

**ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

HAZARD ASSESSMENT

DATA OWNERSHIP IN THE CONTEXT OF SIDS INITIAL ASSESSMENTS

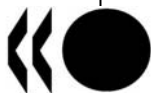
**45th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals,
Pesticides and Biotechnology**

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This document outlines the status of data ownership regarding experimental studies used for the OECD HPV Chemicals Programme as well as proposals for communicating this status to users of the assessments produced in the programme.

This document was updated based on written comments following the 45th Joint Meeting and is resubmitted to the Joint Meeting by a written procedure.

ACTION REQUIRED:

The Joint Meeting is invited to endorse the proposals outlined in this document, amended as appropriate.

DATA OWNERSHIP IN THE CONTEXT OF SIDS INITIAL ASSESSMENTS

Background

1. The 44th Joint Meeting discussed issues relative to the protection of regulatory data, following a proposal by BIAC [see ENV/JM(2009)16]. The Joint Meeting indicated its reluctance to pursue this issue any further at this time, unless the problem and possible solution in OECD could be more clearly defined [see ENV/JM/M(2009)1].

2. Nevertheless, a specific issue regarding data ownership has come up in the OECD HPV Chemicals Programme. Indeed, with the increase in regulatory data requirements in national/regional programmes, producers and importers of chemicals regularly request authorisation from the OECD Secretariat to use ~~test study results published~~ used in SIDS Initial Assessments to fulfil their national/regional legal obligations. It is therefore necessary to clarify the situation regarding the data ownership of study results submitted to the OECD HPV Chemicals Programme. The proposals contained in this document were discussed at the 2nd meeting of the Task Force on Hazard Assessment on 18-20 November 2009 and this document takes those discussion into account.

Situation with data ownership in OECD countries

3. The data ownership of study results used in the OECD HPV Chemicals Programme is not addressed in the OECD Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Existing Chemicals [C(90)163/Final]. The protection of proprietary rights of such study results is handled by national/regional legislation.

4. Nevertheless, the OECD Recommendation of the Council concerning the Protection of Proprietary Rights to Data submitted in Notifications of New Chemicals [C(83)96/Final] “recommends that authorities responsible in member countries for receiving notifications of new chemicals not accept from a notifier health, safety, and environmental data for which the notifier cannot provide a certification of the right of use, if the laboratories are not owned or otherwise affiliated with the notifier”. ~~This Recommendation has been implemented for new as well as existing chemicals in national/regional legislation of member countries. There are elements of national/regional legislation of member countries that are consistent with this recommendation.~~

5. For example:

- In the Toxic Substances Control Act of the United States, persons subject to a Section 4 test rule have an obligation from the date the test rule becomes effective until the end of the reimbursement period, to test or to obtain an exemption. Persons granted an exemption based on data submitted by others may be required to pay reimbursement to those conducting the test [see 40 CFR sec. 791]. When the test data are submitted to the authorities, the non-confidential information is made publicly available. ~~In the Toxic Substances Control Act of the United States, persons subject to a Section 4 test rule have an obligation from the date the test rule becomes effective until the end of the reimbursement period, either to test or to obtain an exemption and pay reimbursement to those conducting the test [see 40 CFR sec. 791]. When the test data is submitted to the authorities, the non-confidential information is made publicly available.~~

- Under EU REACH, the legitimate possession or access to study results is a prerequisite for registration of substances [Article 10]¹.

6. It is therefore clear that the use of study results published in SIDS Initial Assessment Reports to fulfil data requirements under national/regional assessment schemes is subject to the proprietary rights protection as defined in the legislation of those national/regional schemes. In other words, the ~~publication use~~ use of a company-owned ~~test-study~~ result in a SIDS Initial Assessments does not mean that the proprietary rights of that company are forfeited.

Proposal

7. It is proposed that the policy regarding the proprietary rights protection of study results used in the OECD HPV Chemicals Programme be published and disseminated. The following text (based on a text developed by OECD for pesticide monographs) could be used:

~~“The summaries and evaluations contained in this [these] assessment report[s] may be based on unpublished proprietary data submitted for the purpose of the OECD assessment. Authorities usually do not accept a regulatory submission based on the summaries and evaluation of unpublished proprietary data contained in this [these] assessment report[s] unless they have received the data on which the summaries and evaluation are based, either from:~~

- the owner of the data; or
- a second party that has obtained permission from the owner of the data for this purpose; or alternatively
- the applicant has received permission from the data owner that the summary and evaluation contained in this [these] assessment report[s] may be used in lieu of the data; or
- following expiry of any period of exclusive use, mandatory compensation, where required, has been offered unless the period of protection for the proprietary data concerned has expired.

~~Applicants wishing to avail themselves of information in this [these] assessment report[s] should seek advice from the regulatory authority to which application is made concerning the requirements in their country.”~~

8. This text could be published in several locations:

- On the OECD public web site referring to the published SIARs [http://www.oecd.org/document/63/0,3343,en_2649_34379_1897983_1_1_1_1,00.html].
- On the UNEP page publishing final SIARs [<http://www.chem.unep.ch/irptc/sids/OECD/SIDS/sidspub.html>].

¹ However, due to the mandatory data sharing provisions under REACH, the authority may also grant permission to use the data in specific cases without permission of the data owner.

- On the cover page of any newly published SIAR.

9. In addition to the text, links to external web pages where information is provided on how data ownership is protected in the different legislations could be provided if such web pages exist.

Copyright issues

~~10. The OECD Secretariat also frequently receives requests from companies for reuse of text from the SIAR and Dossier for drafting assessments for national/regional assessment schemes. OECD policy requests that users first ask for permission before reproducing OECD material [see http://www.oecd.org/document/56/0,3343,en_21571361_33915056_34508792_1_1_1_1,00.html].~~

~~11. As the aim of the OECD HPV Chemicals Programme is that its products are used for national/regional decision making, there should be no obstacles for reproducing text from SIARs, provided that data ownership rights are respected. It is therefore proposed to complete the above text with the additional sentences below:~~

- ~~“Provided that proprietary rights of data are protected, permission to reproduce this document is granted. The permission to reproduce OECD protected material does not extend to any material whose copyright is identified as belonging to a third party. Authorisation to reproduce such material must be obtained from the copyright holders concerned.”~~