CHAPTER 1

FUNCTIONING OF THE PROGRAMME

1.1 SCOPE

1.1.1 Quick Summary and objectives of the OECD Cooperative Chemicals Assessment Programme

Through a 1991 OECD Council Decision member countries decided to undertake the investigation of high production volume (HPV) chemicals in a co-operative way. These HPV chemicals include all chemicals reported to be produced or imported at levels greater than 1,000 tonnes per year in at least one member country or in the European Union region. The Decision means that member countries co-operatively:

- select the chemicals to be investigated;
- collect characterisation, effects and exposure information from government and public sources and encourage industry to provide information from their files;
- complete the agreed dossier for the Screening Information Data Set (SIDS) by testing; and
- make an initial assessment of the potential hazard of each chemical investigated.

One of the main features of the OECD Cooperative Chemicals Assessment Programme is the fact that member countries share the burden of investigating the chemicals. Each country investigates a proportion of the HPV or non-HPV chemicals in the Programme and benefits, in turn, from receiving similar data on the other chemicals from other member countries, and industry benefits from the fact that duplicative testing is reduced. Any chemical, be it an HPV or non HPV chemical, can be "sponsored" by a member country as its share of the co-operative work on HPV chemicals, or industry can decide to sponsor a chemical assessment and submit it directly. There are currently more than 1,000 substances in the Programme that have been selected for investigation by member countries. The specific selection is occasionally done in consultation with the national chemical industry.

A chemical assessment contains: *i)* an assessment report discussing the key findings for each hazard endpoint covered in the assessment, *ii)* a profile summarising the conclusions for each hazard endpoint, and *iii)* study summaries or robust study summaries for data gathered on each hazard endpoint covered in the assessment (either separately or as part of the assessment report). When a draft chemical hazard assessment is available from a sponsor, an initial assessment of the information is undertaken and conclusions are drawn on the potential hazard(s) posed by the chemical. The chemical assessment can cover all SIDS endpoints or a sub-set of SIDS endpoints (i.e. targeted assessment), with the addition of non-SIDS endpoints occasionally. A Cooperative Chemicals Assessment Meeting (CoCAM) is organized twice a year to discuss draft chemical assessments submitted by sponsors and to agree on hazard conclusions. The conclusions present a summary of the hazard(s) of the chemical, written with sufficient detail and clarity as to be informative and to assist countries with classification work and other hazard-based national decision making; and succinct exposure information to put the hazard information into context (e.g. on use of the chemical(s) in the sponsor country).

The hazard conclusions agreed at a Cooperative Chemicals Assessment Meeting (CoCAM) are endorsed by both the Task Force on Hazard Assessment and the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology consecutively. Summary conclusions are then published in the OECD Existing Chemicals Database, which is presented further in this chapter. When the hazard assessment (including the assessment report and study summaries) is finalized, it is made available to the public via the Existing Chemicals database. The hazard assessment itself can be lodged on a government website, in the Existing Chemicals database itself or on the UNEP Chemicals website.

The chemical industry supports the OECD activities on the assessment of chemicals because this work avoids duplication of costs, efforts and animal testing to fulfill various national and regional requirements and international commitments. Modalities have been established for close co-operation with the industry in the various stages of the Programme, which is undertaken in co-ordination with national, regional and other international existing chemicals programmes. The chemical industry may also submit draft assessment directly to the OECD Cooperative Chemicals Assessment Programme. Similar to any other type of chemical assessments, these draft assessments are reviewed, discussed and conclusions agreed at a CoCAM.

1.1.2 History of the programme and experience gained between 1998 and 2010

From 1988 to 1998, OECD existing chemicals activities have focused primarily on the investigation of high production volume (HPV) chemicals, based on the assumption that production volume is a surrogate for data on occupational, consumer and environmental exposure (Council Acts (1987, 1991)). The overall objective of the HPV Chemicals Programme was to co-operatively undertake an initial assessment of HPV chemicals to screen them and identify any need for further work. The Programme, based on a tenet of "learning by doing", has undergone various changes in procedural as well as policy aspects since its inception to meet the needs of the national/regional programmes of member countries. With this background and in light of the desire to significantly increase the output of the Programme and to make best use of the various industry initiatives announced at the end of the 1990s, a major refocusing was agreed in 1998. The aim of the refocused HPV Chemicals Programme in 1998 was to increase transparency, efficiency and productivity of the Programme and allow longer-term planning for governments and industry. Therefore the OECD work began to focus on initial hazard assessments of HPV chemicals and no longer included extensive exposure information gathering and evaluation. Instead,detailed exposure information gathering and assessment was no longer part of the SIDS initial assessment, but could be carried out in follow-up at the national (or regional) level as appropriate, following national (or regional) priority setting as post-SIDS work. Detailed international assessment of risks to human health and/or the environment was also no longer carried out under the guise of SIDS initial assessments.

Experience gained in the Programme since 1998, but also in member countries, in particular for grouping chemicals, using (Q)SAR results, has been formalized in a number of guidance documents and workshop reports published in the OECD Series on Testing and Assessment. A computerized (Q)SAR Application Toolbox has been developed by a dedicated Expert Group under the Task Force on Hazard Assessment and is publicly available.

Few years prior to 2010, regulatory-binding comprehensive chemical assessment programmes started to be implemented at the national or regional levels, making the voluntary OECD HPV Chemicals Programme less attractive for sponsors to participate in the way it was initially designed. This evolution forced the OECD to invent ways to maximize the usefulness of national or regional products: annexes 1 to 4 describe the synergies between national or regional chemicals assessment programmes and the OECD HPV Chemicals Programme. This evolution also promoted integrated approaches to testing and assessment. These approaches encourage the regulatory acceptance of non-test data, allow reduction of animal testing, and enable the assessment of larger numbers of chemicals based on e.g. similarity in structure, mode of action, metabolic pathways, etc.

1.1.3 Main features of the OECD Cooperative Chemicals Assessment Programme starting in 2010

The OECD Cooperative Chemicals Assessment Programme continues to examine full SIDS assessments, and also encompasses assessments covering a sub-set of SIDS endpoints or non SIDS endpoints (targeted assessment) for chemicals of sufficient global interest, be they HPV or non HPV chemicals. Procedures for submitting a targeted assessment are developed in section 1.3.1 of Chapter 1. Another new feature is the assessment of groups of chemicals for a sub-set of SIDS or non SIDS endpoints (e.g. bioaccumulation or carcinogenicity). Guidance and procedures for the submission of targeted chemical categories are developed in section 1.3.2 of Chapter 1.

A strong focus of the new OECD Programme is also the use of *in silico* methods such as the (Q)SAR Application Toolbox for predicting or estimating (eco-)toxic or fate properties, or simply to support weak experimental results.

Another change is that the outcome of the assessment does not result in a recommendation. Experience has demonstrated that these recommendations were not followed by countries in setting their national priorities, while considerable time was spent at SIAM discussing the wording of such recommendations. In the new OECD Programme, the assessment concludes on the hazard(s) identified, if any.

Finally, requirements on exposure information in the new OECD Programme have been reduced to use pattern and indication of production volumes.

1.1.4 The OECD List of High Production Volume Chemicals, the OECD Existing Chemicals Database and the global portal to information on chemical substances (eChem Portal)

The OECD List of HPV Chemicals serves as the overall priority list from which HPV chemicals are selected for SIDS data gathering and testing and initial hazard assessment. It is compiled by the Secretariat on the basis of regular submissions by member countries reporting those industrial chemicals for which a Chemical Abstracts Service (CAS) Registry Number had been assigned and which are produced or imported at levels greater than 1000 tonnes per year. The most recent OECD HPV Chemicals List is that compiled in 2007, which contains 4,636 substances and is based on submissions of eight national inventories and that of the European Union. The next List will be compiled in 2012.

The status of all chemicals within the process of investigation in the OECD Cooperative Chemicals Assessment Programme is recorded in the OECD Existing Chemicals Database. At any moment, a status report can be generated from the database. The database contains the list of all OECD chemicals together with any annotations on each chemical which has been provided by member countries to the Secretariat. Each chemical is identified as to which stage it is at in the assessment process for those chemicals which have already been selected for sponsoring. Once the assessment of a chemical is finalized it shows the conclusions of the assessment. A link to internet pages where completed assessments can be downloaded is also included.

