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Criteria and Procedures ensuring independence of the Committees, Panels and Working Groups

Procedures and criteria for selecting members and external experts

EC independent Scientific Committees

The conditions regarding the appointment of the members of the Scientific Committees and their term of office are described under Chapter 2 of the [Commission Decision 2008/721/EC](#)  (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).

For the current mandate, the Committee members, advisors, members of the Pool have been selected after a call for expression of interest ([2008/C 245/05](#) ).

The procedure regarding the selection of Advisors and external experts to participate in Working Groups is described on § 9.7 of the [Rules of procedure](#)..

ECDC

A scientific opinion from the ECDC is always produced in three steps (see paper on [Relation with Stakeholders](#))

1. A draft opinion is produced either internally or by and ad hoc external Scientific Panel.
2. This opinion is revised by the ECDC Advisory Forum (AF) who advises the Director.
3. The Director issues the opinion.

The Members of the ECDC Advisory Forum declare interests in writing annually and orally at each meeting (4 times per year).

The text below describes the process in the ad hoc Scientific Panels:

According to the Internal procedure (work instruction) on handling Requests for Scientific Advice at the European Centre for Disease Prevention and Control (approved and being implemented in 2009, attached): *"In a case where no ECDC expertise is available, or where the Chief Scientist agrees that there is a need to involve external expertise, external experts are selected to create an ad hoc scientific panel (MB6/9/9).*

The process of external expert selection and nomination includes:

- a) Consulting internal ECDC Expert Database; and/or:
b) Approaching AF members/ ECDCs list of learned societies/competent bodies to nominate experts; and/or:
c) Literature search to identify additional names.
- Applicants for the scientific panels should have extensive expertise in the area of communicable diseases and/or related areas with a proven capacity to handle multidisciplinary scientific questions related to communicable disease threats.
- Identified experts are asked about the availability on short notice to respond to ECDC requests. The names of experts are publicly available on [ECDC website](#)."

ECHA

According to Article 85 of [Regulation \(EC\) No 1907/2008](#) (the REACH Regulation), Members of Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis are appointed by the ECHA Management Board following their nominations from a Member State. For the Member State Committee. Each Member State shall appoint one member. In addition, the Committees may co-opt a maximum of 5 members chosen on the basis of their specific competence (Article 85(4) of the REACH Regulation).

EMA

The membership of the scientific committees and the handling of its members' conflicts of interest are governed by the following rules, which have put in place a system that allows the EMA to benefit from the best scientific expertise available, whilst guaranteeing the impartiality of the Committee's opinions:

- [Regulation 726/2004/EC](#) (Articles 61 to 63) EC
- [CHMP Rules of Procedure](#) (Article 19)
- [EMA Code of Conduct](#) (Annex I)
- EMA Policy on the handling of conflicts of interests of Management Board and scientific committee members and EMA experts (Section IV) ([EMA/H/31653/03/Rev1 final](#))
- EMA Procedure on the handling of conflicts of interests for EMA scientific committees members and EMA experts ([EMA/H/5475/04/Rev1 Final](#))
- EMA Standard Operating Procedures on Checking of Experts ([SOP/EMA/0040](#))

These rules are publicly available and can be downloaded from the EMA website.

The relevant Rules of Procedure for the different Committees outline the composition of each committee.

The Expert needs to provide a completed nomination form (signed by the relevant nominating authority), detailing areas of expertise and a Declaration of Interest and to provide a CV. An updated Declaration of Interest form should be provided on an annual basis (paper format, since this must be signed). In addition, members and experts are invited to make any oral declarations of interest specific to a meeting agenda at the start of the relevant meeting.

The EMA Management Board is involved in the consultation with respect to members and alternates of the CHMP and CVMP.

Declarations of Interest (DoI)

EC independent Scientific Committees

An Annual Declaration of Interests is required from all members of the Scientific Committees and scientific advisors from the Pool. These declarations shall be made in writing and published in the Commission's website [[Commission Decision 2008/721/EC](#)], §5.2 and Annex II of [Rules of Procedure](#)].

A Specific Declaration of Interests is required from all Advisors and experts participating in Working Groups (including the relevant Scientific Committee members) and the Advisors associated to a Scientific Committee. [[Commission Decision 2008/721/EC](#) and Annex II of [Rules of Procedure](#)].

