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

ANNEX 1: SYNERGIES BETWEEN REACH AND THE OECD HPV CHEMICALS PROGRAMME[1]

SYNERGIES

1. The OECD has worked intensely over the last 8 years to develop harmonised formats, templates and guidance documents (among other tools) with the primary goal of applying them in an OECD context, but always ensuring consistency with national and regional programmes. The EU Member States and the European Commission have been contributing significantly to this process, with the clear objective to apply the output of the OECD also in the implementation of REACH.

2. The output of the OECD HPV Chemicals Programme can contribute to REACH implementation and vice versa at many stages, in particular in the following REACH processes:

- Registration;
- Evaluation, be it the dossier evaluation of testing proposals or compliance check and substance evaluation;
- Preparation of Annex XV Dossiers to lead into harmonised classification and labelling, restriction proposals or identification of substances of very high concern.

3. Which OECD processes are most relevant for REACH and vice versa, is highly dependent on the timeline. For example before 1 December 2010 (the registration deadline for, among others, the high volume "phase-in" substances), the participation in the OECD programme will provide an efficient vehicle for industry to prepare registration dossiers; whereas after 1 December 2010 the registration dossiers would be an efficient basis to prepare OECD SIDS documents. Synergies between the OECD HPV Chemicals Programme and specific REACH processes are outlined in more detail below. Further details of technical similarities or even identical technical solutions can be found in the Annex.

Registration

4. Registration of a substance in the framework of REACH means that manufacturers and importers have to provide a registration dossier to the European Chemicals Agency. A registration dossier for substances manufactured or imported in quantities of 10 tonnes or more comprises a technical dossier which contains information (among others) on the properties of the substance and a Chemical Safety

[1] This document was prepared by the OECD Secretariat based on the agreements reached in the OECD Existing Chemicals Programme up to March 2007

Report (CSR) which documents the hazards, the exposure and the appropriate risk management measures for the substance.

5. Many of the aspects required of manufacturers and importers in preparing a registration dossier in the framework of REACH are similar or identical to the requirements of the OECD HPV Chemicals Programme:

- All substance related information will be entered in IUCLID 5, which utilises the OECD Harmonised Templates. Key study data is entered as OECD Robust Study Summaries.

- Consistent guidance is applied when waiving information requirements using the chemical category approach or (Q)SARs (see also section 4 of the Annex).

- New information is generated using the OECD Test Guidelines, when available.

- When writing the Chemical Safety Report (CSR), formats and the content requirements for the hazard assessment part are fully compatible with those of the OECD SIDS Initial Assessment Report (SIAR) (see also section 5 of the Annex).

Evaluation

6. There are two types of evaluation in the framework of REACH. On one hand, during dossier evaluation, the Agency may perform a compliance check, i.e. check the compliance of registration dossiers with the requirements laid down for registration, or the agency may check a testing proposal. On the other hand, during substance evaluation, the Agency in co-ordination with the EU Member States may clarify suspicions of risk to human health or the environment by requesting further information. In carrying out any of the different types of evaluation in the framework of REACH, the Agency or EU Member States will prepare a draft evaluation decision[2]. This is comparable to the outcome of the SIDS Initial Assessment Meeting (SIAM) in the OECD HPV Chemicals Programme, based on the SIDS Initial Assessment Report (SIAR).

7. As a consequence, for example, for substances where the SIDS Dossier and SIAR have been prepared for and agreed at a SIAM, the Agency will not need to review the completeness of the REACH Registration Dossier for the SIDS endpoints. Furthermore, for substances where the REACH Registration Dossier is based on the OECD Dossier and SIAR and where no new information has become available, if the SIAM has concluded that a substance is of low priority for further work due to its low hazard profile, then it is not likely that the Agency will identify further information needs during dossier evaluation in relation to the SIDS endpoints (see also section 7 of the Annex).

8. Similarly, the results of REACH evaluation for substances that have not yet been assessed within the OECD Programme can help identify substances for which there is a need for an international assessment via the OECD Programme. As REACH substance evaluation will first start in 2011, the OECD HPV Chemicals Programme would provide EU Member States with a convenient and efficient “bridge” between the current EU legislative evaluation work and substance evaluation under REACH, hence advancing on the work coming under REACH and gaining valuable experience.

[2] REACH is constructed in such a way that draft evaluation decisions are only prepared in cases where there is a need for further work, and so all draft evaluation decisions will conclude that there is a need for further work.