1.2 GENERAL PROCEDURES

1.2.1 Role of SIDS Contact Points

Each member country as well as non-governmental organizations (Business and Industry Advisory Committee or BIAC, Trade Union Advisory Committee or TUAC, European Environmental Bureau) involved in the OECD work on chemicals nominates a SIDS Contact Point who organizes the actual work and acts as a point of contact with the OECD Secretariat. The list of SIDS Contact Points can be found in the OECD Existing Chemicals Database (http://www.oecd.org/env/existingchemicals/data; see also section 1.10). Occasionally, the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology is consulted to update the list of SIDS Contact Points.

- The responsibilities of the SIDS Contact Point in member countries include: nominating chemicals or groups of chemicals that will be sponsored by the corresponding member country, in collaboration or not with a chemical company or consortium;
- overseeing the preparation and peer-review of draft assessment documents in its country prior to submission to the OECD Programme and submitting all draft assessments to be reviewed by other countries on time before the Cooperative Chemicals Assessment Meeting (CoCAM);
- coordinating the review of draft assessment documents prepared by other member countries, regions or by industry, as well as other proposals and documents prepared by the Secretariat. This involves distributing draft assessments or documents to national experts, compiling the various comments and contributions received domestically and submitting the compilation to the Secretariat on time before the CoCAM;
- ensuring that any revisions needed to the hazard assessment based on comments received from other member countries are addressed on time prior to the CoCAM;
- nominating through official OECD channels (ENV Counsellors to OECD Permanent Delegations in Paris) the participants to the CoCAM who will present the draft assessments;
- overseeing the finalization of assessment documents for publication and transferring final documentation or a link to the relevant site of publication to the Secretariat.

The role of the SIDS Contact Point of BIAC includes:

- facilitating the preparation of the initial assessment documents by industry;
- distributing comments on initial assessment documents, testing plans and category proposals posted on the community website for discussion by member countries as well as any other proposals from the Secretariat within industry;
- co-ordinating and posting on the community website for discussion industry comments on proposals from member countries or the Secretariat;
- nominating the industry experts participating in the CoCAM (both on the community website for discussion and at the meeting itself) directly to the OECD Secretariat;
- nominating delegates participating in the CoCAM on behalf of BIAC.

SIDS Contact Points in non-member countries contributing to the Programme are nominated in a coordinated way by the United Nations Environment Programme (UNEP), or the International Programme on Chemical Safety (IPCS).

Their roles and responsibilities are similar to those described above for SIDS Contact Points in member countries, but limited to reviewing stages of the assessment documents or proposals and documents from the Secretariat. For EEB and TUAC, the task of their SIDS Contact point is also limited to the review of assessment documents or proposals and documents from the Secretariat.

1.2.2 Selection and registration of sponsored chemicals

SIDS Contact Points should select chemicals or categories of chemicals that they wish to sponsor according to the current list of candidates on the OECD Existing Chemicals Database (the OECD HPV-List). Non-HPV chemicals can also be selected. Direct submission of a chemical assessment by industry is also possible. Co-sponsorship of chemical assessment by two member countries is also possible, if there is mutual interest or benefit to it.

In selecting chemicals to sponsor, SIDS Contact points should be mindful of the need to avoid duplicative work and avoid selecting chemicals for which assessment work might be on-going in another country, region or organization . Information on the status of assessments of substances in other countries, regions or organizations may be available through the eChemPortal database (http://www.oecd.org/ehs/eChemPortal)

In case member countries wish to sponsor a category that includes non-HPV chemicals, the Secretariat will add the non-HPV chemicals to the OECD Existing Chemicals Database and create the new category.

If member countries want to withdraw the sponsorship of a chemical, they should inform the Secretariat, who will revise the entry in the OECD Existing Chemicals Database. Information on new registrations or changes of sponsorships will be posted by the Secretariat on the community website for discussion (https://community.oecd.org/community/cocam) under "*Recent changes to the status of SIDS Chemicals*" approximately once a month as appropriate.

1.2.3 Submission of SIDS Documents and Use of the Community Website

As described in following chapters of the *Manual for the Assessment of Chemicals*, in preparation for a Cooperative Chemicals Assessment Meeting (CoCAM), several documents need to be prepared and submitted by sponsors. All member countries (sponsors and non-sponsors) are invited to prepare and submit their comments to these documents. Other documents that may be distributed for comments and review by member countries include:

- SIDS Plan (see Chapter 2, section 2.3 The SIDS Plan);
- Category Proposals (see Chapter 2, section 2.3.3 Determining What Chemical to Test).

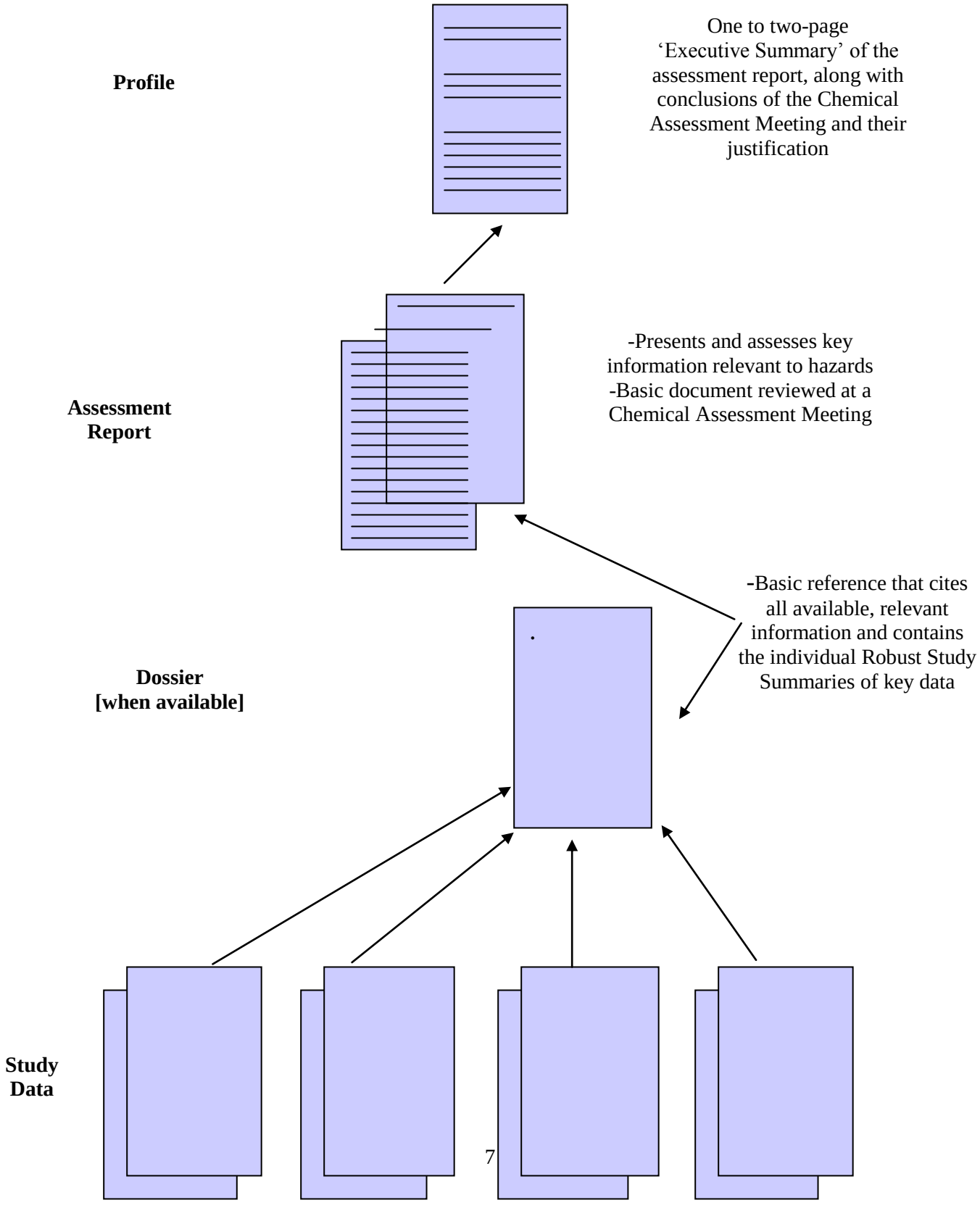
Documents that are usually prepared for the initial hazard assessment of a substance or chemical category are:

- SIDS Dossier(s) or Robust Study Summaries (see Chapter 2);
- SIDS Initial Assessment Report or Initial Targeted Assessment Report (see Chapter 5);
- SIDS Initial Assessment Profile or Initial Targeted Assessment Profile (see Chapter 6).