Members, Scientific Advisors and external experts participating in meetings of the Scientific Committees or in a Working Group or in any other activity of the Advisory Structure shall declare at each meeting or event any activity, situation, circumstance or other fact potentially involving a direct or indirect interest, as indicated in the explanatory notes included in the relevant Annex in order to allow the Scientific Committee and/or the Commission to identify those interests which might be considered prejudicial to their independence in relation to the items on the agenda for that meeting or event. This declaration shall be made in writing or verbally, following a request of the Chair or the Commission [§5.3 of [Rules of Procedure](#)].

Trainees attending the Scientific Committees' meetings as provision in Art 8 of [Commission Decision 2008/721/EC](#) shall sign a declaration of interest [§17 of [Rules of Procedure](#)].

A detailed guidance on the completion of the declaration of interest, as well as an example of the form, can be found in Annex II of the Rules of Procedure.

ECDC

Before being appointed for working in a panel, experts are informed on the code of conduct for experts (ethical principles and rules about confidentiality, discretion, non disclosure, integrity, independence, objectivity, impartiality, the obligations to declare at each meeting conflicts of interest, the sanctions in case of non compliance, false declaration) and must fill out (or update) a conflict of interest form, confidentiality declaration and a declaration of interest. An explanatory leaflet is provided to guide experts on how to complete the declaration of interest. In addition an oral declaration will be obtained from each member at each meeting of any interests which might be considered prejudicial to expert's independence in relation to items on the agenda. The declaration of interest forms are filled in by experts before they are appointed for working in a panel (written) and at each meeting (oral).

ECHA

Declarations of interests (DoIs) are made as follows:

Initial declaration: Upon his/her appointment, each member is required to fill in and sign a declaration of interests form.


Appointment as rapporteur: A member should not accept appointment as a rapporteur or co-rapporteur if he/she indicates any interest that might be prejudicial to the independent consideration of that case. For each case, the rapporteurs and co-rapporteurs must make a declaration of commitment and a declaration of interests in writing according to Article 87(1) of the [REACH Regulation](#).


Update of the initial declaration: Declarations must be updated annually or without delay once relevant changes have occurred.

Spontaneous declarations: At each of their meetings, members, their advisers and invited experts or its working group must declare any interests which could be considered to be prejudicial to their independence with respect to any points on the agenda. Anyone declaring such interests shall not participate in any voting on the relevant agenda point. The spontaneous declarations will be recorded in the minutes of the meeting.

The Declaration of Interest is to be completed according to Article 9 of the RAC [Rules of Procedure](#).

EMA

All scientific Committees members and alternates are required to complete an Annual [Declaration of Interest](#) , which is published on the EMA webpage. In addition, members, rapporteurs and experts who participate in scientific committees meetings shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence with respect to the items on the agenda. These declarations shall also be made available to the public.

Where a scientific committee member has declared an interest, this interest will be evaluated in accordance with the procedure for the Handling of Conflicts of Interest for EMA Scientific Committees Members and Experts and the expert will only be allowed in EMEA activities to the extent defined by the assigned risk level ([EMA Procedure on the handling of conflicts of interests for EMA scientific committees members and EMA experts](#)  - Revision 1)

On a general point, it should also be noted that experts are required to provide information on all declared interests within the previous 5 years. Experts are invited (but not obliged) to provide information on interests over 5 years ago. Such information is not used in the evaluation of declared interests but is useful in the context of an increased transparency as regards previous interests.

Nature of interest to be declared

EC independent Scientific Committees

Members of the Scientific Committees, Advisors as well as external experts shall declare current and past activities in the Annual and Specific Declaration of Interest (same form) in the following areas:

1. Ownership of shares or other investments.
2. Membership in a Management Body or equivalent structure.
3. Membership in another Scientific Advisory Body
4. Employment
5. Consultancy/Advice
6. Research
7. Intellectual property rights (IPR)
8. Other membership or affiliation
9. Interests of close family members
10. Other

A detailed guidance on the completion of the declaration of interest, as well as an example of the form, can be found in Annex II of the [Rules of Procedure](#).

ECDC

Several types of interests can be identified, including (1) financial holdings in companies, (2) activities resulting in personal payments, (3) activities resulting in payments to an organization where the expert is a member, and (4) other unpaid links.

ECHA

Annex 2 of the rules of procedure for the ECHA Committees contains a model for the annual declaration of interests by Committee members. The interests required to be declared include relevant work and activities during the previous five years; financial interests and any other relevant interests or facts.

EMA

Direct interests:

Interests of personal benefit to the individual at any point in time, likely to influence or give the appearance of influencing his behaviour (e.g. employment with a pharmaceutical company, financial interests of a certain magnitude)

Personal interests:

Relate to salaries, shares, share options, or fees earned by acting as a consultant – (A consultant is defined as an expert who charges a fee (personal, institutional or both) for providing advice or services in a particular field).