9. Further details regarding the synergies between the OECD HPV Chemicals Programme and evaluation in the context of REACH could be elaborated at a later stage, i.e. before 2011 when substance evaluation starts.

Restrictions, harmonised Classification and Labelling or identification of substances of very high concern

10. In the framework of REACH, proposals and justifications for restrictions, harmonised Classification and Labelling or identification of substances of very high concern are elaborated by the Agency or EU Member States in accordance with the requirements of Annex XV of REACH. Those proposals and justifications (Annex XV Dossiers) will be in the same format and with the same requirements in terms of content as foreseen in the Chemical Safety Report, which is compatible with the OECD SIAR Format (See Appendix III to the Annex) and using IUCLID 5.

Conclusion

11. In conclusion, in developing the technical details for REACH and in the REACH Implementation Projects (RIPs) the European Commission, the EU Member States and experts from many sectors have strived to ensure that an OECD SIDS Dossier and SIAR can be used, in its entirety to prepare a REACH registration dossier, though for the purposes of REACH that dossier will necessarily need to contain additional information. This also means that a SIDS Dossier and SIAR can be directly extracted from a REACH registration dossier and that parts of a SIDS Dossier and SIAR can be directly extracted from a REACH Dossier prepared to justify restrictions, harmonised Classification and Labelling or identification of substances of very high concern.

12. Furthermore, the harmonized tools, templates and approaches developed under the OECD HPV Chemicals Programme provide the mechanisms for industry and authorities to continue to achieve shared goals, and to reduce the burden of information gathering and assessment activities in the implementation of their national/regional programmes, as well as to contribute to the goals of SAICM.

PROCEDURES FOR FURTHER INTEGRATION OF THE TWO PROGRAMMES

13. As demonstrated in the Annex, the technical similarities between the two programmes allow for writing the hazard assessment part of a Chemical Safety Assessment (CSR) for Registration under REACH using and moderately modifying a SIDS Initial Assessment Report (SIAR). Similarly, a SIAR can be written using the hazard assessment part of the CSR, with deletions and minor modifications. Three cases can be distinguished:

- agreed SIDS Dossier and SIAR exist prior to the registration deadline for REACH;
- the SIDS Dossier and SIAR are developed after Registration;
- the SIDS Dossier and SIAR and the Registration Dossier are developed in parallel.

14. In the following, flexible procedures for these three cases are briefly outlined. The relation between REACH substance evaluation and the OECD HPV Programme can be developed in a similar

fashion. However, as REACH substance evaluation for HPV existing chemicals first commences in 2011, there is no urgent need to consider this in the current document.

Use of SIDS Documents for the preparation of REACH Registration Dossiers[3]

15. If an agreed SIDS Dossier and SIAR exist prior to the registration deadline for REACH, these documents should be used to prepare the Registration Dossier. Significant deviations from the content, conclusions and recommendations within the agreed SIDS Dossier and SIAR would need to be explained. In Appendix III to the Annex, the relations between the headings in the SIAR and the CSR are outlined.

16. The existence of SIDS Documents prior to the preparation of a Registration Dossier does not exempt the registrant from the obligation to be in legitimate possession of or have permission to refer to the full study reports summarised in the SIDS Documents [article 10(a) of the REACH legislation]. In other words, by preparing and submitting SIDS Documents for the OECD HPV Chemicals Programme, data owners do not loose their data ownership rights under REACH, even after publication of the SIDS Documents by UNEP Chemicals, i.e. robust study summaries published through the OECD HPV Chemicals Programme cannot be used for registration under REACH without the prior consent of the data owner.

17. If the corresponding Registration Dossier is selected for a compliance check by the Agency (dossier evaluation), the conclusions regarding the hazard assessment would be accepted as such by the Agency and no further review would be necessary, unless there are indications that such a review could lead to deviations from the conclusions reached within the OECD HPV Chemicals Programme (e.g. due to additional test results). Furthermore the recommendations made within the OECD HPV Chemicals Programme can be used by the Agency [as would be done by any member country] to focus the compliance check on whether new information gives rise to concern or whether recommended further work is appropriately addressed by the registrants (see section 7 of the Annex).

18. EU-Member States and the Agency, when setting priorities for substance evaluation under REACH will take into account the recommendation made by the OECD HPV Chemicals Programme (see section 7 of the Annex) and use the agreed conclusions of the hazard assessment for the evaluation.

