

MANUAL FOR INVESTIGATION OF HPV CHEMICALS

CHAPTER 1 : PROCEDURES, INCLUDING THE USE OF THE ELECTRONIC DISCUSSION GROUPS AND THE ON-LINE HPV DATABASE¹

1.1 Introduction.....	2
1.2 Role of the SIDS Contact Points.....	2
1.3 Selection and registration of sponsored chemicals	3
1.4 Submission of SIDS Documents and Use of the Electronic Discussion Groups (EDGs)	4
1.5 Names of files posted on the EDG	7
1.6 Submission of additional exposure information by non-Sponsor countries.....	7
1.7 Endorsement of SIDS Profiles by the Task Force on Existing Chemicals and the Joint Meeting.....	8
1.8 Revision of a previously endorsed SIDS Profile.....	8
1.9 Submission of final documents to the Secretariat.....	9
1.10 On-line use of the HPV database.....	10

Annexes (separate documents)

Annex 1: Synergies between REACH and the OECD HPV Chemicals Programme

Annex 2: Synergies between the US HPV Challenge Programme and the OECD HPV Chemicals Programme

Annex 3: Synergies between the CEPA 1999 Programme and the OECD HPV Chemicals Programme

Annex 4: Synergies between the Japan HPV Challenge Programme and the OECD HPV Chemicals Programme

¹ This document was prepared by the OECD Secretariat based on the agreements reached in the OECD Existing Chemicals Programme up to July 2008.

1.1 Introduction

The overall aims and procedures of the HPV Chemicals Programme are described in the Description of OECD Work on Investigation of High Production Volume Chemicals (http://www.oecd.org/document/21/0,3343,en_2649_34379_1939669_1_1_1_1,00.html). Guidance on how to prepare the initial assessment documents is provided in Chapters 2 and 5.

The present chapter sets out a certain number of practical procedures agreed by SIAM and the Task Force on Existing Chemicals, which add to the efficiency of the whole process. As experience is gained with the different procedures, they are revised periodically and other procedures can be added.

1.2 Role of the SIDS Contact Points

Each member country as well as organisations representing non-governmental organisations in the OECD work on chemicals (BIAC, TUAC, EEB) nominate a single SIDS Contact Point who organises the actual work and acts as point of contact with the Secretariat.

The responsibilities of a SIDS Contact Point in member countries include:

- nominating HPV Chemicals which will be sponsored by the corresponding member country;
- identifying and collaborating with a lead organisation, usually a chemical company or consortium, for each chemical;
- overseeing the preparation of the initial assessment documents, either by the lead organisation or by national experts or organisations;
- overseeing the national peer review of the draft documents;
- transferring all draft initial assessment documents to the Secretariat for posting on the Electronic Discussion Groups (EDGs);
- overseeing the review of initial assessment documents, testing plans, category proposals or revised assessments prepared by other member countries as well as any other proposals from the Secretariat, by:
 - distributing them to experts or organisations in their country for comments;
 - collating all the received comments while ensuring the consistency between them;
 - submitting the comments and responses to comments to the EDGs;
- nominating through official OECD channels (Environment Counsellors to OECD Permanent Delegations in Paris) the participants at the SIAM who will present the initial assessments sponsored by their country and discuss any outstanding issues on their chemicals as well as chemicals sponsored by other member countries;
- overseeing the finalisation of the initial assessment documents for publication and transferring them to the Secretariat.

Contact Points in non-member countries contributing to the Programme are nominated in a co-ordinated way by UNEP, IPCS or IFCS. Their roles and responsibilities are similar to those as described above for SIDS Contact Points in member countries but limited to the reviewing stages of the assessments

as well as review of testing plans and category proposals (bullet point 6 above). For EEB and TUAC, the tasks of their SIDS Contact Point is also limited to the review of assessments.

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 EDG by member countries as well as any other proposals from the Secretariat within industry;
- co-ordinating and posting on the EDG industry comments on proposals from member countries or the Secretariat;
- nominating the industry experts participating in the SIAM (both on the Electronic Discussion Group and at the meeting itself) directly to the OECD Secretariat;
- nominating delegates participating in the SIAM on behalf of BIAC.

