EUROPEAN COMMISSION
HEALTH & CONSUMERS RECTORATE-GENERAL

Public Health and Risk Assessment
Risk assessment

Brussels, 10.11.2008

COMMON GUIDELINES ON PRACTICAL ARRANGEMENTS FOR THE SHARING OF SCIENTIFIC DATA BETWEEN THE SCIENTIFIC COMMITTEES AND PANELS OF EUROPEAN AGENCIES AND THE SCIENTIFIC COMMITTEES OF THE COMMISSION

1. BACKGROUND

1. Several agencies and scientific committees/panels provide scientific advice to the European Commission and, for some among them, to other EU institutions. Whilst the remit of these agencies and scientific committees/panels are clearly distinctive, there is a common interest in improving cooperation in order to develop synergies and share knowledge. One of the most useful tools to capitalise on these possibilities is by the sharing of data/dossiers of common interest. Moreover, some agencies and committees (EMEA, EFSA, ECHA and the Commission scientific committees) are statutorily required to prevent divergent opinions and may therefore have a particular need to access data available to other agencies or committees. Agencies such as ECDC and EEA for which similar requirements have not been established may be usefully associated to this, where appropriate, as part of their general commitment to provide high quality advice.

2. The agencies and scientific committees/panels referred to here are those established by the following legislative acts: EEC Regulation 1210/1990, as amended by EC Regulations 933/1999 and 1641/2003 (EEA), EC Regulation 178/2002 (EFSA), EC Regulation 726/2004 (EMEA), EC Regulation 851/2004 (ECDC), Commission Decisions 95/320/EC and 2008/721/EC (Commission scientific committees), and EC Regulation 1907/2006 (ECHA).

3. Work of the EU bodies' referred to here is based on the principles of excellence, independence and transparency. In providing their advice to EU institutions they need to take into account best scientific knowledge available and to have access to all relevant data. It is therefore of paramount importance that when the necessity arises, the scientific committees/panels are able to exchange information as necessary, in addition to the information provided by the business operators or interest groups. However, due regard must be paid to the legitimate interests of the applicants. In particular, in case of exchange of data, confidentiality requirements must apply as foreseen in the relevant legislation and unauthorised use of data provided by a third party for the benefit of another party shall not be allowed.

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2. SCOPE & OBJECTIVE

4. The exchange of data/dossiers between scientific committees/panels will take place when the necessity arises, on an ad-hoc and on-request basis, as described in paragraphs 5 and 6.

5. All EU bodies concerned produce scientific opinions which are made public and include information and data that are also publicly available (not covered by data protection or confidentiality rules). Such data include published scientific opinions, non-confidential studies, summary reports on data etc. In such cases, the objective of the guidelines is to facilitate the identification and exchange by the interested bodies of the relevant information and data already available to another body, on a matter of common interest.

6. In addition, as part of their functions certain agencies and committees/panels receive and hold data/dossiers which are confidential. This is notably the case of SANCO scientific committees, EMEA, EFSA and ECHA. In this case, confidential data/dossiers provided by a third party, which are not published as part of opinions, might need to be exchanged between agencies/scientific committees/panels. Those data/dossiers may, in particular, relate to authorisation dossiers provided by applicants/petitioners from industry in order to be assessed by the scientific committees/panels. Depending on the scope of the various scientific committees/panels mandates and legislative instruments applicable, various scientific committees/panels may look at a substance used in various applications, within the framework of different legislative requirements. The data submitted and available to the various scientific committees/panels may therefore be quite diverse as they are often submitted at different times and for different purposes.

7. The need to exchange data/dossiers may, in particular, arise when a scientific committee/panel has to assess a substance which is being, or has already been considered by another scientific committee/panel in another EU body. Such cases include, but are not limited to:

    7.1. An opinion of a scientific committee/panel on the substance considered is finalised and available. The exchange of dossier is particularly important if the scientific committee/panel which is evaluating the substance is coming to conclusions or recommendations which are different from those of the previously published opinion.

    7.2. Different scientific committees/panels are making or plan to make evaluations of the same substance for different uses. In this respect, it is expected that they exchange information in an appropriate and effective way concerning the relevant activities, in order to facilitate the identification of areas of potential overlap.