Use of REACH Registration Dossiers for the preparation of SIDS Documents

19. As outlined in paragraphs 1-12 above, there are a number of advantages for industry and authorities if they bring a chemical to the OECD HPV Chemicals Programme after its registration under REACH. If a consortium of companies has submitted a Registration for an HPV chemical to the European Chemicals Agency, it would also be possible to subsequently submit a SIAR and SIDS Dossier to the OECD HPV Chemicals Programme. Such a process could benefit the industry by obtaining an international assessment on their substance(s) prior to a possible evaluation in the EU, and could benefit the European Chemicals Agency by reducing various aspects of their assessment activities. In such a case, the following procedure can be envisaged:

[3] The proposals outlined in this section are outside of the scope of the OECD Existing Chemicals Programme. They are based on documents drafted by the European Commission and endorsed by the EU member countries [JM/03/2004; JM/41/2004]

- The consortium of companies would extract the SIAR from the CSR as outlined in section 5 and Appendix III of the Annex. The IUCLID 5 file for the registration is used as a SIDS Dossier.

- The SIDS Documents can be submitted at any time to the OECD HPV Chemicals Programme, either directly by industry, or via a Sponsor country (either an EU Member State or a non-EU member country).

- The OECD Secretariat would inform the European Chemicals Agency of the identity(ies) of the chemical(s) assessed (or being assessed), so as to prevent as far as possible duplicative review activities.

- After review of the SIDS Documents and endorsement of the conclusions and recommendations by the OECD member countries (including 19 EU member countries), the consortia would prepare the final SIDS Documents for publication by UNEP Chemicals.

- The OECD Secretariat would inform the European Chemicals Agency of the outcome of the initial assessment and the industry consortium would update the registration if necessary.

Development in parallel of SIDS Documents and REACH Registration Dossier

20. For chemicals for which no agreed SIDS Documents exist yet and for which the REACH registration deadline is sufficiently far in the future, it could be envisaged to develop the SIDS Documents and REACH Registration Dossier in parallel. The following procedure could be followed:

- A SIAR and SIDS Dossier in IUCLID 5 format is elaborated by an industry consortium of individual companies.

- The SIDS Documents are submitted to the OECD HPV Chemicals Programme, either directly by industry, or via a Sponsor country (either an EU Member State or a non-EU member country).

- In parallel, the industry consortium of companies elaborates the REACH-specific part of the CSR (exposure assessment, risk characterisation etc.).

- After review of the SIDS Documents and endorsement of the conclusions and recommendations by the OECD member countries (including 19 EU Member States), the industry consortium prepares the final SIDS Documents for publication by UNEP Chemicals and uses these SIDS Documents to finalise the Registration Dossier and register the chemical with the European Chemicals Agency.

- The OECD Secretariat would inform the European Chemicals Agency of the outcome of the OECD initial hazard assessment.

ANNEX: Technical Similarities between REACH and the OECD HPV Chemicals Programme[4]

1. Introduction

The Whiter Paper, which was the basis of REACH, stated, in Section 6, Action 6A, that

"Dossiers drawn up in the context of the voluntary initiative on the part of the International Council of Chemicals Associations (ICCA) which comply with the OECD format will be valid for [registration] purpose[s]. However, the information contained in these dossiers will have to be supplemented in order to meet the requirements described in the previous chapters."

The European Commission has fulfilled this pledge, in the development of the REACH proposal and in the design and implementation of the **R**EACH **I**mplementation **P**rojects [**RIP**s]. This can particularly be observed, through the introduction of the OECD definition of a robust study summary (Art. 3 (27)), the use of equivalent rules for when robust study summaries should be developed (Sections 1 and 3 of Annex I of REACH), the format of the **C**hemical **S**afety **R**eport [**CSR**] (Sections 7 of Annex I of REACH) and in the design of RIP 2 (the REACH – IT) and RIPs 3 and 4 (Technical Guidance Documents for Industry and Authorities).

The present Annex investigates in detail the commonalities and differences between the OECD HPV Chemicals Programme and REACH, addressing in particular the compatibilities of the processes and the deliverables.

2. OECD and REACH

The main technical difference between the Existing Chemicals programmes lie in the scope of the programme objectives: the OECD Programme aims at obtaining OECD-wide agreed initial hazard assessments and making recommendations on the priority for further work, whereas REACH aims at assessing and documenting safe handling and use of chemicals. Thus the OECD Programme and REACH have significant differences in the information requirements and in the allocation of responsibilities.