The list of SIDS Contact Points can be found in the HPV Database (<http://cs3-hq.oecd.org/scripts/hpv/>; see also section 1.10).

1.3 Selection and registration of sponsored chemicals

SIDS Contact Points should select chemicals or categories of chemicals which they wish to sponsor according to the current list of candidates on the HPV database (the OECD HPV-List). Non-HPV chemicals can also be selected. Direct submission of a chemical assessment by industry is also possible. The following points need be considered:

- on-going work in the ICCA Initiative;
- the possibility of selecting a category of chemicals;
- avoiding any duplicative work;

If member countries wish to select a chemical emanating from the ICCA Initiative, SIDS Contact Points should check whether it is part of a category of chemicals assessed under the ICCA Initiative. The ICCA HPV Chemicals Tracking system (<http://www.iccahpv.com>) can be queried for "Commitment by Chemicals" in "View Reports". If a substance is a member of a category, it is recommended that member countries sponsor the whole category. Furthermore, SIDS Contact Points should contact the BIAC Contact Point before formally selecting a HPV Chemical for sponsorship.

Co-sponsorship of chemical assessment by two member countries is also possible, if there is mutual interest or benefit to it. The Electronic Discussion Group for chemicals not assigned to a SIAM (see 1.4 for definition) offers the possibility to seek co-sponsors.

In order to avoid any duplicative work, SIDS contact points should not choose chemicals which have recently been or are being evaluated in the IPCS Programme, e.g. CICADs or EHCs, without a rationale. Information on the status of assessments of substances in the IPCS Programme is available on the HPV database (<http://cs3-hq.oecd.org/scripts/hpv/>). However it is strongly recommended to double check the IPCS website (http://www.who.int/pcs/pcs_act.htm) to ascertain the current situation.

In case member countries wish to sponsor a category which includes non-HPV chemicals, the Secretariat will add the non-HPV chemicals to the HPV 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 HPV database.

Information on new registrations or changes of sponsorships will be posted by the Secretariat on the EDG for Chemicals Not Assigned at a SIAM (http://webdomino1.oecd.org/comnet/env/pre_siam.nsf, see section 1.4) approximately once a month if necessary.

1.4 Submission of SIDS Documents and Use of the Electronic Discussion Groups (EDGs)

As described in Chapters 2 – 6 of the *Manual for Investigation of HPV Chemicals*, in preparation for SIAM, several documents need to be prepared and submitted by Sponsor countries. All member countries (Sponsors and non-Sponsors) are invited to prepare and submit their comments to these documents. Documents that may be prepared and distributed before preparation of the SIDS Initial Assessment Report (to achieve agreement on certain difficult issues) are:

- SIDS Plan (see Chapter 2, section 2.3 The SIDS Plan);
- Category Proposals (see Chapter 2, section 2.3.5 Chemical Categories).

Documents that must be prepared for the initial hazard assessment of a substance or category are:

- SIDS Dossier(s) (see Chapter 2);
- SIDS Initial Assessment Report (see Chapter 5, section 5.2);
- SIDS Initial Assessment Profile (see Chapter 5, section 5.3).

For the SIDS Initial Assessment report (SIAR), other formats than the one described in Chapter 5 of the Manual can be accepted if they comply with the objectives of the SIAR, i.e. outline the rationale for the hazard conclusions. The submission of the above documents by Sponsor countries to the Secretariat as well as all other SIDS Contact Points is achieved via the Electronic Discussion Groups (EDG). The EDG is an electronic dialogue mechanism to exchange information and comments among SIDS Contact Points and the Secretariat. It was introduced prior to SIAM 11 (held in January 2001) and enables participants to view the comments posted by others prior to the actual meeting. 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”. This results in some saving of time at the SIAMs, as it is not necessary to repeat all of the comments made prior to the meeting on the EDG. It also allows Sponsor countries to prepare their responses to these comments in advance of the SIAM. Thereby only outstanding issues need to be discussed at the SIAM.

There are now three EDG sites dedicated to the work on Existing Chemicals:

- Existing Chemicals not assigned to a SIAM (pre-SIAM EDG)
- Existing Chemicals to be discussed at a SIAM (SIAM EDG)
- Existing Chemicals – post SIAM (post-SIAM EDG).