8. These common guidelines highlight also the relevant responsibilities of each Secretariat involved and the safeguards of legitimate interests of third parties. They are without prejudice to the legislative requirements set in EC Regulations 726/2004, 178/2002, 1907/2006, Commission Decision 2008/721/EC and other EU legislation on confidentiality.

9. These guidelines do not concern the exchange of information and relation with third countries or with Member States and their agencies and are without prejudice to the requirements, criteria and arrangements in that respect.

3. PRINCIPLES

10. Each EU body applying these guidelines confirms its commitment to allow and facilitate access on request for other EU bodies to the information and data referred to in paragraphs 5 and 6.

11. Each EU body applying these guidelines, to which specific provisions on the prevention of diverging opinions apply, is responsible for facilitating and ensuring appropriate and timely exchange of any relevant data if a potential for diverging advice with other EU bodies related to the availability of different data is identified, with the aim of preventing or reducing any such divergence

12. The sharing of information must safeguard the legitimate interests of third parties. In particular, scientific data provided by a business operator may not be used to the benefit of another applicant [1] (as for example stated in Article 31 of EC Regulation 1829/03), unless otherwise provided by law or by the data owner himself.

13. The transmission of relevant information should take place upon request of the concerned EU body, if the scientific committees/panels involved have identified a mutual interest in such exchange.

4. PROCEDURE

14. Requests for data sharing should be initiated by the Chairs of the scientific committee/panel via their own Secretariat. The Secretariats will take care of contacts and provide assistance for the exchanges between the EU bodies involved.

15. Any request for data sharing should be as specific as possible so as to maximise the efficiency of the exchange.

16. Each of the Secretariats involved in the exchange of information will ensure that provisions on the protection of personal data are complied with as appropriate.

17. Before exchanging dossiers, the EU bodies concerned shall agree on the modalities for their return or destruction.

18. Where relevant, submitters of dossiers/requests (business operator/applicants/ petitioner/notifiers) may be consulted when confidential data and information they provide to the scientific committees/panels, need to be exchanged within the scientific committees/panels of the EU bodies applying this guideline. The exchange will be done under condition of strict confidentiality. The Secretariat of the recipient EU body shall in particular ensure that applicable confidentiality principles and provisions, be complied with by the members of the receiving scientific committee/

[1]The possibility for the scientific committees /panels to consult other dossiers shall not exempt a requestor from providing a complete dossier.

panel, so that documents and data shared are never divulged outside the receiving EU body and that confidential data is not disclosed in the published opinions. Members of the committees and panels should be fully committed to the applicable confidentiality requirement each time information is shared.

19. It is noted that the rules covering confidentiality of SANCO scientific committees are set out in Commission decision 2008/721/EC and its Rules of Procedures as adopted on 7 September 2004 by the three scientific committees (SCCP, SCHER and SCENIHR)[2].

20. It is noted that the rules covering confidentiality of EMEA scientific committees, as well as confidentiality rules pertaining to EMEA experts and staff are applicable.

21. The rules covering confidentiality of EFSA scientific committee and panels are set out in EFSA decision on implementing measures of confidentiality and transparency requirements[3] and their Rules of Procedures as adopted by the Management Board of the EFSA[4].

22. The rules covering confidentiality of ECHA scientific committees and experts are applicable as provided for in the Rules of Procedures[5] of these Committees and in Article 105 of Regulation 1907/2006.

5. PUBLICITY OF THE COMMON GUIDELINES

23. These guidelines should be publicly available on the website of each relevant EU body.

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[2] SANCO webpage at the address: http://ec.europa.eu/health/ph_risk/documents/ev_20040907_rd01_en.pdf

[3] Decision of the Management Board of the EFSA concerning implementing measures of confidentiality and transparency requirements MB 10.05.2003 – 10, available at http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620791387.htm.

[4] Decision concerning the establishment and operations of the Scientific Committee and Panels, MB 11.09.2007 – 4.1 available at http://www.efsa.europa.eu/EFSA/AboutEfsa/WhoWeAre/ManagementBoard/efsa_locale-1178620753812_StatutoryTexts.htm.

[5] http://echa.europa.eu/about/organisation/committees_en.asp