The information requirements in OECD aim at providing sufficient information to carry out an initial hazard assessment of the substance, where as the REACH information requirements aim at being sufficient for classification and labelling, risk assessment and risk management (both for the companies themselves and to all their customers) purposes.

On comparing the actual information requirements in REACH and in the **S**creening **I**nitial **D**ata **S**et [**SIDS**] (see Appendix I) it is evident that there is a large degree of consistency between the SIDS requirements and the information requirements at 10 tonnes in REACH, though the REACH requirements are more extensive. Any REACH information requirement above this threshold is subject to Annex XI of REACH, i.e., provides substance specific and exposure driven information requirements and waiving possibilities. Furthermore, for registration purposes for substances produced or imported in volumes above 100 tonnes per year, manufacturers and importers should not perform additional animal testing, but should only make proposals for such testing.

---

[4] This annex is based on a document [JM/42/2004] originally drafted by the European Commission for the 10th Joint Meeting of the Competent Authorities for the implementation of Directive 67/548/eec (New substances) and Council Regulation 793/93/EEC (Existing substances), held in Leiden, 25 – 26 November 2004.

In conclusion: the SIDS information requirements and the information requirements for REACH at registration of HPVCs are similar, though REACH requires more information than that in the SIDS.

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. Under REACH, the Technical Dossier, the CSR and the industry identified needs for further testing are the responsibility of (the consortium of) manufacturers and importers, though certain information needs and the compliance check (under Dossier Evaluation) are confirmed by European Chemicals Agency, whereas the authorities' identified needs for further information (under Substance Evaluation) are the responsibility of the authorities. Furthermore, OECD is a voluntary cooperative programme, whereas REACH will be a mandatory legislative programme.

In conclusion: the division of responsibilities between authorities and industry at the drafting stage is considerably different, between REACH and OECD.

In considering the inter linkage between REACH and the OECD Programme, it is convenient to distinguish between three cases:

(1) an agreed SIDS Dossier and SIAR exist prior to the registration deadline for REACH

(2) the SIAR is developed after Registration

(3) the SIAR and the registration dossier are developed in parallel;

In relation to the first case, Paragraph 0.5 (1st para) of Annex I to REACH gives a clear statement:

"Available information from assessments carried out under other international and national programmes shall be included. […] Deviations from such assessments shall be justified."

There is therefore a legislative obligation for the industry consortium to use the OECD agreed SIAR when developing a CSR. If industry deviates from the OECD agreed SIAR, including the recommendations, then they would need to justify such deviations.

In conclusion: if an agreed SIDS Dossier and SIAR exist prior to registration, then there is a legislative obligation to use the SIAR in developing the Technical Dossier and the CSR.

3. OECD and REACH Procedures[5]

The current OECD programme, is constructed with the following main steps, when input from the ICCA initiative is used[6]:):

[5] The presentation of the two procedures is clearly simplified and is intended to highlight the similarities, not the differences.

[6] This is not always the case. Currently about 80-90% of the cases dealt with at SIAM emanate from ICCA. Countries also submit without industry input, or through other bilateral arrangements with their national industry

(1) Consortium of ICCA Member Companies is formed;

International **C**ouncil of **C**hemical **A**ssociations [**ICCA**] Member Companies develop a SIDS Dossier and a SIAR;

A sponsor country volunteers to be 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 **S**IDS **I**nitial **A**ssessment **M**eeting [**SIAM**];

After possible modifications by the Member Companies, the SIDS Dossier and the SIAR is submitted to the SIAM, including EU Member States and Industry, by the sponsor country;

The SIAM discusses and agrees on the (possibly modified) 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 REACH comparable steps in the development and processing of the registration dossier would be:

- Consortium of Manufacturers and Importers is formed;
- Consortium develops a technical dossier and a CSR;
- For some of the substances the Agency reviews the technical dossier and where relevant the CSR;
- The Agency develops an opinion, which could conclude that there is or that there is not a need for further information, and submits it to the Agency's MS Committee;
- The MS Committee discusses and agrees on the (possibly modified) opinion regarding the need for further work.

In conclusion: the OECD process and the relevant REACH process are similar.

4. Formation and use of Chemicals Categories

One of the most efficient way 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 OECD guidance document on the formation and use of chemical categories is currently being revised in a joint project between OECD and the European Commission, with the aim to achieve common guidance that can be used both for the OECD HPV Chemicals Programme and for REACH.

Conclusion: assessments elaborated within the OECD programme via the chemical category approach can be used for Registration under REACH and vice-versa.