The relationship between the assessment report, the profile and the dossier containing study summaries is presented in Figure 1. Care should be taken to ensure that the assessment report describes and interprets the relevant hazards focusing on key studies for each endpoint rather than merely repeat the details given in the SIDS Dossier. The profile only describes the summary conclusions of the hazard assessment.

Although a separate dossier with robust study summaries is recommended to be submitted along with the profile and assessment report, some assessment reports from national or regional programmes will not have separate robust summaries. When no dossier is submitted, however, the assessment report should provide information that is comprehensive enough in experimental details and results, especially for unpublished studies.

Figure 1: Illustration of Documents Considered at a Chemical Assessment Meeting



The sharing of the above documents with other SIDS Contact Points is achieved via the community discussion group . The community discussion group is an electronic dialogue tool to exchange information and comments among SIDS Contact Points and the Secretariat. It is a useful mechanism for the Secretariat to produce a consolidated list of all the comments pertaining to each individual chemical for discussion (the "collated comments") and to disseminate useful information and documents for a CoCAM. This enables efficiency of discussions at the CoCAM, as it is not necessary to repeat all of the comments made prior to the meeting on the community website. It also allows sponsors to prepare their responses to these comments in advance of the CoCAM. Thereby only outstanding issues need to be discussed at the CoCAM.

1.2.4 Who places documents on the community discussion group

The posting of documents on the community website is limited to SIDS Contact Points and the Secretariat.

- The incoming draft hazard assessments are generally uploaded on the community website by the Secretariat who received them via email from sponsors.
- Comments on draft hazard assessments are posted directly by SIDS Contact Points.
- Responses to comments and revised SIAPs/ITAPs are posted directly by sponsors.

A typical time schedule for the preparation of a CoCAM is as follows:

Posting of SIDS Documents on the community website for Chemicals to be discussed at a CoCAM.	At least 13 weeks in advance of the CoCAM.
Submitting comments on the SIDS Documents to the community website.	At least 5 weeks in advance of the CoCAM.
Submitting responses to comments as well as a revised SIDS Initial Assessment Profile to the community website.	At least 1 week in advance of the CoCAM.

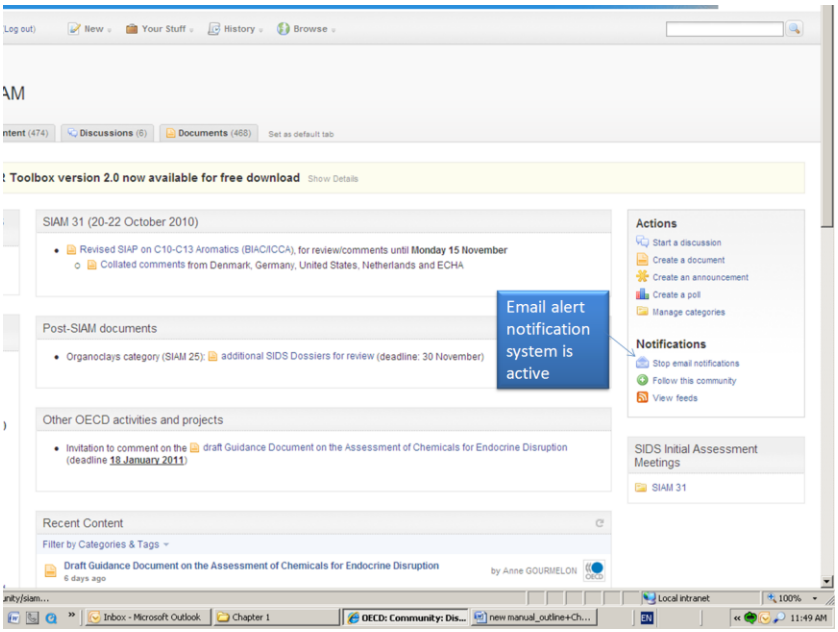
Following submission of SIDS documents on the CoCAM community website, the Secretariat circulates a *Review plan* where countries can indicate which substance(s) and which part of the assessment(s) (environment or human health) they wish to review and submit comments for. A template file for the submission of comments is always available on the CoCAM community website for use by the reviewers. The use of the template facilitates the collation of comments and the response to comments.

Following the final deadline for comments on the CoCAM community website, the Secretariat collates all comments from all reviewers into a single document for each chemical assessment. The sponsor then uses the file with collated comments to enter its responses to comments.

The CoCAM may decide, on a case by case basis, that the assessment for a chemical is agreed by written procedure. Revised documents will be posted on the CoCAM community website for final review and agreement by the member countries. Thereby only a *pro forma* endorsement will be needed at a CoCAM.

Documents on any other issues to be discussed at a specific CoCAM are also posted and discussed on this community website.

Whenever a new document is placed on the community website, the notification system can automatically informs all SIDS Contact Points that a new document has been posted, if such system is activated.



Furthermore, an e-mail message is sent from the Secretariat to SIDS Contact Points (and copied to Task Force members) whenever a particularly important issue is placed on the community website for which the sponsor needs comments (e.g. a proposal for a testing plan).

1.2.5 Names of files posted on the Community Website

To facilitate the exchange of files posted on the community website, common names for certain files are proposed below. All documents should be submitted as WORD files (not PDF files).

Document	**File name**
SIDS Dossier	"CAS No._Dossier" (e.g.: 50000_Dossier) This rule also applies to IUCLID reports. Robust Study Summaries should be integral part of the SIDS Dossier and should not be submitted separately.
SIAR or ITAR	"CAS No._SIAR" (e.g.: 50000_SIAR) or "Name of category_SIAR" (e.g.: alphaOlefins_SIAR) "CAS No_ITAR"
SIDS Profile	"CAS No._SIAP" (e.g.: 50000_SIAP) or "Name of category_SIAP" (e.g.: alphaOlefins_SIAP) or "CAS No_ITAP"
Comments	"COM_CAS No_countryname"
Response to comment	"RCOM_CAS No_countryname"
Revised SIDS Profile	"CAS No_SIAP_rev" or "CAS No_ITAP_rev"

1.2.6 Data Collection and Preparation of SIDS Dossiers and/or Robust Study Summaries, Assessment Report and Profile

Once a chemical is selected by a sponsor for investigation, the first activity involves collection of existing information on the substance and collating it in a SIDS Dossier. When no experimental information is available for a given data element, calculation or estimates derived from Quantitative Structure Activity Relationships (QSARs) can be provided, on condition that the chemical is in the applicability domain of the estimation method, and that the relevance and reliability of the method are already established [adequate documentation should be readily available]. Chapter 3 of the Manuel provides further guidance on using (Q)SARs.

The quality of the data collected is of great importance. In order to harmonize data evaluation and to assist preparation of SIDS Dossiers for selected chemicals, OECD has prepared guidance for evaluating and documenting the quality and adequacy of test and non-test data (see also Chapter 3, Section 3.1 of the Manual).

The most efficient way of collecting data is to use the robust study summaries — they allow collection of all information necessary to a good assessment of the study reliability. Templates have been developed for the various SIDS endpoints. The robust study summaries form the basis of the SIDS Dossier (Chapter 2 of the Manual), which is itself the basis for the SIDS Initial Assessment Report (SIAR) (see also Chapter 5 of the Manual). A Profile (SIAP or ITAP) summarizing the conclusions of the chemical assessment is prepared and submitted with the SIAR and SIDS Dossier including the Robust Study Summaries.

Hazard assessments submitted to the OECD programme may sometimes vary depending on whether they were prepared explicitly for the OECD Programme, or whether they are derived from national assessment programmes. In order to make the maximum use of assessment products coming from national programmes, it was agreed that the SIDS Dossier containing the Robust Study Summaries is not a must. However, assessment reports not containing a SIDS dossier should at a minimum provide detailed information equivalent to a robust study summary on the key studies used to derive conclusions on SIDS and non SIDS endpoints.