The entry screens of each EDG contain a link to a Help file which provides guidance on how to use all the functions of the EDG.

Who places documents on the EDGs

The posting of documents on the EDG is limited to SIDS Contact Points and the Secretariat. Non-SIDS Contact Points can get access as readers to the SIAM EDG. The EDGs are ordered by “categories”. The first time a document on a chemical is put on the EDG, a new “category” has to be created for that chemical. Only the Secretariat can create a new “category”. Therefore, the first time a document on a chemical is to be posted on an EDG, the SIDS Contact Point sends the document to the Secretariat, requesting it to post the document on the appropriate EDG. Once the category is created, any subsequent documents (e.g. comments) can be posted by any SIDS Contact Point. SIDS Contact Points are encouraged to post documents themselves on the EDG, once the “category” is created.

EDG for Existing Chemicals not assigned to a SIAM (pre-SIAM EDG)

Member countries are encouraged to post initial hazard assessments to the EDG continuously. A specific EDG has been set up for chemicals selected for sponsorship by a member country, but not yet allocated to a particular SIAM. This EDG is used for all documents on chemicals received well in advance of the cut-off date for submission to a particular SIAM and also for early discussions on certain, potentially controversial, aspects such as testing plans and category proposals, i.e. where sponsors would feel more comfortable if there was broad support for their approach early on in the process. For each document posted on this EDG, a cut-off date for submission of comments is proposed as well. Depending on the size of the document or the complexity of the issue, the commenting period is between 4 and 10 weeks.

For example SIDS Plans which propose exemptions from SIDS testing should be placed on the EDG by SIDS Contact Points for a period of eight weeks. Consulting periods should not overlap with lead-in time to a SIAM. Attempts to resolve opposing views are discussed bilaterally between the SIDS Contact Point or Points and the Sponsor country on the EDG. Complex issues that cannot be resolved on the EDG may need to be resolved at a SIAM.

The pre-SIAM EDG may also be used by Sponsor countries of chemical categories to submit the category rationale for review prior to a SIAM. This can be useful to resolve opposing views on a category rationale prior to a SIAM, thereby keeping discussion at the meeting confined to the assessment itself.

EDG for Existing Chemicals to be discussed at a SIAM (SIAM EDG)

For those chemicals which are prepared for a specific SIAM, documents need to be posted on the corresponding EDG sufficiently in advance to allow for a 10-week commenting period and if possible a 3-week period where Sponsor countries can prepare responses to comments before the SIAM if appropriate. It has been agreed that this 10 week period for comments should apply from the date that the documents were posted. After the cut-off date of 13 weeks in advance of the meeting, no new documents should be posted on the EDG for that specific SIAM but should be posted on the EDG for chemicals not yet allocated to a particular SIAM with the commenting period of 10-weeks starting the day after the SIAM. On a case by case basis, a more flexible approach can be taken for e.g. documents which are submitted in a revised form and for which only a few issues remain open for discussion, or very straightforward assessment documents.

A typical time schedule for the preparation of a SIAM would be the following:

Posting of SIDS Documents on the EDG for Chemicals to be discussed at a SIAM.	At least 13 weeks in advance of the SIAM.
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Submitting comments on the SIDS Documents to the EDG.	At least 3 weeks in advance of the SIAM.
Submitting responses to comments as well as a revised SIDS Initial Assessment Profile to the EDG.	At least 1 week in advance of the SIAM.

Following submission of SIDS documents on the SIAM EDG, 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 SIAM EDG for use by the reviewers. The use of the template facilitate the collation of comments and the response to comments.

Following the final deadline for comments on the SIAM EDG, 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 SIAM 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 SIAM EDG for final review and agreement by the member countries. Thereby only a *pro forma* endorsement will be needed at a SIAM.

Documents on any other issues to be discussed at a specific SIAM can also be posted and discussed on this EDG.

EDG for Existing Chemicals – post SIAM (post-SIAM EDG)

This EDG can be used after SIAM to resolve any issues which could not be agreed upon at the SIAM. It can also be used for revisions of SIDS Documents which have already been agreed at a previous SIAM due to new information which was located or generated on the respective chemical and which would need a revision of the conclusions and/or recommendations (see section 1.8).