5. The OECD SIDS Dossier and the REACH Technical Dossier

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 Technical Dossier is intended to provide the information basis on which the CSR is carried out. The purposes of the SIDS Dossier and the Technical Dossier are thereby identical, though the technical dossier in most cases will need to be extended beyond the SIDS dossier, to fulfil the information requirements of REACH.

The technical dossier is therefore a further elaboration of the SIDS Dossier, fully in-line with the intention of the OECD Programme. Appendix II compares the technical dossier and the SIDS dossier. It follows that the two are consistent, with:

- Both using the same definition for robust study summaries and comparable definitions for summaries;
- Both applying the same rules for when to develop a robust study summary and when to develop only a summary;
- Both utilise the same date reporting templates;
- Both use the same IT system to for data entry and exchange.

The only compatibility problems which can be encountered in using existing SIDS dossiers for the purposes of the future REACH registration, are therefore only those inherent in the porting of data from currently used IUCLID version 4 to the future IUCLID version 5.

In conclusion: the SIDS Dossier and the Technical Dossier are compatible, though the Technical Dossier will often be more extensive.

6. The SIAR and the Chemical Safety Report

The SIAR is a SIDS Initial Assessment Report and as such is intended to provide an OECD-wide agreed initial hazard assessment and recommendation on the priority for further work. The latter is a common OECD starting point for decisions on national, regional or international work to be carried out on the substance. The CSR is a Chemical Safety Report, based on risk assessment principles, intended for industry to document that they have assessed that the implemented risk management measures or those measures recommended down stream are sufficient.

The CSR is therefore a “down stream” report to the SIAR, fully in-line with the intention of the OECD Programme. Appendix III compares the formats of the CSR and the SIAR. It follows that the two are generally consistent, with:

- the CSR being more extensive, including more information on exposure, risks, some end-points and risk management;

- most sections headers being identical, with minor modifications;
- a very limited number of sections are listed in another order;
- the CSR applies a consistent approach to information presentation which is consistent with most parts of the SIAR.

The effects and the end-points SIAR are all listed in the CSR, with the only inconsistency being that the SIAR lists "other environmental effects" where the CSR specifies these as being "atmospheric" and "microbial"[7].

In conclusion: the hazard assessment part of the CSR can be written using and moderately modifying the SIAR. Similarly, a SIAR can be written using the hazard assessment part of the CSR, with deletions and minor modifications.

Regarding the content of the SIAR and the SIDS Dossier, as do all non-EU OECD Member Countries, the EU Member States agree to the SIAR and the SIDS Dossier and endorse the conclusions and recommendations. There is therefore a commitment to the validity and correctness of the content. This is not a legally binding commitment but does reflect an OECD-wide government agreement.

In conclusion: In the OECD, EU MS's agree to the SIAR and the SIDS Dossier, and endorse the conclusions and recommendations on HPV chemicals, as do all non-EU OECD Member Countries, and are thereby committed to that agreement.

7. The RECOMMENDATIONS of the SIAR and REACH[8]

Section 5 of Chapter 5 of the OECD Manual for Investigation of HPV Chemicals states that:

The 'Recommendation' section of the SIAR proposes one of two possible statements regarding the need for further work on the chemical. The recommendation options, based on the conclusions and their context, are either that:

(1) "the chemical is currently of low priority for further work" ; or

(2) "the chemical is a candidate for further work" (in national/regional/international programmes, e.g. REACH)

A more extensive extract regarding the recommendations of the SIAR can be found Section 5 of Chapter 5. In summary, recommendations (2) could be subdivided into:

(2) a - the chemical is a candidate for further work: more hazard information is needed;

[7] It is an objective of the REACH Implementation Projects to try to reach full compatibility.

[8] In this section the terminology from the OECD HPV Chemicals Programme is used, which may be different from the terminology used in REACH.