1.2.8 SIDS Testing

For any SIDS element on effects or characterization for which no data are available or the data are not considered adequate, testing will in principle be carried out. In certain cases (e.g. site limited intermediates) supported by adequate rationale chemicals can be exempted from new testing. Nevertheless, countries are discouraged from selecting chemicals with limited exposure potential.

Any new testing to complete the SIDS should be conducted according to the OECD Test Guidelines and the Principles of Good Laboratory Practice (GLP), in order to ensure that generated data are mutually acceptable among member countries, as specified in the 1981 OECD Council Decision on the Mutual Acceptance of Data.

1.2.9 Data quality and review

The initial data quality review is performed by the sponsor preparing the hazard assessment (member country, regional authority or industry). For transparency on the assessment process, it is important that the modalities of the data review are described in the assessment report.

The CoCAM provides the final check of the quality and adequacy of the SIAR and the data behind it, as well as the acceptability of assessing a group of chemicals together or not undertaking specific testing. Sponsors may, of course, request comments or advice from other SIDS Contact Points at any time in the process leading up to finalization of a SIDS Initial Assessment Report or an Initial Targeted Assessment

Report (through the community website for discussion) and are encouraged to do so, especially in the case of the use of chemical categories. In every case, the SIDS Dossier - the adequacy and quality of data therein and any rationale for not undertaking SIDS testing - can be reviewed by all stakeholders in the framework of the evaluation of the SIAR at and leading up to the SIDS Initial Assessment Meeting.

1.2.10 SIDS Initial Assessment Report (SIAR) and Initial Targeted Assessment Report (ITAR)

Once all the data elements of the full SIDS assessment or of the targeted assessment have been obtained for the sponsored chemical, the SIDS Initial Assessment Report (SIAR) or the Initial Targeted Assessment Report (ITAR) is prepared based on the information in the full SIDS Dossier or in the robust study summaries for the key studies. The SIAR or ITAR draws conclusions on the potential hazard(s). A SIDS Initial Assessment Profile (SIAP) or an Initial Targeted Assessment Profile (ITAP) summarises the rationale for the conclusions (see also Chapter 5).

Guidance on the initial assessment of aquatic effects (see also Section 4.2 of Chapter 4 and health effects (see also Section 4.3 of Chapter 4) to be used in carrying out initial assessments and preparing conclusions on these endpoints have been developed by OECD, taking into account experience from CoCAM.

The assessment report (SIAR or ITAR), which includes evaluations and conclusions and an Initial Assessment Profile (SIAP or ITAP), together with the SIDS Dossier (including robust study summaries), is made available electronically by the Secretariat to SIDS Contact Points prior to the Cooperative Chemicals Assessment Meeting (CoCAM) via the community website for discussion at the following URL: (https://community.oecd.org/community/cocam) for review and comments by member countries.

1.2.11 Review and agreement by CoCAM

At the CoCAM itself, the SIAP or ITAP is discussed.

Other assessment documents (e.g., SIAR or ITAR) may be discussed if there are questions about data as it pertains to the SIAP or ITAP. However, consensus is reached only on the hazard(s) conclusions that are presented in the SIAP or ITAP.

This process results in an internationally agreed hazard assessment for each chemical with agreed conclusions.

Participants in the CoCAM include:

- representatives of the country or industry that sponsored the chemical or category;
- representatives from other member countries and the European Commission;
- experts from non-member countries nominated by IPCS or UNEP;
- experts nominated by OECD's BIAC, TUAC and by environmental citizens' organizations;
- representatives of companies which produce the chemical (for that part of the discussions which concerns their chemical);
- secretariat staff from OECD.

The Chair of CoCAM is usually designated by the OECD Secretariat.

1.2.12 In case of comments following a CoCAM

This document is intended to clarify the process of review, agreement (or endorsement), and declassification of draft hazard assessment conclusions (i.e. SIAP/ITAP) following submission of a chemical assessment to the CoCAM.

It should be noted that the process outlined below follows the OECD procedures, namely that a document agreed by an expert group requires endorsement by its parent body (Working Group or **Task Force**), followed by an agreement from the **Joint Meeting** to declassify the document. At each step of the process, comments may arise. These rules apply to all documents and it should be noted that revisions to a document are not unusual, even after it has been agreed by an expert group.

Generally, when a document has been agreed by an OECD expert group, the technical part of the document is not revised substantially by the parent body upon submission for endorsement. However, it happens regularly that the parent body may wish to use its technical expertise to review a technical document when the document presents specific challenges.

Concerning the specific case of the Cooperative Chemicals Assessment Meeting, the following was discussed and agreed at CoCAM. For difficult cases (e.g. large chemical categories, UVCBs), sponsor countries and industry could use a stepwise submission process extending over two CoCAM periods to ensure that all concerns from countries are taken into account by the time the SIAP/ITAP is agreed at the meeting. The advantage of this stepwise process is that sponsors take the time they need to address extensive comments, provide the responses to comments and revised SIAP/ITAP in a thorough way before final approval at a meeting; but the disadvantage is that sponsors have to attend two meetings instead of one. Although this option could be chosen by sponsors occasionally, it was not favored. Generally for anticipated difficult cases, they are placed early on the CoCAM meeting agenda. Alternatively, the review of the chemical assessment can be split between the human health and the environment sections of the assessment, or other variations as appropriate. In case of a split of the chemical assessment between the human health and the environment part, each part is declassified as a stand-alone document. In other words when only one part (human health or environment) of a SIAP is agreed it will be published with other agreed SIAPs/ITAPs from the same meeting to avoid being declassified at a later date when the other part is completed and declassified.

Process for cases of serious considerations after the CoCAM

In case of serious further considerations following agreement at CoCAM, commenters contact the Secretariat in the two-week period after the meeting, and the whole CoCAM is informed via the community site of such comments, and an action is taken to address the problem. In case of no comment, the IAPs/ITAPs are submitted to the Task Force on Hazard Assessment without further delay.

Process followed in case of comments at the level of the Task Force on Hazard Assessment

Upon submission of SIAPs/ITAPs to the Task Force, a six-week period is given for review and endorsement. Whenever comments/proposed revisions to a SIAP/ITAP arise from the Task Force, the Secretariat posts the comments (be they editorial or technical in nature) on the community site for CoCAM. It is the responsibility of the sponsor to accept or not accept the comments.

When a reaction from the sponsor of the assessment is solicited, the timeline is **two weeks** for review and reaction. In the absence of reaction the proposed changes are accepted and considered agreed by the CoCAM, to avoid delaying the process leading to declassification for other SIAPs presenting no particular issue. In case of disagreement, the SIAP/ITAP is referred back to another meeting.

In case the Task Force or the Joint Meeting has **questions**, these questions should be clearly raised outside the SIAP/ITAP document to maximize chances of obtaining a response to the question.

When agreement is finally reached at the CoCAM and its parent body (Task Force on Hazard Assessment), the SIAPs/ITAPs are submitted to the Joint Meeting for agreement on declassification. Even then, the Joint Meeting may use its technical expertise to make comments, in rare cases.

