

MANUAL FOR INVESTIGATION OF HPV CHEMICALS

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

ANNEX 4: SYNERGIES BETWEEN THE JAPAN HPV CHALLENGE PROGRAMME AND THE OECD HPV CHEMICALS PROGRAMME¹

SYNERGIES

1. The JP HPV Challenge Program is carried out in a manner consistent with the OECD HPV Chemicals Programme, to ensure that testing and assessments can be contributed to the international effort.

2. After a company or consortium of companies agrees to “sponsor” a chemical or category of chemicals under the JP HPV Challenge Program, the sponsor prepares a JP HPV Challenge Submission and sends it to the Japanese Authorities. The submission consists of a cover letter, a Test Plan and Robust Study Summaries.

3. Many of the aspects required of manufacturers and importers in preparing a JP HPV Challenge Submission are similar or identical to the requirements of the OECD HPV Chemicals Programme:

- The data requirements are based on the OECD SIDS test battery (see also section 2 of the Annex).
- Key study data is entered as OECD Robust Study Summaries (see also section 5 of the Annex).
- The chemical category approach can be used to waive information requirements (see also section 4 of the Annex).
- New information is generated using the OECD Test Guidelines.

4. The JP HPV Challenge Program focuses on safety information collection at this stage. The actual hazard assessment, based on the collected information, is not yet covered by the programme.

5. In conclusion, in developing the technical details for the JP HPV Challenge Program, the Japanese authorities ensured that the OECD HPV Chemicals Programme and the JP HPV Challenge Program are equivalent in terms of data collection, and that there are no overlaps in terms of substances. The main difference is that the elaboration of hazard assessment documents is currently not a part of the JP HPV Challenge Program. Therefore, further work would be needed in order to submit the collected data to the OECD HPV Chemicals Programme. If a sponsor company to the JP HPV Challenge Program decides to voluntarily submit its data to OECD HPV programme, the Japanese government will support its efforts. In addition, it should be noted that the information is mostly collected in Japanese under the JP HPV Challenge Program.

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

FURTHER INTEGRATION OF THE TWO PROGRAMMES

6. The JP HPV Chemicals Program continues to accept sponsors until the end of March 2009. An interim assessment of the programme will be performed in fiscal year 2008. Possibilities for further integration between the two programmes could be addressed at a later stage.

ANNEX : TECHNICAL SIMILARITIES BETWEEN THE JP HPV CHALLENGE PROGRAM AND THE OECD HPV CHEMICALS PROGRAMME

1. Introduction

The Japan HPV Challenge Program, officially launched in 2005, was created to ensure that a baseline set of data on approximately 650 High Production Volume (HPV) chemicals would be made available to the public. The programme only addresses those chemicals which are currently not addressed within either the OECD HPV Chemicals Programme or the US HPV Challenge Program.

2. Scope, information requirements and responsibilities

While the OECD HPV Chemicals Programme aims at obtaining initial hazard assessments for HPV Chemicals and making recommendations on the priority for further work, the JP HPV Challenge Program aims at collecting information, and making that information available to the public. There is currently no decision as to the eventual elaboration of hazard or risk assessments, based on the gathered information.

Both programmes focus on HPV chemicals, using the same definition of what a High Production Volume chemical is (production or import at quantities of 1000 tonnes/year or above). Furthermore, as indicated above, the JP HPV Challenge Program addresses chemicals which have not yet been assessed or are not being assessed within either the OECD programme or the US HPV Challenge Program.

In conclusion: in terms of data gathering, the scope of the two programmes is fully consistent and complementary. No decisions on the elaboration of hazard assessments in the JP HPV Challenge Program have been taken yet.

The information requirements in both the OECD and JP programmes aim at providing sufficient information to carry out an initial hazard assessment of a substance. Both programmes rely on the Screening Initial Data Set [SIDS]. A detailed comparison of the information requirements is outlined in Appendix I, which shows that they are identical.

In both programmes, it is also recommended to provide existing information on endpoints which are not included in the SIDS (e.g. carcinogenicity). Furthermore, in both programmes reduced testing for closed system intermediates can be considered on a case-by-case basis.