(2) b - the chemical is a candidate for further work: more exposure information or an exposure assessment is recommended;

(2) c - the chemical is a candidate for further work: a risk assessment is recommended;

(2) d – other

At registration, the registration dossier will either include a testing proposal or not. Using the terminology of the OECD, the registration dossier will conclude, among other things, that either

(1) the chemical currently needs no further work (under REACH); or

(2) a - the chemical needs further work (under REACH): more hazard information is needed

This recommendation will be reached on applying the Annexes VI - XI of REACH and considering the information needs arising from the CSR. At dossier evaluation, the Agency will either confirm this proposal or reject it. At its own initiative, an EU Member State may initiate substance evaluation and conclude with any of the following recommendations:

(1) the chemical currently needs no further work (under REACH); or

(2) a - the chemical needs further work (under REACH): more hazard information is needed;

(2) b - the chemical needs further work (under REACH): more exposure information is needed;

(2) c - the chemical needs further work (under REACH): a risk assessment should be carried out;

If the recommendation is that further information needs to be generated (i.e., (2) a or b), then this must be based on reasons of suspicion that the substance presents a risk[9]. If the recommendation is that a risk assessment needs to be carried out (i.e., (2) c), then this can be done by the authorities as part of the restrictions procedure.

There are therefore considerable similarities between the recommendations of the OECD Programme and those of registration and evaluation under REACH. However, the objectives are very different, so the content of the recommended further work would probably be different.

In conclusion: the conclusions of Registration and Evaluation relating to the need for further information are very similar to the recommendations of the OECD Programme. However, as the frameworks of the two programmes are very dissimilar, the content of the recommendations would most likely also be dissimilar.

It is therefore only relevant to investigate how an OECD conclusion could be used with in the REACH context. The following table considers this in summary:

[9] Art. 43 (1)

OECD recommendation		Follow-up before registration	Substance Evaluation
(1)	low priority for further work	Manufacturers/Importers may consider if the information is relevant in relation to Annex IX waiving/derogation.	Authorities to consider if new information (e.g. exposure) gives rise to concern
(2) a	Further work: hazard	Manufacturers/Importers to carry out the further work and include it in the CSRs.	Authorities to consider if the further work is appropriately addressed by M/Is in the CSRs
(2) b	Further work: exposure	Manufacturers/Importers to consider issues leading to this conclusion in their CSRs	Authorities to consider if concern is appropriately addressed by M/Is in the CSRs
(2) c	Further work: risk assessment	Manufacturers/Importers to consider issues leading to this conclusion in their CSRs	Authorities to consider if concern is appropriately addressed by M/Is in the CSRs

In conclusion: the recommendations of the SIAR gives indications to Manufacturers and Importers of where to focus the attention in preparing the CSR.

–

Appendix I

Information Requirements

7. Information on the physicochemical properties of the substance	**OECD HPV Programme**	**1 tonne or more**	**10 tonnes or more**	**100 tonnes or more***	**1000 tonnes or more***
7.1. State of the substance at 20o C and 101,3 kPa		X			
7.2. Melting/freezing point	X, unless	X, unless			
7.3. Boiling point	X, unless	X, unless			
7.4. Relative density	X, unless	X, unless			
7.5. Vapour pressure	X, unless	X, unless			
7.6. Surface tension		X, unless			
7.7. Water solubility	X, unless	X, unless			
7.8. Partition coefficient n-octanol/water	X, unless	X, unless			
7.9. Flash-point		X, unless			
7.10. Flammability		X, unless			
7.11. Explosive properties		X, unless			
7.12. Self-ignition temperature		X, unless			
7.13. Oxidising properties	X, unless	X, unless			
7.14. Granulometry		X, unless			
7.18. Stability in organic solvents and identity of relevant degradation products				X, unless	
7.19. Dissociation constant	X, unless			X, unless	
7.20. Viscosity				X	
8. Toxicological information	**OECD HPV Programme**	**1 tonne or more**	**10 tonnes or more**	**100 tonnes or more***	**1000 tonnes or more***
8.1. Skin irritation or skin corrosion		X(*in vitro*) , unless	X *(In vivo)*, unless		
8.2. Eye irritation		X(*in vitro*) , unless	X *(In vivo)*, unless		
8.3. Skin sensitisation		X, unless			
8.4. Mutagenicity					
8.4.1. *In vitro* gene mutation study in bacteria	X	X			
8.4.2. *In vitro* cytogenicity study in mammalian cells	X		X, unless		
8.4.3.*In vitro* gene mutation study in mammalian cells			X, if + unless		
8.4.4 *In vivo* mutagenicity studies	X, if			X, if	(X)
8.5. Acute toxicity	X (1 route), unless	X (oral), unless	X (1 other route), unless		