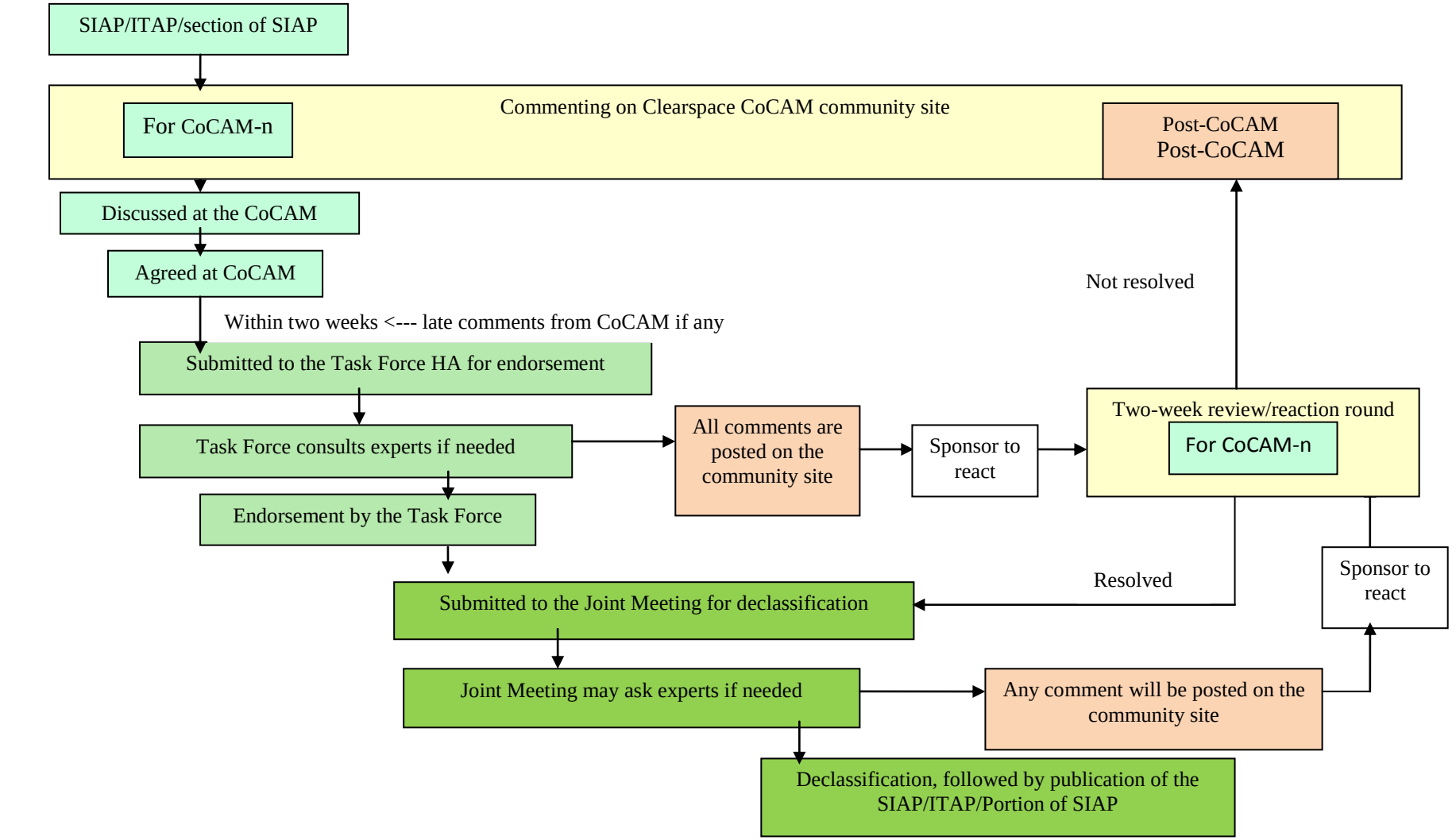


Figure: proposal for a general process for Cooperative Chemicals Assessments

1.2.13 Outcome and public availability

For each chemical assessment, the end product of the work, in the framework of the OECD Cooperative Chemicals Assessment Programme, is quality information addressing all or a sub-set of the SIDS endpoints, contained in an assessment report. This information will have been evaluated, and conclusions on the potential hazard(s) posed by the chemical agreed among member countries.

The conclusions present: i) a summary of the hazards of the chemical, written with sufficient detail and clarity as to be informative and to assist countries with classification work and other hazard-based national decision making, and ii) exposure information to put the hazard information into context (e.g. on use in the sponsor country).

The conclusions on the chemicals agreed at a CoCAM are reported together with their rationale in the SIDS Initial Assessment Profile to the Task Force on Hazard Assessment and confirmed. They are subsequently transmitted to the Joint Meeting for endorsement. It is expected that these conclusions will be used by member countries for national and regional priority-setting activities.

Sponsors finalise the assessment report by seeing that the comments provided by other countries and the discussion at a CoCAM are taken into account, and submit it to the OECD Secretariat together with the revised SIDS Dossier or robust study summaries, as appropriate. If the assessment report is published on a national website, the sponsor provides the link to the website to the OECD Secretariat for inclusion in the Existing Chemicals database.

The Secretariat transfers the submitted SIAR and other information to UNEP Chemicals for inclusion in their database and publication as a contribution to the Inter-organisational Programme on the Sound Management of Chemicals (IOMC). They are also made available on the Internet (UNEP SIDS document) or in the Existing Chemicals database. In this way, all information resulting from the OECD Cooperative Chemicals Assessment Programme is available worldwide.

1.2.14 Data and information management

An internet database (OECD Existing Chemicals Database) has been developed by the Secretariat that tracks the status of investigation of all HPV chemicals on the list[1], so that all stakeholders will be able to follow the progress made through the various stages of the Programme.

In addition, consensus has been reached on the development and use of a single electronic system (i.e. IUCLID) for capture, storage and circulation of data for use in the Programme.

1.2.15 Policy Oversight

The Task Force on Hazard Assessment —open to membership by all member countries and observers from industry, labour and environmental citizens' organizations —oversees the policy development and implementation of the OECD Cooperative Chemicals AssessmentProgramme. Broad oversight and co-ordination with other parts of the OECD Chemicals Programme is the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

[1] The list of HPV chemicals is available in the Existing Chemicals database and is periodically updated by member countries.

1.2.16 Co-operation with other International Organisations

In the 1990 Council Act, it was decided that member countries shall make information obtained from the co-operative investigation of existing chemicals in OECD publicly available via UNEP Chemicals, while respecting legitimate claims for protection of confidential data. UNEP Chemicals has agreed that it will not only work as an archive for the data collected or generated in the OECD Programme, but also disseminate data through its databases. Therefore, SIDS Initial Assessment Reports and all information summarised in the SIDS Dossiers are transmitted to UNEP Chemicals once agreement on the initial assessment has been reached. Responding to the request made by UNCED in Agenda 21, Chapter 19 to expand and accelerate the international assessment of chemical risks, UNEP Chemicals issues a series of documents including the OECD initial assessments of HPV chemicals, both in paper form and on the Internet (UNEP SIDS document).

The International Programme on Chemical Safety (IPCS) was invited, also through the Council Act, to use the results of the investigations of existing chemicals by OECD member countries in preparing its assessments of the health and environmental impacts of existing chemicals. Information collected in OECD will be used in the preparation of Environmental Health Criteria or other documents by the IPCS on specific chemicals of concern. IPCS and the Intergovernmental Forum on the Chemical Safety (IFCS) are also invited to nominate experts from non-member countries to review SIARs and take part in CoCAMs. IFCS, IPCS and UNEP Chemicals are SIDS Contact Points.

A Co-ordinating Group on the Assessment of Existing Chemicals and Industrial Pollutants was established in 1999 under the auspices of IOMC to co-ordinate the work on existing chemicals between IPCS and OECD. One of the tasks of the Group is to oversee any pilot projects on international co-operation.

1.3 PROCEDURES FOR TARGETED ASSESSMENTS, TARGETED CHEMICAL CATEGORIES AND NATIONAL ASSESSMENTS

1.3.1 Guidance on procedures specific to targeted assessments

Nature and purpose of a targeted assessment

A targeted assessment in the context of the OECD Cooperative Chemicals Assessment Programme is a hazard assessment that addresses only a limited number of hazard endpoints, e.g., short of the full SIDS elements.

The purpose of preparing targeted assessments at OECD is to increase the availability of internationally agreed hazard assessments (even if it is on a limited number of endpoints) and thereby to contribute to the overall goal of SAICM of sound management of chemicals.

It is not necessary to develop criteria for elaborating targeted assessments, but sponsors should provide an explanation for targeting an assessment. Possible explanations for preparing a targeted assessment may vary and could include:

- Focus on identified hazards that might be significant in relation to subsequent risk assessment or risk management.

- Hazard communication, i.e. dissemination of agreed hazard characterizations for specific endpoints that were not previously public.

Targeted assessments can be prepared for HPV and non HPV chemicals. Furthermore, to maximise the usefulness of targeted assessments to member countries, the endpoints assessed should be relevant for purposes of risk assessment, classification and labelling and/or risk reduction.

Endpoints considered to be assessed in the targeted assessment and information on non-targeted endpoints?

Any endpoint for which an (initial) hazard conclusion can be drawn can be regarded as assessed. For any given SIDS element, to be able to propose a conclusion, the information requirements as outlined in the *Manual* should be fulfilled.

It should be considered that some endpoints other than the targeted endpoint need sometimes to be addressed to reach a conclusion on the targeted endpoint (e.g. water solubility and Kow for aquatic toxicity).