General

SIDS Contact Points are encouraged to submit comments via the EDG on all documents posted, including positive reactions. If a SIDS Contact Point is satisfied with a document posted on the EDG and has no further comments, it should post this statement on the EDG. This helps to build confidence of member countries that did not have the resources to review all the documents. If no reactions are submitted on a document, it should not be considered as agreed, but the Secretariat will resubmit it to member countries, asking for explicit agreement. On the other hand, if SIDS Contact Points wish to discuss a particular issue on a chemical at a SIAM then they should also post a comment on the EDG stating this fact and explaining the reasons for wishing to do so. All documents which are agreed on the EDG are put on the agenda of the next SIAM for a final *pro forma* endorsement by the SIAM.

Comments posted on the EDG should be classified as one of two types – editorial and substantive. It would also be helpful if the reviewing SIDS Contact Point indicated whether they (in spite of their editorial and/or substantial comments) support the conclusions and recommendation as proposed by the sponsor. When comments are posted, each should begin by noting whether it is simply an editorial comment or a comment of more substance. Editorial comments are not discussed at a SIAM but are dealt with by the author of the document, in consultation with the Secretariat where necessary. All comments, but especially comments of substance, should be put on the EDG as early as possible in order to encourage discussion and resolution on the points raised.

Whenever a new document is placed on the EDG, the notification system automatically informs all SIDS Contact Points that a new document, or a set of comments, have been posted. 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 EDG for which the sponsor needs comments (e.g. a proposal for a testing plan).

1.5 Names of files posted on the EDG

To facilitate the exchange of files posted on the EDG, 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	“CAS No._SIAR” (e.g.: 50000_SIAR) or “Name of category_SIAR” (e.g.: alphaOlefins_SIAR) This rule also applies for EU draft documents submitted as SIAR.
SIDS Profile	“CAS No._SIAP” (e.g.: 50000_SIAP) or “Name of category_SIAP” (e.g.: alphaOlefins_SIAP)

1.6 Submission of additional exposure information by non-Sponsor countries

The SIDS Programme requires only a relatively limited amount of information on production of and exposure to the chemical, sufficient to put the identified hazards into context (see Chapter 5.2.2). However, if other SIDS Contact Points have additional information regarding chemical use which bears directly on the formulation of the conclusions and recommendations, they should provide it to authors of the SIAR or via the EDG as far in advance of the meeting as possible. In cases where the additional exposure information is derived from a national product register, the information should include sufficient detail to allow the authors of the SIAR to determine whether the information is current, accurate and relevant to the conclusions and recommendations of the hazard assessment. In that regard, the following information should be provided:

1. Chemical name and CAS Number.
2. Country providing information and a name and contact information for a person who can answer questions about the use information.
3. Source of information (e.g., name of database or product register).
4. Description of product use(s), chemical functions, concentrations in products and volumes per use as specifically as possible. If the information indicates that the product is used by consumers, please so indicate.
5. Date (year) the information being submitted was collected/reported (if a date is not readily available, indicate the collection date for the general source of information). If a product register was used, describe the date of the last update or give a reference to where general information about the product register can be found.

For more detailed exposure information, the format and guidance for the collection of detailed exposure information (see Chapter 6, section 6.3) can be used.

1.7 Endorsement of SIDS Profiles by the Task Force on Existing Chemicals and the Joint Meeting

The following basic principles should be applied for the elaboration of a SIDS Profile:

- each SIDS Profile should be dated (with the date and number of the SIAM at which it was agreed);
- each SIDS Profile should bear the name of the Sponsor country;
- if a new SIDS Profile is prepared it replaces a previously agreed one;
- for category chemicals and other chemicals assessed together, the SIDS Profile should cover all chemicals within the category.

Once a SIDS Profile has been agreed at a SIAM, the following actions are taken by the Secretariat.

Where required, the agreed SIDS Profile is tidied up, i.e. put in the standard format, any minor typographical errors are corrected, etc.