8.6. Repeated dose toxicity	X (28 day), unless		X (28 day), unless X (90 day), if	X (90 day), unless	(X (long term))
8.7 Reproductive toxicity			X, unless	X, unless	
8.7.1. Screening for reproductive/developmental toxicity	X, unless		X, unless		
8.7.2. Developmental toxicity study,			X, if	X, unless	
8.7.3. Two-generation reproductive toxicity study (2nd species)			X (1st species), if	X (1st species), unless	X (2nd species), unless
8.8 Toxicokinetics			Assessment of the toxicokinetic behaviour of the substance to the extent that can be derived from the relevant available information		
8.9. A carcinogenicity study					(X)
9. Ecotoxicological information	**OECD HPV Programme**	**1 tonne or more**	**10 tonnes or more**	**100 tonnes or more***	**1000 tonnes or more***
9.1. Aquatic toxicity					
9.1.1. Short-term toxicity testing on *Daphnia*	X, unless	X, unless			
9.1.2. Growth inhibition study on algae	X, unless	X, unless			
9.1.3. Short-term toxicity testing on fish	X, unless		X, unless		
9.1.4. Activated sludge respiration inhibition testing			X, unless		
9.1.5 Long-term toxicity testing on *Daphnia*	X, if	X, if		X, unless	
9.1.6. Long-term toxicity testing on fish	X, if		X, if	X, unless	
9.2. Degradation					
9.2.1. Biotic 9.2.1.1 Ready biodegradability	X, unless		X, unless		
9.2.1.2. Simulation testing on ultimate degradation in surface water			X, if	X, unless	
9.2.1.3. Soil simulation testing			X, if	X, unless	
9.2.1.4. Sediment simulation testing			X, if	X, unless	
9.2.2 Abiotic 9.2.2.1 Hydrolysis as a function of pH	X, unless		X, unless		
9.2.3. Identification of degradation products				X, unless	
9.2.4 Further degradation				X, if	

testing					
9.3. Fate and behaviour in the environment					
9.3.1.Adsorption/desorption screening study			X, unless		
9.3.2.Bioconcentration in (one) aquatic species, preferably fish				X, unless	
9.3.3. Further studies on adsorption/desorption				X, unless	
9.3.4. Further environmental fate and behaviour studies					X, if
9.4. Effects on terrestrial organisms (short term)	X, if			X, unless	
9.4. Effects on terrestrial organisms (long term)					X, if
9.5. Long-term toxicity to sediment organisms					X, if
9.6. Long-term or reproductive toxicity to birds					X, if

* subject to alternative fulfilment of information requirements as outlined in Annex VI of REACH

–

Appendix II

Technical Dossier and SIDS Dossier Formats

Technical Dossier	**SIDS Dossier**
ROBUST STUDY SUMMARY **1. Definition** *Robust study summary* means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report (cf. Art. 3 (27)). **2. When to Use** For the study used and all studies demonstrating a higher concern than the study being used (Annex I, paragraphs 1.1.4 and 3.1.5).	**ROBUST STUDY SUMMARY** **1. Definition** *Robust study summary* 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). **2. When to Use** 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).
SUMMARY **1. Definition** Not defined, but same wording as for data submission under Reg. 793/93 (cf. Art. 3). **2. When to Use** For all other relevant and valid studies	**SUMMARY** **1. Definition** Not defined in detail, but has a "minimal level of detail". **2. When to Use** For all other relevant studies
TEMPLATE OECD Harmonised Templates are being implemented in IUCLID 5 and used for the	**TEMPLATE** The OECD has developed Harmonised Templates for the use of data reporting in Pesticides, Biocides, Existing Substances and New

Technical Dossier	**SIDS Dossier**
REACH – IT system if developed in time.	Chemicals.
IT SUPPORT TOOL Under REACH, registration must be done using the software supplied by the Agency. This software is currently under development by the Commission and is entitled REACH – IT. IUCLID 5, as developed with the assistance of the OECD IUCLID User Expert Panel, will be used in the REACH – IT system.	**IT SUPPORT TOOL** It is currently recommended to use IUCLID when preparing the SIDS Dossier.

