the Commission's website after the publication of the opinion to which they have contributed.
- Exceptions to publication shall be possible where disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) No 1049/2001.
- (3) Paragraphs 1 and 2 shall be applied in accordance with the requirements of Regulation (EC) No 45/2001 and of Regulation (EC) No 1049/2001 of the European Parliament and of the Council⁵, especially with regard to processing of personal data and commercial confidentiality.

CHAPTER 5

FINAL PROVISIONS

Article 20

Replacement of the Scientific Committees

Without prejudice to Article 21, the Scientific Committees established by Article 1 of this Decision shall replace the existing Scientific Committees set up by Decision 2008/721/EC as follows:

- (a) the Scientific Committee on Consumer Safety shall replace the Committee of the same name;
- (b) the Scientific Committee on the Health, Environmental and Emerging Risks shall replace the Scientific Committee on Health and Environmental Risks and the Scientific Committee on Emerging and Newly Identified Health Risks.

⁵ 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 (OJ L 145, 31.5.2001, p. 43).

Article 21

Transitional provisions

All the Scientific Committees established by Decision 2008/721/EC shall continue to operate in accordance with the relevant provisions of that Decision, and their members shall remain in office until the members of the Scientific Committees established by this Decision are appointed.

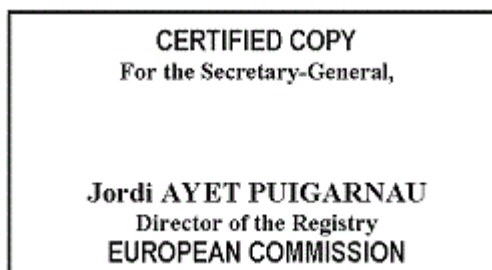
Article 22

Repeal

- (1) Decision 2008/721/EC is repealed.
- (2) References to the repealed Decision shall be construed as references to this Decision. References to the Committees established by the repealed decision shall be construed as references to the Committees established by this Decision.

Done at Brussels, 7.8.2015

For the Commission
Vytenis Andriukaitis
Member of the Commission





Brussels, 7.8.2015
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ANNEXES 1 to 2

ANNEXES

to the

**Commission Decision
on**

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ANNEX 1

Fields of Competence

(3) Scientific Committee on Consumer Safety (SCCS)

The SCCS on request of Commission services shall provide opinions on questions concerning health and safety risks, notably chemical, biological, mechanical and other physical risks, of:

(a) non-food consumer products such as

- cosmetic products and their ingredients, including nanomaterial, hair dyes, fragrance ingredients;

- personal care and household products such as detergents; toys, textiles, clothing, etc.

(b) services such as tattooing, artificial sun tanning, etc.

(4) Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)

The SCHEER on request of Commission services shall provide opinions on questions concerning health, environmental and emerging risks.

In particular, the Committee 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 Union risk assessment bodies.

Examples of areas of activity include potential risks associated with 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, physical hazards such as noise and electromagnetic fields, interaction of risk factors, synergic effects, cumulative effects, and methodologies for assessing new risks. It may also be invited to address risks related to public health determinants and non-transmissible diseases.

The SCHEER shall also provide opinions on 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.

Without prejudice to the competences conferred on the European Chemical Agency (ECHA) and other Union bodies undertaking risk assessment, it may also be invited to address questions relating to examination of the toxicity and eco-toxicity of chemical, biochemical

and biological compounds whose use may have adverse effects for human health and the environment, including biocides.

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.

ANNEX II
Special Allowance

- (5) The work of the Committees effectively contributes to improving public health, and protecting citizens and the environment. This is achieved by evaluating the latest available scientific data to provide the Commission with sound and timely evidence-based risk assessment and scientific advice for the development and monitoring of Union policies and legislation relating to public health, consumer safety and environmental risks. Due to the fact that the advice provided is specific and of a such a nature that without it the Union policy concerned could not reach its objectives, the members of the Scientific Committees and external experts are entitled to a special allowance as stipulated by the Commission Decision C(2014)2220.
- (6) The members of the Scientific Committees and external experts are entitled to a special allowance which compensates them for their participation, in person or by distance, and related preparatory work in the meetings of the Committees, working groups and other activities organised by the Commission services related to the application of this Decision. The special allowance consists of a maximum of EUR 450 in the form of a daily unit cost for each full working day. The total allowance shall be calculated and rounded upwards to the amount corresponding to the nearest half working day.
- (7) The members of the Scientific Committees and external experts are entitled to a special allowance for acting as rapporteur to compensate them for the work performed. This special allowance shall be calculated depending on the number of working days needed to do the work. The calculation of the number of the working days is modulated depending on the workload related to the complexity of the matter, the length of the period needed to complete the opinion, the amount and accessibility of data and scientific literature and information to be collected and processed and the extent and complexity of public and stakeholder consultations and contacts with other bodies, in light of the following indicative criteria:

working days	Indicative criteria
1 full working day	<ul style="list-style-type: none"> - simple and routine issue - opinion based on examination of a dossier, with limited data search and limited literature examination - no public consultation - indicatively, six months between first and last meeting
2 full working days	<ul style="list-style-type: none"> - complex issue - opinion based on significant data and literature search and examination - stakeholder and/or public consultation with limited feedback examination workload - indicatively, from six to twelve months between the first and the last

	meeting
3 full working days	<ul style="list-style-type: none"> - very complex issue - need for very extensive data and literature search and analysis - extensive and complex consultations with stakeholder, the public and other scientific bodies, with important feedback to be examined - indicatively, more than twelve months between the first and the last meeting

- (a) In each specific case, on the basis of the criteria mentioned in the table above, the Commission services shall indicate the total allowance for the rapporteur. The total allowance may be modified by the Commission services during the preparatory work for the requested opinion if that is justified by unforeseen changes in relation to the relevant criteria.
- (b) In case of more than one rapporteur is needed to produce an opinion, the total allowance applicable to each rapporteur is calculated by the Commission services in the form of working days needed to do the work, taking into consideration the above relevant criteria and the specific tasks assigned to each rapporteur.