All the agreed SIDS Profiles are put on a designated place on an OECD password protected web site (SIDS Profiles under endorsement by the Task Force) and a 6 week date set for comments by members of the Task Force on Existing Chemicals (TF). An e-mail (together with a list of the chemicals with SIDS Profiles that require endorsement) is sent to all TF members; this message is also copied to SIDS Contact Points. If no substantive comments have been received on a SIDS Profile at the end of the 6-week period, then the SIDS Profile is considered to have been endorsed by the TF.

The conclusions and recommendations contained in the SIDS Profile are then put up for endorsement by members of the Joint Meeting (JM). The SIDS Profiles which have been endorsed by the TF are put on the OECD password protected web site (SIDS Profiles under endorsement by the Joint Meeting) and a new 6 week period is set for comments. An official letter is sent (together with a list of the chemicals that require endorsement) to all JM members; this letter is also copied to Task Force members and SIDS Contact Points.

During the endorsement procedure, the SIDS Profiles are available from the Secretariat. If no substantive comments have been received at the end of the second 6 week period, then the conclusions and recommendations in the SIDS Profile are considered to have been endorsed by the JM. The agreed SIDS Profiles are then included in the HPV Database.

1.8 Revision of a previously endorsed SIDS Profile

For a chemical that has been agreed at a SIAM and the conclusions endorsed by the Task Force on Existing Chemicals and the Joint Meeting, there are four reasons why the SIDS Profile may subsequently need to be altered:

- (a) recommended post-SIDS work has been carried out;

- (b) new data have been discovered which affect the conclusions / recommendations of the SIDS Profile;
- (c) the chemical covered by the current SIDS Profile has been included in a new category (either with or without new data for this particular chemical);
- (d) when changes in the SIAR cause a need for changes in the SIDS Profile for consistency reasons.

In the case of (a), (b) or (d) the Sponsor country should add the new information to the SIDS Profile (in track changes mode) and send it to the Secretariat with an explanation as to why the SIDS Profile has been changed. The Secretariat will then put the revised SIDS Profile, together with any necessary supporting documentation, on the **post-SIAM EDG** for comments and set an 8-week commenting period. Also the supporting documentation in the form of an addendum to the SIAR and the SIDS Dossier should be posted on the EDG. Subsequently, the chemical will be listed on the agenda of the next appropriate SIAM, either for resolution of any major comments received or, in the absence of comments (or only minor ones), solely for endorsement. Following agreement at the SIAM, the revised SIDS Profile will be given the date of the most recent SIAM where it was discussed as an agenda item and then the Secretariat will process the SIDS Profile for endorsement through the procedure described in section 1.7. After endorsement of the SIDS Profile, the addenda to the SIAR and SIDS Dossier, revised as appropriate should be submitted to the Secretariat for publication, according to the procedure outlined in section 1.9.

In the case of (c) the Sponsor country, or the country requesting a new category, should **not** amend the SIDS Profile, unless new data is available. The SIDS Profile, and any new information, together with documentation on the other chemicals making up the category, should be sent to the Secretariat together with the arguments for forming the category. The Secretariat will put this information on the **post-SIAM EDG** for comments and set an 8-week commenting period. When/if the formation of the category is agreed, it will be assigned to a SIAM for discussion. Following agreement at the SIAM, dependent on whether or not new data for this particular chemical was submitted, there are two possible outcomes with regard to the revision of the existing SIDS Profile:

- I. If no new data were submitted on the current chemical (i.e. the existing SIDS Profile has not been revised), then the current SIDS Profile should not be revised but simply referenced in the SIDS Profile prepared for the category.
- II. If new data were submitted on the current chemical, then a new SIDS Profile shall be prepared and the current SIDS Profile shall be considered as having been replaced and be suitably labelled.

These procedures were agreed at SIAM 14 and at the 11th meeting of the Task Force on Existing Chemicals, and are periodically updated to reflect practical experience and necessary adaptation or clarification.

1.9 Submission of final documents to the Secretariat

Once the SIAM has agreed with the results of the initial hazard assessment, Sponsor countries should revise the remaining SIDS documents according to the result of the discussions at the SIAM and submit them to the Secretariat as soon as possible after the meeting but at maximum **within six months**. The documents to be submitted to the Secretariat are:

- Final SIAR (including the cover page for the SIAM at which the documents were discussed);
- Final SIDS Dossier;
- Responses to comments as formulated at the time of the SIAM, and any further amendment to the responses since then as visible changes in the document.