Appendix III

CSR and SIAR Formats

Chemical safety report format	**SIDS Initial Assessment Report Format**
GENERAL STRUCTURE **1. Assessment Type** (Environment/Phys-Chem/Health) **1.1. Effect** 1.1.1. *End/point* 1. Studies in Animals 1.1 In vitro [Requested to use tables] 1.2 In vivo [Requested to use tables, clearly indicating route of administration] 2. Studies in Humans 3. C and L 4. DNEL: [Section includes conclusions (integration of the previous sections) and derivation of DNEL/PNEC]	**GENERAL STRUCTURE** **1. Assessment Type** (Environment/Health) **1.1. Sub-Assess Type** (Hum/Aqu/Ter/Other/Init Ass.) 1.1.1. *Effect* <u>End-point</u> 1. Studies in Animals 1.1 In vitro [Requested to use tables] 1.2 In vivo 1.2.X route of administration [Requested to use tables] 2. Studies in Humans 3. Conclusions: Note: The order of "route of administration" and "studies in animals/humans" not consistent for all end-points

Chemical safety report format	SIDS Initial Assessment Report Format
PART A **1. Summary of Risk Management Measures** **2. Declaration that Risk Management Measures are Implemented** **3. Declaration that Risk Management Measures are Communicated**	**SIDS Initial Assessment Profile [SIAP]**
PART B **1. identification of the substance and physical and chemical properties** ***1.1. Identification of the Substance*** ***1.2. Purity/Impurities/Additives*** ***1.3. Physical-Chemical properties*** ***1.4. Category Justification***	**OECD SIDS Initial Assessment Report** **1. identification of the substance and physical and chemical properties** **1.1. Identification of the Substance** **1.2. Purity/Impurities/Additives** **1.3. Physical-Chemical properties** **1.4. Category Justification**
2. Manufacture and Uses **2.1 Manufacture** **2.2 Identified Uses** **2.3 Uses advised against**	**2. General Information on Exposure** **2.1 Production volume and use pattern**
3. Classification and labelling	

Chemical safety report format	SIDS Initial Assessment Report Format
4. Environmental Fate Properties	**2.2 Environmental Exposure and Fate**
4.1. Degradation	
4.1.1. Photodegradation	**2.2.2. Photodegradation**
41.2. Stability in Water	**2.2.3. Stability in Water**
4.1.3. Biodegradation	**2.2.5. Biodegradation**
4.2. Environmental distribution	**2.2.4. Transport Between Environmental Compartments**
4.3. Bioaccumulation	**2.2.6. Bioaccumulation**
5. Human Health Hazard Assessment	**3. Human Health Hazards**
	3.1 Effects on Human Health
5.1. Toxicokinetics metabolism and distribution	**3.1.1 Toxicokinetics metabolism and distribution**
5.2. Acute toxicity	**3.1.2. Acute toxicity**
5.3. Irritation	**3.1.3. Irritation**
5.3.1. *Skin*	Skin
5.3.2. *Eye*	Eye
5.3.3. *Respiratory Tract*	Respiratory Tract
5.4. Corrosivity	**[3.1.4. Corrosivity]**
5.5. Sensitisation	**3.1.4. Sensitisation**
5.5.1. *Skin*	Skin
5.5.2. *Respiratory system*	Respiratory system
5.6. Repeated dose toxicity	**3.1.5. Repeated dose toxicity**
5.7. Mutagenicity	**3.1.6. Mutagenicity**

Chemical safety report format	SIDS Initial Assessment Report Format
5.8. Carcinogenicity **5.9. Toxicity for reproduction** 5.9.1. *Effects on fertility* 5.9.2. *Developmental Toxicity* **5.10 Other effects**	**3.1.7. Carcinogenicity** **3.1.8. Toxicity for reproduction** Effects on fertility Developmental Toxicity **3.2 Initial Assessment for Human Health**
6. Human Health Assessment of Physicochemical properties **6.1. Explosivity** **6.2. Flammability** **6.3. Oxidising potential**	
7. Environmental Hazard Assessment **7.1. Aquatic Compartment (including sediment)** **7.2. Terrestrial Compartment** **7.3. Atmospheric Compartment** **7.4. Microbiological Activity in Sewage Treatment Systems**	**4. Hazard to the Environment** **4.1. Aquatic Effects** **4.2. Terrestrial Effects** **4.3. Other Environmental Effects** **4.4. Initial Assessment for the Environment**
8. PBT and vPvB Assessment **9. Exposure Assessment**	**2.1. Production Volume and Use Pattern** **2.2. Environmental Exposure and Fate** **2.2.1. Sources of Environmental Exposure**

Chemical safety report format	SIDS Initial Assessment Report Format
10. Risk Characterisation	**2.3. Human Exposure**
	5. Recommendations
Note: Section Headers in italics mean that the issue header is not specified in Section 7 of Annex I, but that this is the information content under the section.	**Note:** Section Headers in yellow are specified in the SIAR format, but have been moved to be adjacent to the CSR corresponding header.