Financial interests:

Any financial interests in the pharmaceutical industry, including holding of stocks and shares, stock options, equity, bonds, partnership interests in the capital of a pharmaceutical company, one of its subsidiaries or a company in the capital of which it has a holding.

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

Contract /collaborative research or clinical trials would normally be defined as institutional interests – (see definition of institutional interest – related to institutional contracts or supervisory research interests).

Institutional interests:

Relate to institutional contracts or supervisory research interests.

Indirect interests:

Other interests that may have some influence over the individual's behaviour.

Criteria and practises for decision on possible conflict of interest

EC independent Scientific Committees

Declarations of Interest are addressed by an expert to his/her peers and the Secretariat as an indication of where conflicts of interest could arise and do not require from the author to assess whether there is a conflict. The assessment of whether there is a potential conflict is performed by the peers (i.e. the Chair and the other members of the SC) and the Secretariat [Annex II of [Rules of Procedure](#)].

The Chair, in collaboration with the Secretariat examines the declarations of interest, deciding, in consultation with the Committee and in agreement with the Commission the relevant conclusions and action in order to ensure the effective application of the independence requirements [§ 9.2.1 of [Rules of Procedure](#)].

It is well understood that, in general, individuals who are involved in a particular process have an inherent professional interest in the subject and in being involved in the process as such. In particular, interests of an intellectual nature are considered as essential to safeguard the quality and overall objectivity of the scientific work. The Commission recognizes that high quality and up-to-date scientific expertise is by nature based on prior experience, connection to the scientific world and involvement in current research. Therefore, having an "interest" declared does not necessarily mean having a conflict of interest. [Annex II of [Rules of Procedure](#)].

ECDC

The declaration of interest and conflict of interest forms are reviewed and an appropriate action recommended by:


- The Chairman of a specific panel, if in doubt, the case will be referred to:
- The ECDC Chief Scientist, if still in doubt, the case will be reviewed by:
- The Conflict of Interest Committee.

ECHA

The declared conflict of interest is checked against the [Rules of Procedure](#) and guidance.

EMA

The first general screening takes into consideration the background of the expert and the nature of the interest declared (personal / institutional). This screening would not consider the activity for which the involvement of the expert is required, at this stage. Risk level 2 / 3 at initial screening is assigned to any expert who has indicated any declared interest on his / her Declaration of interest form.

The declared interests of such experts (risk level 2 at initial screening) are then screened with respect to the specific EMA activity for which their involvement is proposed. The re-classification criteria are outlined in the [EMA procedure on the handling of conflicts of interest for EMA scientific committees members and experts](#)  document (section III.2.2)

In the majority of cases, the interests declared are either in an area other than that for which involvement is requested, or the type and timeframe of their involvement will be such that their declared interests are not considered to represent a conflict of interest with respect to the specific activity. However, in some instances, this second phase analysis will lead to a re-classification of Risk level 2 or 3, with respect to the specific activity for which involvement is requested. Such experts are then referred to the Declaration of Interest Assessment Group.

Modulation of involvement of experts declaring interest

EC independent Scientific Committees

In case of conflict of interest of the Chair with an item on the agenda, he/she may be replaced by one of the Vice-Chairs or failing that another member chosen in common accord by the members [§ 9.2.3 of [Rules of Procedure](#)].

Any member, Advisor or external expert who, in accordance with his/her declaration or in the opinion of the Scientific Committee, the Working Group or the Commission, may not be able to act independently, shall be excluded from the activities considered or may only be allowed to participate to the extent and in a way compatible with the objective to preserve the process from any undue influence. In such a case, the member, advisor or expert may not act as Rapporteur or as Chair in relation to the specific matter and may not participate in decision-making. The extent of the concerned individual's participation in the Committee's work shall be decided by the Chair in consultation with the Committee or Working Group members and in agreement with the Commission within the framework of these Rules of Procedure. Measures may include the physical withdrawal from the meeting for the point under discussion, or participation limited to the provision of factual information [§ 5.5 of [Rules of Procedure](#)].

Conclusions and decisions taken in relation to the declarations of interest, as well as their rationale, shall be recorded. In the case of declarations presented during meetings, such records will be part of the minutes [§ 5.6 of [Rules of Procedure](#)].

ECDC

The declaration of interest indicates either the absence of any interest which might be considered prejudicial to the expert's independence or any direct or indirect interests which might be considered prejudicial to his/her independence.