After a final consistency check, the Secretariat publishes the final documents in the OECD HPV database and forwards the final documents to UNEP Chemicals who will publish the documents. They are made available world wide through the internet (<http://www.chem.unep.ch/irptc/sids/OECDSEIDS/sidspub.html>).

SIDS Profiles are also published via the OECD HPV Database (see section 1.10). This ensures that the results of the work on each of the chemicals in the HPV Chemicals Programme can be easily and rapidly obtained.

If the SIDS Dossier is prepared using the IUCLID software, the Sponsor country also submits the export file(s) to the Secretariat. The OECD Secretariat will also make the export files available through the public OECD internet site.

To distinguish, in any installation of IUCLID, the records which have been generated by the OECD HPV Chemicals Programme from any others, the former should be clearly labelled and contain the following text:

“OECD HPV Chemicals Programme, SIDS Dossier, approved at SIAM ...(date)”

The identity of the submitter of the data should be either the chemical company or consortium who submitted the data to the reviewers in the sponsor country or one of the reviewers.

These IUCLID files will not be merged with other files in the database and will remain easily identifiable as coming out of the OECD HPV Chemicals Programme and be accessible to users in the same manner as other information in the database.

1.10 On-line use of the HPV database

The OECD HPV database was developed as a tracking system for the status of all HPV chemicals through the process of investigation in the OECD HPV Chemicals Programme. It allows member countries to select chemicals for sponsorship and shows the stage of investigation of any particular chemical at any given time. Finally, once endorsed by the Joint Meeting, it shows the agreed SIDS Profile.

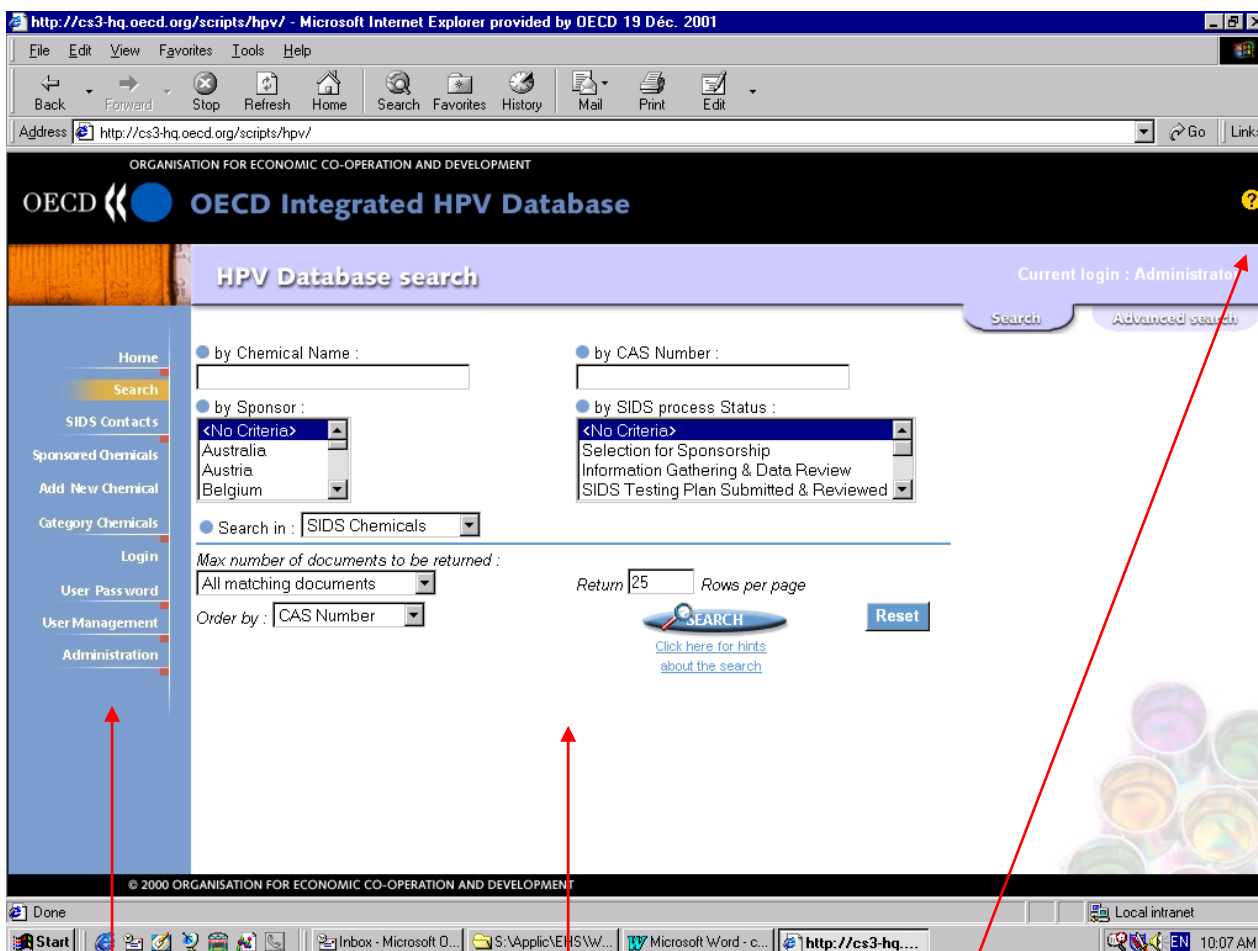
The database contains the list of HPV chemicals together with any annotations provided by Member countries to the Secretariat. It also contains for each substance a list of existing review reports (e.g. IPCS reports). Each chemical is identified as to exactly which stage it is at in the assessment process, and for those chemicals which are being sponsored (i.e. SIDS chemicals), there are links to relevant documents. Those chemicals which are not yet sponsored can be readily identified thus facilitating future sponsorship. Users can also find further information via different links e.g. UNEP Chemicals, IPCS, ECB, ICCA or EXICHEM.