A sponsor submitting a targeted assessment commits only to drafting and finalising the assessment on the targeted endpoints. If additional information on the targeted endpoints is made available by other parties (member countries, industry, NGOs), these should be taken into account by the sponsor. If another sponsor wants to expand the targeted assessment to other endpoints, it should be the responsibility of that second sponsor to prepare the assessment for those additional endpoints.

A targeted assessment can also address non-SIDS endpoints or even address only non-SIDS endpoints, e.g. bioaccumulation.

For endpoints for which conclusions are proposed, all available information should be presented. For endpoints for which no conclusion is proposed, the available information could be omitted if it is clearly stated that such information has not been gathered. The Initial Targeted Assessment Profile (ITAP, see also Chapter 6 for a template) should contain only the conclusions on the targeted endpoints.

A targeted assessment for a chemical category

Assessments for chemical categories can be targeted to a limited number of endpoints (e.g. aquatic toxicity for aliphatic aldehydes), similar to assessments for individual substances. Nevertheless, endpoint results which are relevant for the category justification, e.g. for some physical-chemical properties, should be available. Additional guidance on targeted categories is provided below.

Disclaimer

A TA should clearly be labelled as such and it should be clear to the reader that it is not a full SIDS Initial Assessment. Furthermore, those endpoints for which conclusions can be drawn should be clearly listed in the disclaimer. The disclaimer would be inserted on top of the Initial Targeted Assessment Profile (ITAP) and on the cover page of the assessment report. Proposed wording for the disclaimer is:

- "The present assessment is targeted to address only the following endpoint(s): [list of endpoints]. It cannot be considered as a full SIDS Initial Assessment. Nevertheless, the conclusions for the endpoints addressed have been agreed by member countries and may be used by chemical safety professionals."

Documentation to accompany the targeted assessment

Documentation can be flexible. The same SIAR and SIDS Dossier templates as for full SIDS Initial Assessments, as outlined in the *Manual*, can be used by filling them only with the information to be communicated. Other types of reports can also be used if they fulfil the objectives of a SIAR and SIDS Dossier. For endpoints for which conclusions are proposed, all available information should be presented and details comparable to a Robust Study Summary should be available for the key studies. An ITAP according to the template in Chapter 6 should also be elaborated. This will be the basis for the discussion and will have to be agreed upon by member countries.

Procedures for submission and update of a targeted assessment

TAs can be assessed in the OECD using the same procedures as for full SIDS assessments and be discussed at CoCAMs. The ITAP would be published by OECD. The underlying documents e.g. targeted assessment report and Robust Study Summaries could be published by OECD, but also national/regional authorities or industry, depending on whether they were originally drafted for national/regional or industry programmes. Guidance on procedures for submitting national/regional or industry reports to the OECD are available below.

Targeted assessments can be updated at any time by any sponsor country or by a company or consortium of companies via BIAC. Proposals for updating could concern new information on endpoints previously agreed or proposals for agreement on endpoints that had previously not been assessed.

Credit for a targeted assessment?

Sponsors of TAs should get recognition for their work. The sponsorship will be published in the OECD Existing Chemicals Database. To distinguish between full SIDS Initial Assessments and TAs, separate statistics will nevertheless be made available to member countries.

1.3.2 Guidance on procedures specific to targeted chemical categories

Definition

A targeted chemical category in the context of the OECD Cooperative Chemicals Assessment Programme can be defined as a hazard assessment for a group of chemicals that addresses only a limited number of hazard endpoints, e.g., short of the full SIDS elements or a focus on one or more non-SIDS endpoints.

Preliminary considerations

- The concept of chemical categories defined by an applicability domain (or targeted extended categories) is viable. This kind of product can be elaborated within the OECD Cooperative Chemicals Assessment Programme. Sponsors in countries or industry can submit draft targeted extended categories to CoCAM for discussion at any time, in line with the review schedules.

- It is a means to assess more systematically larger groups of chemicals including low-tonnage chemicals.

- Mechanistic understanding of the effects seen in tested category members increases the confidence for predicting the effects in untested members.

- Elaborating and publishing such targeted extended categories is useful even if no firm conclusion can be drawn for the untested chemicals provided that recommendations are made as to the information that has to be generated to be able to draw conclusions.

Options for application

Option 1: Classic targeted categories

Numerous chemical categories have been assessed within the OECD HPV Chemicals Programme. They have usually been developed for a limited number of clearly identified chemicals and data gaps for the listed category members are filled individually.

Such categories can also be targeted to a limited number of endpoints (e.g. repeat dose toxicity for menthols). There would be no difference in the type of documentation made available compared to full SIDS chemical categories. The guidance as developed for targeted assessments would also apply.

In addition to the endpoints targeted in the assessment, reliable information would need to be available for all category members for endpoints which are crucial for the category justification, e.g. physical-chemical properties relevant for the targeted endpoints.

Option 2: Extended targeted categories

A category can also be defined by its applicability domain (AD). The AD of a category identifies the structural requirements and ranges of physicochemical, environmental fate, toxicological or ecotoxicological properties within which reliable estimations can be made for the category members [see Chapter 3 for Guidance on Grouping of Chemicals].

It can therefore be envisaged that categories are developed with well defined applicability domains and targeted towards one or several regulatory endpoints, e.g.:

- Skin sensitisation for chemicals having the potential of protein conjugation via nucleophilic addition to ketones.

- Reproductive toxicity for ethylene glycol ethers.

- Acute toxicity to fish for saturated aliphatic aldehydes.

Compared with the classical chemical categories outlined above, not all members of the category would be identified individually but a hazard assessor would have to decide whether a chemical belongs to a category or not by verifying whether the chemical fulfils the requirements of the applicability domain.

To be useful to member countries and other stakeholders, these categories have to propose conclusions for the regulatory endpoints covered as well as proposals as to how to fill data gaps (either qualitatively or quantitatively) for untested chemicals in the applicability domain.

The advantage of developing such categories is that they can be published and referenced, i.e. whenever a chemical is assessed that falls within the respective applicability domain, the chemical category is referenced and the data gap is filled according to the proposals outlined in the category. It is not necessary

to redevelop an analogue approach or full category approach to fill a data gap. These categories can also be updated as new experimental information becomes available.

Such categories can also be based on existing categories that are extended to other candidate chemicals.

Guidance

The guidance below only applies to extended targeted categories as outlined in option 2 above. It is meant to be complementary to the guidance provided in Chapter 3. Existing guidance from that document is not repeated here. No new guidance is needed for elaborating targeted categories according to option 1 above, as the existing guidance for grouping chemicals and for elaborating targeted assessments is sufficient.

For illustrative purposes, an example is provided throughout this section.

Defining the members of the category

The membership of a chemical to an extended targeted category is defined by the applicability domain (AD) of the category. The AD of a category identifies the structural requirements and ranges of physicochemical, environmental fate, toxicological or ecotoxicological properties within which reliable estimations can be made for the category members [see OECD Guidance on Grouping of Chemicals, ENV/JM/MONO(2007)28]. The structural requirements of the applicability domain include a description of the functional groups that a chemical can contain or which are excluded.

While it is not necessary to list all the chemicals that are covered by the category, it is necessary to define as precisely and unambiguously as possible the applicability domain of the category so that any reader of the category assessment can easily determine whether a given chemical belongs to the category.

The category definition can combine structural characteristics, physical-chemical properties, mechanism or mode of action as well as results from other (eco)toxicological endpoints including from *in vitro* test systems.

Example: primary saturated aliphatic C2-C8 (linear and branched) thiols

The example chemical category is: primary saturated aliphatic C2-C8 (linear and branched) thiols. The domain of the category is defined by structure only: only primary saturated linear and branched aliphatic thiols with chain lengths between C2 and C8 are members of the category. No other functional groups are allowed in the structure. Furthermore structures with more than one thiol moiety are excluded. Secondary and tertiary thiols are also excluded.

Defining the endpoint(s) covered by the category

An extended targeted category can address any endpoint(s) of regulatory relevance. The endpoint(s) that can be addressed is (are) not restricted to the SIDS elements.

If results for other endpoints are needed, either to decide whether a chemical belongs to the applicability domain of the category or to estimate the targeted endpoint(s), these should be highlighted.

Some endpoints, such as repeat-dose toxicity are not well defined endpoints in the sense that the derived NOAEL from an experimental study can be based on one or several out of a multitude of observable effects. For these endpoints it is necessary to specify which specific effect is covered by the category.

