Legislation

EC independent Scientific Committees

The Scientific Committees receive their mandates from the European Commission services, as provided by the Commission Decision 2008/721/EC

ECDC

The ECDC Advisory Forum receives its mandate from the ECDC Founding Regulation. The role of the ad hoc Scientific Panels is defined in these same regulations, Article 6.

ECHA

Based on Article 77(3) of Regulation (EC) No 1907/2006 (the REACH Regulation), Articles 69(4) and 70 of the REACH Regulation provide two mandates for Risk Assessment Committee (RAC) to consider proposals for Community-wide restrictions:

Article 64(1) of the REACH Regulation requires RAC to give an opinion on an application for authorisation.

Article 37(4) of the Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP Regulation) of substances is the mandate for RAC to provide an opinion on harmonised classification & labelling (CLH):

It should also be noted that the roles of two other ECHA Committees, the Member State Committee (MSC) and the Committee for Socio Economic Analysis (SEAC), are closely related to that of RAC.

The MSC, amongst other things, provides an opinion for recommending priority substances to be included in Annex XIV (list of substances subject to authorisation) under Article 58(3) of the REACH Regulation. SEAC evaluates restrictions suggested by a Member State or ECHA and the related socio-economic impacts. Comments and socio-economic analysis submitted by the interested parties will also be assessed (Article 71 of the REACH Regulation). Both Committees work in a closely similar way to RAC. Further details are available here.

EMA

The legal basis (including all details) for the relationship between risk manager and risk evaluators is the pharmaceutical legislation itself. For the scientific committees and the centralised procedure and

referrals in the Regulation (EC) No 726/2004. and in the codified Directives 2001/83/EC. (medicinal products for human use) and 2001/82/EC. (medicinal products for veterinary use) for other procedures.

Mandate

EC independent Scientific Committees

As listed in Commission Decision 2008/721/EC, Art.2 §1,2,3:

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

Mandates may be put to public consultation according to the procedures set out in Annex IV of the Rules of Procedure. of the Scientific Committees. The Commission will welcome motivated and documented suggestions for new topics for the Scientific Committees, provided the suggested topics follow the conditions set in the Annex IV of the Rules of Procedure [§ 9.3 and Annex IV and of the Rules of Procedure.].

ECDC

Terms of reference of panels are set up by ECDC, no public consultation is currently foreseen

ECHA

As indicated above the mandates for the Committee's tasks are derived directly from the legislation.

Proposals for restrictions may be prepared by the Agency, on request of the Commission, or by the MSCAs. Proposals for harmonised classification and labelling are submitted by MSCAs or, in those cases where a substance is without an entry in Annex VI of the CLP Regulation, there is a new provision which allows manufacturers or downstream users of a substance to submit a proposal for harmonised classification and labelling (CLH).

Proposals for restrictions, CLH and the uses of a proposed authorisation are published on the ECHA web site. (see stakeholder relations section B).

EMA

Mandates set out in relevant legislation and implemented via Rules of Procedure for individual Committees (adopted by Committee and agreed by EMA Management Board and European Commission for CHMP and CVMP)

Execution of work

How closely/actively is the Risk Manager following the Assessors' work?

EC independent Scientific Committees

Commission services with responsibilities relating to the topics on the agenda shall be entitled to be present in the meeting. They may assist for the purposes of clarification or provision of information but shall not seek to influence the outcome of discussions. [§ 9.8.9 of the Rules of Procedure.].

ECDC

The Risk Manager does not participate in panel meetings, however the Commission is represented in the ECDC Advisory Forum.

ECHA

In its role as Risk Manager, the Commission may attend meetings of Risk Assessment Committee as an observer. The Commission has no role to play in commenting or influencing the formulation of the opinion, which should be drawn up by the Committee on the basis of scientific and technical considerations only.

EMA

The Risk Manager participates to the meetings and responds to specific questions relating to legal / procedural issues. No intervention in scientific issues unless scientific issues are not clear enough for the Commission to take the decision. As a general principle the comments relate to legal/regulatory/procedural issues not on scientific issues.
The Commission and the EMA have established working arrangements.

Adoption

Are the Risk Managers involved in the adoption of an opinion?