In conclusion: the information requirements in both programmes are identical.

Both programmes are voluntary programmes. Regarding the differences in responsibilities, a large part of the work under the OECD Programme which results in draft SIDS Dossiers and SIARs is carried out in partnerships between consortia of industry companies and OECD Member Countries. Furthermore direct submissions by industry to the programme are possible. Also, for some chemicals, countries submit without industry input, or through other bilateral arrangements with their national industry. Within the JP HPV Challenge Program, the HPV Challenge Submission, consisting of a Test Plan and the Robust Study Summaries are prepared by a company or consortium of companies. The Submission is then commented on by the authorities (METI, MoE, MHLW), who check the reliability of the submitted data, followed by a revision and testing by the company or consortium if necessary.

There is currently no decision as to the eventual elaboration of hazard or risk assessments, based on the gathered information.

In conclusion: The division of responsibilities between authorities and industry at the drafting stage is similar between the JP HPV Challenge Program and the OECD HPV Chemicals Programme. The main difference is that within the JP HPV Challenge Program, the initial hazard assessment is not requested as part of the Submission, whereas in the OECD Programme, all SIDS Documents are usually drafted by industry and in some cases by authorities.

3. OECD and JP HPV Challenge Procedures

The current OECD programme, is constructed with the following main steps, when input from the ICCA initiative is used:

- Consortium of International Council of Chemical Associations [ICCA] Member Companies is formed;
- ICCA Member Companies develop a SIDS Dossier and a SIAR;
- A sponsor country volunteers to be a sponsor for the substance and reviews the SIDS Dossier and the SIAR, or the consortium submits the SIDS Dossier and the SIAR directly to the SIDS Initial Assessment Meeting [SIAM];
- After possible modifications, the SIDS Dossier and the SIAR is submitted to the SIAM by the sponsor country;
- The SIAM discusses and agrees on the SIDS Dossier and SIAR, including the conclusions of the initial hazard assessment, recommendations on priority for further work and the rationale therefore.
- OECD governments endorse this.

The comparable steps in the JP HPV Challenge Program would be:

- Consortium of Manufacturers and Importers is formed, if necessary;
- A company or consortium volunteers to become a sponsor of a targeted chemical;
- A company or consortium develops a Submission consisting of a Test Plan and a Robust Study Summary;
- The authorities check the reliability of the Submission;
- After possible modifications by the consortium and necessary testing, the authorities publish the information on a publicly available web site.

In conclusion: the OECD process and the JP HPV Challenge process are similar.

4. Formation and use of Chemical Categories

One of the most efficient ways of reducing animal testing and costs involved in the assessment of chemicals is the grouping of substances into chemical categories. In this approach closely related chemicals are considered as a group, or category, rather than as individual chemicals. In the category approach, not every chemical needs to be tested for every SIDS endpoint. Rather, the overall data for

that category must prove adequate to support a screening-level hazard assessment. The overall data set must allow the estimation of the hazard for the untested endpoints.

The JP HPV Challenge Program has adopted the formation of chemical categories and refers to the OECD guidance documents.

In conclusion: data gap filling methods via the chemical category approach are similar between the two programmes.

5. The OECD SIDS Dossier and the JP HPV Challenge Submission

The SIDS Dossier includes all the relevant background information for understanding the SIDS Initial Assessment Report and as such is intended to provide a common OECD information package for any national or regional work to be carried out on the substance. The JP HPV Challenge Submission is based on the OECD SIDS Dossier and, therefore, can provide the information basis on which a hazard or risk assessment can be carried out. The SIDS Dossier and the JP HPV Challenge Submission can be used for the same purpose.

Appendix II compares the HPV Challenge Submission and the SIDS dossier. It follows that the two are consistent, with:

- Both applying the almost same rules when to develop a robust study summary.
- Both utilise similar data reporting templates;

On the other hand, the JP HPV Challenge Program does not recommend a specific IT tool for gathering information and accepts submissions which are mostly in Japanese. These would need to be translated before using them for the purposes of the OECD programme.