In such cases an expert is disqualified from the relevant discussions and decisions.

ECHA


See Articles 9 and 19 of the Risk Assessment Committee [Rules of Procedure](#). 

EMA

Referral to Declaration of Interest Advisory Group (DIAG) in the absence of alternative experts of a lower risk level.

The DIAG will decide:

- in case of the assigned risk level "2", either to grant a waiver leading to level 1 permitted involvement in the specific EMA activity(ies), for which involvement is requested, or to maintain level 2 permitted involvement, and
- in case of the assigned risk level "3", either to grant a waiver leading to level 2 permitted involvement in the specific EMA activity(ies), for which involvement is requested, or to exclude such individual from involvement in those activities.

In line with EMA's [procedure on Handling of Conflicts of Interest](#) , specifically relating to participation in specific product/class related matters, an expert classified at risk level 2 can participate addressing orally or in writing specific questions raised during the evaluation, but cannot draft assessment reports or parts of it. The expert should leave the room when a final decision or a vote takes place. The interests of this expert should be clearly declared and minuted.

Measures taken in cases of non-declared interests

EC independent Scientific Committees

Failure to fulfil in a timely and complete manner any of the obligations detailed above will be considered as a prima facie breach of trust towards the Commission. As a consequence, the

Commission will take any actions deemed necessary, including the dismissal of the concerned persons from the Advisory Structure [Annex II of [Rules of Procedure](#)].

ECDC

Situation will be reviewed by and an appropriate action recommended by:

- The Chairman of a specific panel, if in doubt, the case will be referred to:
- The ECDC Chief Scientist, if still in doubt, the case will be reviewed by:
- The Conflict of Interest Committee.

ECHA

The Chair of the Committee for Risk Assessment (RAC) would be the one to deal with this issue in the first instance, i.e. to discuss with the member and evaluate the alleged conflict of interest. The Chair would discuss with the member their reasons for not declaring. If no agreement is achieved, the Chair will consult the general issue with the Committee in a Closed Session. Depending on the nature of the issue, the Committee may consider appropriate to appoint one or several members to discuss the specific issue with the Member and the Chair; the ECHA Secretariat will provide legal support if required. If no agreement is achieved, the case will be considered by ECHA in consultation with the Committee.

If the Agency considered there was a conflict of interest, and it was identified before adoption of the opinion, where the conflict related to the Rapporteur drafting the opinion he/she would be requested to stand down, or in the case of a member, not to participate in voting. If the conflict of interest was discovered after voting had taken place it would be necessary to check with the Committee whether the vote of the biased member had influenced the result. Generally speaking, it is the responsibility of the member to declare a conflict of interest. If this is not declared, the member is in breach of their obligations and this could be a point for Article 5(2) of the RAC [Rules of Procedure](#) to submit a justified proposal to the Executive Director of the Agency to ask the member to resign.

EMA

The EMA can only evaluate interests declared. If an interest is not declared, and subsequently comes to light, EMA management will discuss the potential impact of this declared interest on the activity with which the expert was involved and decide on any necessary action.

Publication of Declarations of Interest

EC independent Scientific Committees

In accordance with the provisions on transparency foreseen by [Commission Decision 2008/721/EC](#), the Annual and the Specific Declarations of Interest are made public [§ 6 and Annex II and of the [Rules of Procedure](#)].

ECDC

The register of scientific advice, including composition of panels, but not declaration of interest, is planned to be published on [ECDC website](#).

ECHA

Annual declarations and updates are published on the [ECHA website](#):

Declarations for rapporteurships are kept on file and spontaneous declarations at the beginning of meetings are recorded in the minutes. These are kept on register at ECHA premises available to the public on request.

EMA

Declarations of interest and confidentiality undertakings are available to the public on request at the Agency's offices. As part of the Agency's efforts to promote transparency, the declarations of interests of and confidentiality undertakings of Board and committee members are also available on the following EMA webpages:

<http://www.ema.europa.eu/htms/general/contacts/MB.html>

http://www.ema.europa.eu/htms/general/contacts/CHMP/CHMP_members.html

http://www.ema.europa.eu/htms/general/contacts/CVMP/CVMP_members.html

http://www.ema.europa.eu/htms/general/contacts/COMP/COMP_members.html

http://www.ema.europa.eu/htms/general/contacts/HMPC/HMPC_members.html

http://www.ema.europa.eu/htms/general/contacts/PDCO/PDCO_members.html

http://www.ema.europa.eu/htms/general/contacts/CAT/CAT_members.html