EC independent Scientific Committees

Commission services with responsibilities relating to the topics on the agenda shall be entitled to be present in the meeting. They may assist for the purposes of clarification or provision of information but shall not seek to influence the outcome of discussions. [§ 9.8.9 of the Rules of Procedure.].

ECDC

No, the Risk Managers are not involved in the adoption of an opinion

ECHA

No. The Commission however prepares a draft decision in relation to restrictions (Article 73 REACH regulation), authorisation (Article 64(8) REACH regulation) and CLH (Article 37(5) of regulation (EC) No 1272/2008 (CLP Regulation)) taking the opinions into account. A final decision is taken in the Committee procedure as laid down in Decision 1999/468/EC.

EMA

The Risk Assessors are in charge of the adoption of the opinion for marketing authorisation/referrals. The Risk Manager is in charge of the decision making process and is responsible for the adoption of the decision. If the decision of the Risk Manager is not in accordance with the opinion the Risk Manager has to explain the reasons. If a Member State raise new scientific issues not being addressed in the opinion the Risk Manager can send back the opinion to the EMA.
For orphan drugs designation it's the same procedure.
For the Paediatric Investigation Plans that are adopted by the Paediatric Committee (PDCO) the Executive Director signs off the decisions.

Publication

EC independent Scientific Committees

A list of documents which are published on the Commission's website with regard to the activities of the Scientific Committees can be found on § 6.3 of the Rules of Procedure..

The Secretariat, in agreement with the interested Commission Services, will decide about the publication of memoranda, position statements, documents resulting from scientific meetings and thematic workshops [§ 11.14 of the Rules of Procedure.].

All documents mentioned under paragraph 6.3 of the rules of procedure and in particular the adopted Scientific Opinions shall be published on the Internet without undue delay by the Secretariat [§ 13.1 of the Rules of Procedure.].

For any other document, the Secretariat, in agreement with the interested services shall decide about the publication and dissemination case by case [§ 13.2 of the Rules of Procedure.].

ECDC

Technical reports and guidance produced by panels are published primarily electronically on ECDC website. In some cases a written report is prepared and disseminated.

ECHA

The opinions are published on the ECHA website..

EMA

Publication of opinions by the EMA (European Public Assessment report, Summary of Opinion etc.) – post Decision adoption and publication of decisions in the official journal, both electronic and paper.
Publication of Article 5(3) of the regulation on pharmaceuticals concerning opinions on any scientific matter related to medicinal products.
Many other documents are published in the EMA website guidelines, press releases, public statements, reflection papers, recommendations, procedural advices, etc.
"Procedure for European Union Guidelines and related documents within the pharmaceutical legislative framework"

Communication to public

EC independent Scientific Committees

Without prejudice to Art 16 of Decision 2008/721/EC, the Commission shall be responsible for determining the appropriate level of publicity to be given to a scientific opinion and may request the assistance of the chairs, rapporteurs or other members and advisors to ensure the scientific validity of its press releases or related communication actions. [§ 6.6 of the Rules of Procedure..

ECDC

Dissemination to public is ensured in close collaboration with ECDC Health Communication Unit.

ECHA

See information on Mandate and Publication. The public may be informed to the adoption of an opinion via an ECHA press release or news alert.

EMA

The EMA is mainly responsible for the communication to the public.

Feedback on risk management measures

EC independent Scientific Committees

The Secretariat will organise the appropriate dialogue between the Committees and the requesting services at the various stages, including feedback from the services on the adopted opinions [§ 11.10 of the Rules of Procedure.].

ECDC

Feedback is obtained in close collaboration with the European Commission and Member States.

ECHA

The risk management measures are Community–wide restrictions included in Annex XVII of the REACH Regulation; listing of the Community-wide harmonised classification and labelling of substances in Part 3 of Annex VI of the classification, labelling and packaging (CLP) Regulation; or in the case of applications for authorisation, once a decision has been taken, a summary of the decision with authorisation number and reasons for the decision are published in the Official Journal.

EMA

Non applicable as all the details of the procedure setting up the relationships between the EMA and the Commission are in the pharmaceutical legislation.