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

Task Force on Hazard Assessment

**SUBMISSION OF ASSESSMENTS ELABORATED IN NATIONAL/REGIONAL AND INDUSTRY
PROGRAMMES: REPORT ON EXPERIENCE AT SIAM AND IMPLICATION FOR DRAFT
GUIDANCE**

3rd Meeting of the Task Force on Hazard Assessment

**29-30 June 2010, OECD Conference Centre
2 rue André-Pascal, 75016 Paris**

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This document reports recent experience at SIAM on the review of chemical assessments elaborated under national or regional programmes, and submitted for review and agreement to the OECD HPV Chemicals Programme. The document also includes a revised draft guidance for a country, region or industry organisation submitting a chemical assessment to the OECD Programme.

The draft guidance, once agreed, is intended to be part of the revised Manual for Investigation of HPV chemicals. An outline of the revised Manual is presented in [ENV/JM/HA(2010)10].

ACTION REQUIRED:

The Task Force on Hazard Assessment is invited to take note of recent experience with the review of national or regional chemicals assessment and agree on changes proposed to the draft guidance document, amended as necessary.

REPORT ON EXPERIENCE WITH NATIONAL ASSESSMENTS

1. The 44th session of the Joint Meeting in June 2009 endorsed the recommendation of the *Ad hoc* Expert Meeting on the evolution of the HPV Chemicals Programme after 2010 to elaborate procedures for submission of chemical assessments developed in national/regional and industry programmes to the OECD HPV Chemicals Programme.

2. Several countries have already implemented the recommendation successfully at SIAM 29 (October 2009) and SIAM 30 (April 2010) following draft guidance developed by the Secretariat. Table 1 below lists countries having submitted to the OECD HPV Chemicals Programme a chemical assessment prepared under a domestic or regional chemical review programme.

Table 1: List of national chemical assessments formally submitted for review and agreement at SIAM.

Chemical name	Sponsor	Type of assessment	Agreed conclusions
SIAM 29 (October 2009)			
Anthracene oils (Category)	DE	Targeted	Yes
1,2-Benzenedicarboxylic acid, bis(2-methoxyethyl) ester (Di(methoxyethyl)phthalate) (CAS. 117-82-8)	CA	Targeted	Yes
Phthalic acid, di-C7-11-branched and linear alkyl esters (CAS. 62515-42-2)	CA	Targeted	Yes
Phenol, 4,4 -(3H-1,2-benzoxathiol-3-ylidene)bis[2,6-dibromo-3-methyl-, S,S-dioxide, monosodium salt (CAS. 62625-32-5)	CA	Targeted	No ¹
Amines, C18-22-tert-alkyl, (chloromethyl)phosphonates (2:1) (ATACP) (CAS. 79357-73-6)	CA	Targeted	No ²
Lactic acid (CAS. 50215)	US	SIDS (written procedure agreement)	Yes
Methyl acetoacetate (CAS. 105453)	US	SIDS (written procedure agreement)	Yes
Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester (CAS. 61898-95-1)	US	SIDS (written procedure agreement)	No ³
Sulfosuccinates (Category)	US	SIDS (written procedure agreement)	No ⁴

¹ Withdrawn from the agenda, not formally discussed at SIAM 29.

² Not agreed at SIAM 29.

³ Not finalised by written procedure.

⁴ Not finalised by written procedure.

SIAM 30 (April 2010)			
Triclosan	AUS	SIDS	Yes
Triphenylmethyl chloride (CAS. 76-83-5)	JP	Targeted	Yes
2-Nitropropane (CAS. 79-46-9)	CA	Targeted	Yes
1,2-Dihydroacenaphthylene (CAS. 83-32-9)	JP	Targeted	Yes
2-Ethylanthracene-9,10-dione (CAS. 84-51-5)	JP	Targeted	Yes
Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)-(CAS. 17540759)	CA	Targeted	Yes

Documentation submitted

3. Experience demonstrated that the documentation elaborated under these national programmes to address national or regional requirements is very well accepted. The draft guidance was useful to help countries on how to prepare the submission for the OECD Programme.