In conclusion: The SIDS Dossier and the JP HPV Challenge Submission are largely identical.

APPENDIX I : INFORMATION REQUIREMENTS

JP HPV Challenge Program	OECD HPV Chemicals Programme
Exposure information	
Production volume Use pattern Sources of exposure	Production volume Use Pattern Sources of exposure (qualitative)
Physicochemical Endpoints	
Melting Point	Melting Point
Boiling Point	Boiling Point
Vapor pressure	Vapor pressure
Water solubility	Water solubility
Partition coefficient	Partition coefficient
Relative Density required for inorganic chemicals	Relative Density required for inorganic chemicals
Oxidation/Reduction Potential, required for inorganic chemicals	Oxidation/Reduction Potential, required for inorganic chemicals
Dissociation Constants, required if applicable	Dissociation Constants, required if applicable
Environmental Fate Endpoints	
Biodegradation	Biodegradation
Stability in water	Stability in water
Photodegradation	Photodegradation
Distribution/transport (fugacity)	Distribution/transport (fugacity)
Ecotoxicity Endpoints	
Acute aquatic vertebrate	Acute aquatic vertebrate
Acute aquatic invertebrate	Acute aquatic invertebrate
Acute aquatic plant	Acute aquatic plant
	Chronic aquatic (usually invertebrate), if indicated

Mammalian Toxicity Endpoints	
Acute toxicity (oral, inhalation or dermal, as appropriate)	Acute toxicity (oral, inhalation or dermal, as appropriate)
Repeated-dose toxicity (28 day, 90 day or OECD TG 422) oral, inhalation or dermal, as appropriate	Repeated-dose toxicity (28 day, 90 day or OECD TG 422) oral, inhalation or dermal, as appropriate
Gene mutations	Gene mutations
Chromosomal aberrations	Chromosomal aberrations
Reproductive toxicity	Reproductive toxicity
Developmental toxicity	Developmental toxicity

APPENDIX II: JP HPV CHALLENGE SUBMISSION AND SIDS DOSSIER FORMATS

JP HPV Challenge Submission	OECD SIDS Dossier
<p>ROBUST STUDY SUMMARY</p> <p>1. Definition</p> <p>There is no definition of a robust study summary in the JP HPV challenge manual, but the format is based on those proposed in the OECD <i>Manual for Investigation of HPV Chemicals</i>.</p> <p>2. When to Use</p> <p>There is no specific guidance as to which studies should be summarised in a robust way, but in practice the OECD guidance is followed.</p>	<p>ROBUST STUDY SUMMARY</p> <p>1. Definition</p> <p><i>Robust study summary</i> should reflect the objectives, methods, results and conclusions of a full study report. Information within a Robust Study Summary must be provided in sufficient detail to allow a technically qualified person to make an independent assessment as its reliability and completeness minimising the need to go back to the full study report. (cf. Manual for Investigation of HPV Chemicals, Chapter 2, Section 2.4.3, p. 17).</p> <p>2. When to Use</p> <p>For the “key” studies used. In general, a key study is the study (or studies) that has been identified as most suitable to describe an endpoint from the perspective of quality, completeness and representativity of data. Should also be used for all more critical studies (cf. Manual for Investigation of HPV Chemicals, Chapter 2, Section 2.4.3, p. 20).</p>
<p>TEMPLATE</p> <p>A series of templates for the different SIDS endpoints have been developed based on those proposed in the OECD <i>Manual for Investigation of HPV Chemicals</i>. They are thereby coherent, albeit not identical with the OECD Harmonised Templates.</p>	<p>TEMPLATE</p> <p>The OECD has developed Harmonised Templates for the use of data reporting in Pesticides, Biocides, Existing Substances and New Chemicals.</p>
<p>IT SUPPORT TOOL</p> <p>No specific IT Tool has been developed.</p>	<p>IT SUPPORT TOOL</p> <p>It is currently recommended to use IUCLID 5 when preparing the SIDS Dossier. IUCLID 5 has implemented the OECD Harmonised Templates.</p>