- The database operates at three levels (Secretariat, SIDS Contact Points and general public) with control of significant data input (such as confirmation of sponsorship) being at the Secretariat level.
- Using the database, a SIDS Contact Point can select a HPV Chemical for sponsorship within the HPV Programme.
- After selecting a HPV Chemical for sponsorship in the HPV system, the SIDS Contact Point should inform the Secretariat. Any changes to the data in the HPV database should be performed with care as they cannot be cancelled without help from the Secretariat.

The database has a comprehensive search facility, allowing searches to be made with a number of categories: e.g., chemical name, CAS number, sponsoring country, stage of investigation. A single asterisk (*) can be used to look for words that begin with the same letters: e.g., type **gluta*** to find *Glutamic acid*, *Glutaraldehyde*, *Glutaronitrile*, *Glutaric*, and so on.

Members of the general public have “read only” access to the database, but can view all data in the system, and can follow the progress of a chemical both through and after its assessment. They can also obtain completed assessments on individual chemicals once these have been agreed in the OECD HPV Programme.

The database is situated at the following internet location: <http://cs3-hq.oecd.org/scripts/hpv/>.



Menus

Search screen

Help

The menus on the left side of the screen allow access to a certain number of functions, e.g.:

- **Search:** Allows search for a specific chemical (by chemical name or by CAS number), a sponsor country or a SIDS process either in all of the chemicals on the database, the SIDS chemicals or the non-SIDS chemicals. Advanced search facilities are also available.
- **SIDS Contacts:** List of national SIDS Contact Points in all Member countries for the SIDS work.
- **Sponsor Chemicals:** Lists the HPV chemicals which have been selected as SIDS chemicals and are currently being investigated in the HPV Chemicals programme.
- **Add new Chemicals:** Only available to authorised users by OECD Secretariat after Login. Allows insertion of chemical product in the database.
- **Category Chemicals:** List of related chemicals being investigated together in the HPV Chemicals Programme in a single chemical category.
- **Login:** Only available to authorised users by OECD Secretariat. They need to enter their user name and password to access certain activities - essentially data input.

The “help” button gives access to further guidance on how to use the HPV Database.