4. The SIDS Initial Assessment Profile (SIAP, or ITAP for targeted assessments) is always prepared by countries in addition to the pre-existing documentation. The pre-existing documentation, prepared for the national or regional programme varies in nature and content but usually always contains an assessment report where results from key studies or models used are discussed. In half of the cases, robust study summaries are available to describe the details of studies considered and the extent of studies reviewed. Occasionally there were no robust study summaries submitted (e.g. triclosan, Canadian targeted assessments); however the assessment report submitted presented key studies with a sufficient level of details and discussed important aspects of the study leading to the assessment conclusion. In the case of targeted chemical assessments prepared by Canada, endpoints are mostly estimated by models or read-across from analogs. In the case where endpoints were estimated, reviewers requested the additional documentation (e.g. QSAR Model Reporting Format/QSAR Prediction Reporting Format) and this was provided by the sponsor following the commenting round.

5. From the experience so far, there has been no conflict between conclusions reached domestically and OECD conclusions. However, advice to submit national or regional assessments in a step-wise fashion remains current and is further developed in the guidance (i.e. 1st step: pre-submission to the OECD programme for initial feedback before national/regional agreement; 2nd step: formal submission to the OECD programme for agreement when assessment report is in final draft or finalised).

Publication

6. At its last meeting in November 2009, the Task Force on Hazard Assessment recommended to keep options open for the submission of draft documents and publication of final documents [see options outlined in ENV/JM/HA(2009)9], either by the OECD or by a national/regional authority. Concerning the publication however, the SIAM expressed concern that if the assessment report is published at the national, regional or industry level, it might occasionally be difficult to ensure continued access to documents if a programme ceases after some time. If that happened to be the case, OECD might archive the assessment report once published domestically. In any case, a disclaimer should be added in the SIAP/ITAP when the assessment report is not published by OECD, along the following terms: “The final screening assessment is to be published under the responsibility of [country name/authority] and is/will be available at: [URL]”.

REVISED DRAFT GUIDANCE

7. Draft guidance was presented at the second meeting of the Task Force on Hazard Assessment in November 2009 [see ENV/JM/HA(2009)9] and minimal changes are proposed in bolded text, based on experience at SIAM and feedback received. The revised guidance is presented in Annex 1.

ANNEX 1

REVISED DRAFT GUIDANCE ON THE SUBMISSION TO OECD AND PUBLICATION OF ASSESSMENTS ELABORATED IN NATIONAL, REGIONAL OR INDUSTRY PROGRAMME

In the following paragraphs, guidance for the submission to OECD and publication of assessments elaborated in national, regional or industry programmes is outlined. Bolded text reflects the proposed amendments and strikeouts are proposed deletions. This guidance is a working draft resulting from experience and discussions at SIAM and the Task Force on Hazard Assessment until June 2010. This document will be improved further as experience grows.

Documentation

There are three leading principles for the documentation submitted to the programme:

- One principle is flexibility in the documentation submitted. Usually the Manual for Investigation of HPV Chemicals is guiding sponsors in preparing the appropriate documentation. The Manual provides the details on how to prepare documents from the beginning, and should remain to be used when starting an assessment. However, when good quality assessment reports already exist, the programme should be flexible enough to allow re-use without major rewriting.
- Another important principle is to ensure that the objectives of the SIAR and Dossier are still met in a national/regional or industry assessment. The objective of the SIAR is to discuss study results that lead to the conclusion for each endpoint covered by the assessment. In case of diverging study results, the assessment report should discuss reasons for selecting the key study. The objective of the Dossier is to provide a sufficient level of details for each study considered to allow an independent evaluation of the study. Traditionally, SIAR and Dossier were contained in separate documents, but provided the above mentioned objectives are met, the programme can be flexible for the nature of the documentation itself.
- The last important principle is to maintain a common format for the conclusions between all chemical assessments, under the SIDS Initial Assessment Profile (SIAP) or the Initial Targeted Assessment Profile (ITAP). Templates for these documents already exist and should continue to be used. There has been experience in using the ITAP at SIAM 29 in October 2009, and it proves to work well.