Example: primary saturated aliphatic C2-C8 (linear and branched) thiols

The only endpoint covered is 96h LC50 for fish. Furthermore, reliable results for Log Kow have to be available for all chemicals assessed in this category.

Gathering available experimental results

As for a normal chemical category, available experimental results should be gathered and presented in a table. This table will focus on the targeted endpoint(s) as well as any other endpoint relevant for the applicability domain. Furthermore, available results for other endpoints relevant for justifying the robustness of the category approach can be gathered as well.

For endpoints, such as repeat-dose toxicity that are not well defined endpoints in the sense that the derived NOAEL from an experimental study can be based on one or several out of a multitude of observable effects, it is important to report not only the specific effect for which the category provides a conclusion, but the profile of all the effects seen in the tests so as to be able to compare test results between chemicals in the category. The establishment of a common profile of effects in the tested members of the category will be crucial to establish a category justification.

Example: primary saturated aliphatic C2-C8 (linear and branched) thiols

Reliable experimental results are available for three compounds of the category:

Name	**Structure**	**Results**	**Reference**
Ethanethiol CAS No: 75-08-1	CCS	*Oryzias latipes:* 96h-LC50 = 2.2 mg/l Log Kow = 1.3 [a]	Ministry of Environment, Japan, 1998 http://www.safe.nite.go.jp/data/sougou/pk_e_search_frm.html?cas_no=75-08-1
1-Hexanethiol CAS No: 111-31-9	CCCCCCS	*Pimephales promelas*: 96h-LC50 = 0.4 mg/l Log Kow = 3.2 [a]	Environmental Toxicology and Chemistry, Vol 16, No 5, pp 948-967, 1997
1-Octanethiol CAS No: 111-886	CCCCCCCCS	*Oryzias latipes:* 96h-LC50 = 0.33 mg/l Log Kow = 4.2 [a]	Ministry of Environment, Japan, 2002 http://www.safe.nite.go.jp/data/sougou/pk_e_search_frm.html?cas_no=111-88-6

a Log Kow estimated with KowWin, version 1.67

Note: only results included in the databases of the QSAR Application Toolbox were taken into account. No extensive literature search was undertaken.

Justification of the category

A category justification has to be elaborated for an extended targeted category as for any other chemical category. The justification is different from the category definition and applicability domain. The justification should address why a reliable prediction can be made on the targeted endpoint(s) for any

chemical in the applicability domain of the category. Furthermore mechanistic understanding of the effects seen in tested category members increases the confidence for predicting the effects in untested members.

For complex endpoints, such as repeat dose toxicity, it is important to establish a coherent "effect profile" between tested members of the category, i.e. similar effects in the same target organisms should be reported for the different tested chemicals or plausible explanations should be provided for variations in the "effect profile".

Example: primary saturated aliphatic C2-C8 (linear and branched) thiols

The category is defined for a very homogeneous group of substances with only one reactive functional group (thiol) and a saturated aliphatic chain. Therefore the variation of acute aquatic toxicity within the category is only function of the hydrophobicity of the members of the category.

The excess toxicity of this group of chemicals compared to base-line toxicity could be mechanistically explained due to their potential to react with proteins to form disulfides.

Although only very few experimental results are available, results are available for the compounds at the low and high end of the structural variation of the category. The category could be strengthened by deriving experimental results for branched compounds.

As the members of this category have estimated Log Kow values only up to 4.2, it is unlikely that the solubility cut-off will be reached and therefore it can be assumed that this category is homogeneous regarding acute toxicity to fish.

Filling the data gaps

The extended targeted category assessment should provide conclusions regarding the targeted endpoints for all chemicals in the applicability domain. This conclusion is not necessarily the same for all chemicals. It can vary across the category according to a trend or it is possible to define breaking points within the category where the conclusion changes. Different conclusions can be reached for subgroups within the category. The assessment should provide sufficient details so that any reader can unambiguously derive a conclusion for any individual chemical that belongs to the applicability domain.

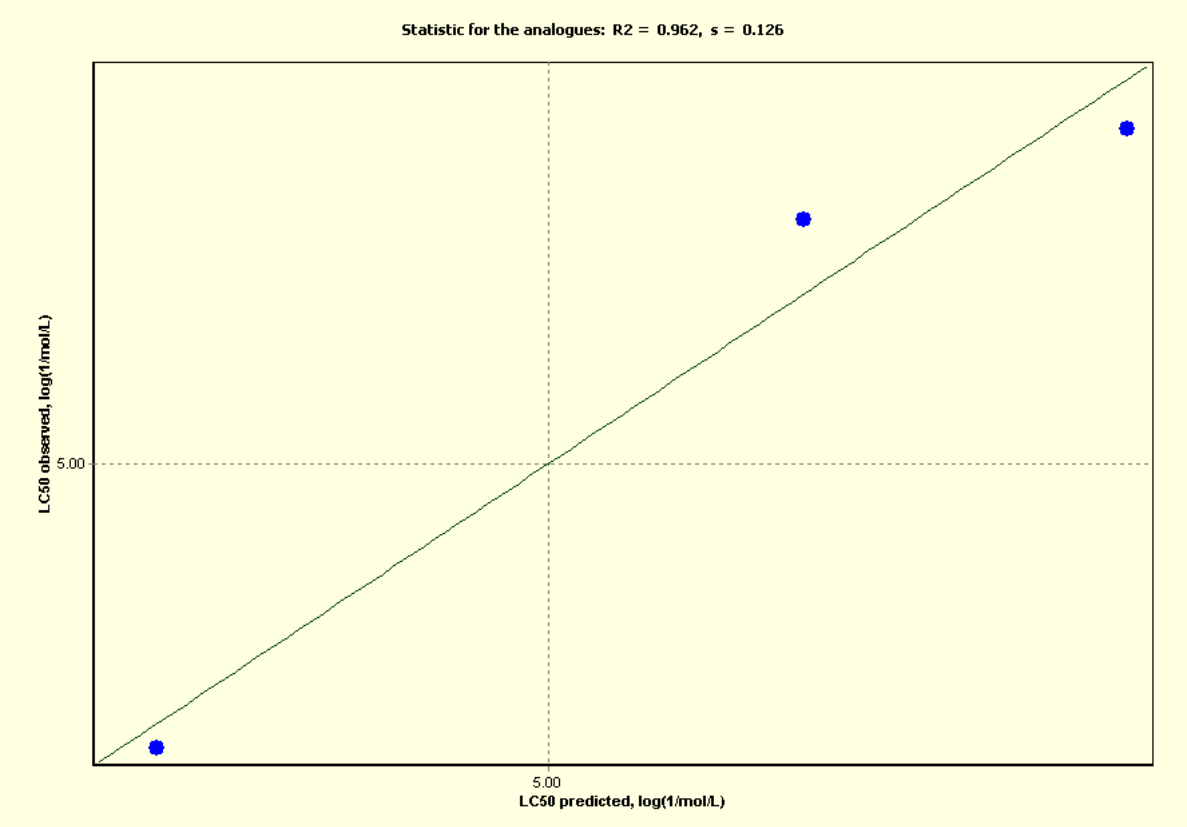
In case no firm conclusion can be reached, the assessment should clearly outline the additional information that is needed to improve the assessment.

Example: primary saturated aliphatic C2-C8 (linear and branched) thiols

Experimental results are available for "border" chemicals of the category, i.e. for C2 and C8 thiols. The results for all other members of the category are expected to be within the interval of 0.33 to 2.2 mg/L. Furthermore, based on a linear interpolation of the experimental results, the following SAR could be derived:

Log LC50 (mol/l) = - 0.422 * Log Kow - 3.96

The adequacy is shown in the following graph:



Documentation

The same documentation as for a classical category should be elaborated, using the reporting format for chemical categories, the SIAR template and the SIDS Dossier. Robust study summaries for the available experimental results of the targeted endpoint(s) would need to be elaborated to demonstrate the reliability of these results.

An Initial Targeted Assessment Profile (ITAP) should be elaborated for the category according to the template outlined in Chapter 6

1.3.3 Guidance on procedures for national assessments

In the following paragraphs, guidance for the submission to OECD and publication of assessments elaborated in national, regional or industry programmes is outlined.