Discussion of documents and agreement on SIAP

Generally, the following steps are followed for all types of assessments, including national, regional or industry assessments (targeted or not):

- Documents are submitted for discussion at SIAM, preferably using the same timeline as for all draft assessments;
- Documents are open for comments on the SIAM electronic discussion group until 4 weeks before the SIAM;

- RCOM⁵ and revised SIAP/ITAP are submitted on the electronic discussion group before SIAM;
- Discussion is held at the meeting on remaining issues and, if possible, the SIAP/ITAP is agreed;
- If there is no agreement at the meeting, the SIAP/ITAP is finalised via the post-SIAM electronic discussion group;

If a different timeline is required for the commenting period, a written procedure might be used to expedite comments and responses to comments to meet national/regional needs, while allowing a full discussion within the OECD via the electronic discussion group. This could be the case when the best way to obtain OECD comments is during a public consultation. In this way, there is more flexibility in accepting comments during a public consultation and making revisions to the draft assessment (situation 2 below).

Elaboration and publication of the final documents

The SIAP or ITAP remains the agreed format for the summary conclusions of the assessment and is always declassified by the Joint Meeting and published on the OECD database. Following SIAM discussions and revision of the draft assessment report, reference is made on the OECD database to such assessment report (and other relevant documentation). The publication of documents (Robust Study Summaries, Assessment Report) can take various forms as proposed below:

Situation 1- Current procedure: sponsor country has not yet published its assessment and submits draft documents to the SIAM

- SIAP or ITAP is agreed at the meeting;
- Documents (SIDS Dossier and Assessment Report) are revised by the sponsor following SIAM, based on comments received from SIAM;
- Sponsor country submits the final documents (SIDS Dossier and assessment report) to the OECD who publishes them in the HPV database;

⁵ RCOM: Responses provided by the sponsor country to comments/requests made by reviewing countries.

Situation 2- Sponsor country has not yet published its assessment and submits draft documents to the SIAM

- SIAP or ITAP is agreed at the meeting;
- Documents are revised by the sponsor following SIAM, based on comments received from SIAM;
- Sponsor country publishes the final documents;
- OECD adds a link on its database to the relevant website;
- A note is added to the SIAP or ITAP to clarify which supporting documentation was used to derive conclusions;
- **A disclaimer is added to the SIAP or ITAP along the following terms: “The final screening assessment is to be published under the responsibility of [country name/authority] and is/will be available at: [URL]”;**
- This procedure has previously been used successfully with the assessments being elaborated in the EU Existing Substances Regulation Programme.

Situation 3- Sponsor country has published its assessment, submits final documents to the SIAM, and revises the domestic assessment as appropriate after SIAM

- SIAP or ITAP is agreed at the meeting;
- **A disclaimer is added to the SIAP or ITAP along the following terms: “The final screening assessment is to be published under the responsibility of [country name/authority] and is/will be available at: [URL]”;**
- The sponsor country revises the original documents and publishes a revised version, based on comments received from SIAM;
- OECD adds a link on its database to the relevant national website where the assessment is published;
- A note is added to the SIAP or ITAP to clarify which supporting documentation was used to derive conclusions;

Situation 4- Sponsor country has published its assessment, submits final documents to the SIAM but does not revise the domestic assessment

- SIAP or ITAP is agreed at the meeting;
- **A disclaimer is added to the SIAP or ITAP along the following terms: “The final screening assessment is to be published under the responsibility of [country name/authority] and is/will be available at: [URL]”;**

- The sponsor country does not revise the original documents already published on its website;
- The OECD publishes the original documents [or adds a link to the relevant national website] and publishes or adds a link to an addendum on its database;
- A disclaimer is added to the addendum to indicate that the SIAP or ITAP reflects comments received and that the details of the original assessment need to be considered in conjunction with additional information provided in the addendum.

The addendum remains under the responsibility of the sponsor submitting the assessment. This addendum should contain any additional information requested during the commenting round as well as any changes in conclusions compared to the original assessment. The level of details in the addendum should satisfy the comments or request from reviewers, but it remains at the discretion of the sponsor. The addendum is published by the OECD, or alternatively by the Sponsor.

The overall objective of any of the options described above is to maintain transparency of decisions taken in the process, while limiting additional resources that might be needed to complete the assessment at the OECD level. Situation 4 described above is considered to be the last resort.

For national/regional assessments, the commenting process preceding a SIAM is easier when it takes place simultaneously with an organised public consultation. It avoids conflicting timelines between national/regional efforts to reach a conclusion and OECD efforts at SIAM. Stakeholders should strive to meet OECD timelines for commenting and discussion at SIAM.