Documentation

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

- One principle is flexibility in the documentation submitted. This Chapter of the *Manual* provides the details on how to prepare documents from the beginning, 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 SIDS Initial Assessment Report (SIAR) or Initial Targeted Assessment Report (ITAR) and Dossier are still met in a national/regional or industry assessment. The objective of the SIAR/ITAR 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/ITAR and Dossier were submitted in separate documents, but provided the above mentioned objectives are met, the programme can be flexible with respect to 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 are available in Chapter 6 and should continue to be used.

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 CoCAM, preferably using the same timeline as for all draft assessments;
- Documents are open for comments on the CoCAM community website until 4 weeks before the CoCAM;
- RCOM[2] and revised SIAP/ITAP are submitted on the community website for discussion before CoCAM;
- 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 usually finalised via a written procedure.

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 community website. This could be the case when the best way to obtain OECD comments is during a public consultation organised by the sponsor country/region. 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 Existing Chemicals database. Following discussions at the CoCAM and revision of the draft assessment report, reference is made on the OECD Existing Chemicals database to such assessment report (and other relevant documentation). The

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

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 CoCAM

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

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 CoCAM, based on comments received from CoCAM;
- 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 CoCAM, and revises the domestic assessment as appropriate after CoCAM

- 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 CoCAM;
- 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 CoCAM 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];
- OECD publishes or adds an addendum to its database that includes new/different studies/interpretation and that includes a disclaimer. The disclaimer indicates 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 situation 4 is the least desirable, and sponsors are encouraged to revise the original assessment. However, if an addendum is necessary, 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.

For national/regional assessments, the commenting process preceding a CoCAM 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 CoCAM. Stakeholders should strive to meet OECD timelines for commenting and discussion at CoCAM.

1.3.4 Guidance on procedures for direct submission of assessments from industry

Background

The assessments planned to be elaborated by chemical companies or consortia of companies to fulfil their national/regional obligations or commitments have been identified by the 44th Joint Meeting as potential contributions to the OECD Cooperative Chemicals Assessment Programme.

Under the ICCA Global Product Strategy (GPS), chemical companies are aiming to elaborate risk assessments for chemicals in commerce exceeding a threshold of 1 tonne/year or having a high toxicity/ecotoxicity profile. These risk assessments will stay company internal and will be the basis for elaborating GPS Product Safety Summaries which are planned to be published through an ICCA GPS IT Portal [a number of Product Safety Summaries are already published via the web site of the American Chemistry Council: http://reporting.responsiblecare-us.com/Search/PSSummarySearch.aspx]. Companies have not committed to submit the hazard assessment part of their internal risk assessment to the OECD Cooperative Chemicals Assessment Programme. Nevertheless, companies or consortia of companies could

decide on a voluntary basis to do so, to have the benefit of an international review and eventual agreement by member countries on the hazard conclusions.

In a number of countries (e.g., European Union countries), companies will use the assessments that they prepare to fulfil their legislative obligations (e.g. REACH) to fulfil their commitments under the ICCA GPS.

The present document summarises the procedures for voluntary submissions of companies' chemical assessments to the programme and lists the incentives for chemical industry to participate in the OECD programme. It can be used by ICCA and BIAC for information purposes among their members.

Procedures for submitting a company assessment to the OECD Chemicals Assessment Programme

Through the ICCA HPV Initiative, the chemical industry has submitted many assessments to the OECD HPV Chemicals Programme since 1998. Most of these assessments were submitted via a sponsor country which performed a first national peer-review. A small number of assessments were submitted directly by the companies or consortia of companies to the programme. Both procedures can also be used for voluntary submission of the assessments prepared by companies in the context of their ICCA GPS commitments.

Further details on options for submitting draft assessments to OECD are outlined elsewhere in Chapter 1 of the Manual for the Assessment of Chemicals. A number of those options have been used successfully in recent SIAMs in 2009 and 2010. A company or consortium of companies can submit a draft assessment - either via a sponsor country or directly - at any point of time. To avoid double work, industry sponsors should inform the OECD Secretariat as early as possible about their intent to submit a draft assessment, so that it can be registered in the OECD Existing Chemicals Database [http://www.oecd.org/env/existingchemicals/data]. This will avoid double work.

1.4 INCENTIVES FOR CHEMICAL INDUSTRY TO SUBMIT AN ASSESSMENT TO THE OECD CHEMICALS ASSESSMENT PROGRAMME

A number of incentives for chemical companies or consortia of companies to voluntarily submit the hazard assessment part of their risk assessments to OECD are outlined below.

International recognition

The assessment becomes part of an international programme that is globally recognised as contributing to the objectives of WSSD and SAICM. The sponsors of the assessment thereby get international recognition for their work.

Practical considerations:

- The agreed Initial Assessment Profile outlining the agreed hazard conclusions and published by OECD identifies the original company or consortium sponsor.

- If the assessment report is published by OECD, it contains a cover page outlining the roles and responsibilities of the sponsor and the reviewers as is currently done for SIDS Initial Assessment Reports.

- If the assessment report is published by the sponsor a similar cover page could be published as part of that report and specifying that the hazard assessment part of the assessment was reviewed and agreed upon by OECD.

Government review

The conclusions of assessments discussed within the OECD chemicals assessment programme are endorsed by member countries. There is therefore a commitment by member countries to the validity and correctness of the content. This is not a legally binding commitment but does reflect an OECD-wide government agreement. This reduces the uncertainty as to how individual authorities in member countries are assessing the hazards of these chemicals and therefore contributes to a level playing field for subsequent national risk assessment and potential risk management activities in member countries.

Practical considerations:

- This is particularly relevant for chemicals for which it is difficult to conclude on the hazards due to conflicting results or for chemicals for which it is proposed to fill data gaps by alternative methods (e.g. in vitro test results, non testing methods such as (Q)SARs or read-across, weight of evidence, grouping of chemicals with similar structures)

One stop shop

The assessment reports elaborated within the OECD chemicals assessment programme are used by OECD member countries within their national programmes for priority setting, risk assessment and classification and labelling. The availability of an OECD-wide agreed hazard assessment thereby limits the need to prepare and submit different assessments to different jurisdictions.

Examples of how national authorities are using the OECD assessments are outlined in the current *Manual for Investigation of HPV Chemicals* as Annexes to Chapter 1: [see http://www.oecd.org/document/7/0,3343,en_2649_34379_1947463_1_1_1_1,00.html]. Currently the following examples are available:

- Synergies with REACH [http://www.oecd.org/dataoecd/58/26/40325223.pdf]

- Synergies with the US HPV Challenge Program [http://www.oecd.org/dataoecd/58/23/44223737.pdf]

- Synergies with the Canadian Programme under CEPA 1999 [http://www.oecd.org/dataoecd/58/24/40325137.pdf]

- Synergies with the Japan HPV Challenge Program [http://www.oecd.org/dataoecd/58/25/40325193.pdf]

Other examples could be developed as needed.

International discussion forum

The draft assessments are discussed between all stakeholders in advance of the assessment meeting as well as at the meeting where agreement is reached on hazard conclusions. The company or consortium of companies sponsoring the assessment is participating in all the discussions. The submission of a draft assessment prepared by a company or consortium of companies thereby allows for open discussion with assessment authorities in all OECD member countries in a flexible and informal way. The outcome of the discussion can be of specific interest for the preparation of separate official submissions under specific national/regional legislations.

Technical facilitation

As outlined elsewhere in Chapter 1 of the *Manual for the Assessment of Chemicals*, the submission of assessments elaborated for different national/regional chemical review programmes has been greatly facilitated. While the formats for Dossier and Assessment Report outlined in the OECD *Manual for Assessment of Chemicals* remain the recommended formats, any other formats can be used provided a number of principles are fulfilled (e.g., level of details on key studies). This approach has been successfully tested at assessment meetings in 2009 and 2010 with a number of assessments elaborated for review programmes in the European Union, the United States, Canada and Australia.

ANNEXES

Annex 1: Synergies with REACH [PDF]
(Date of last update : December 2009)

Annex 2: Synergies with the US HPV Challenge Programme [PDF]
(Date of last update: December 2009)

Annex 3: Synergies with the Canadian Programme under CEPA 1999 [PDF]
(Date of last update: December 2009)

Annex 4: Synergies with the Japan HPV Challenge Programme [PDF]
(Date of last update: December 2009)