CHAPTER 5
PREPARING ASSESSMENT REPORTS

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. critically reviews the key results and outline the rationale for the hazard conclusions.

5.1 INTRODUCTION

In the context of the OECD Cooperative Chemicals Assessment Programme, *assessment reports* are the substantive documents that provide information on relevant hazards typically accompanied by limited exposure information. They are vehicles upon which the key scientific data on a chemical or category are presented for technical review and discussion at periodic chemical assessment meetings or via written procedures. The assessment report is submitted for discussion along with the *profile* (a summary of the assessment report; see Chapter 6) and study summaries of underlying data (see Chapter 2) for each endpoint. Once finalized, the assessment report, along with the accompanying documents, is made public.

There are two primary types of assessment report that are used on the programme. SIDS Initial Assessment Reports (SIARs) are prepared using a standard format for chemicals or categories with full Screening Information Dataset (SIDS) (most often these are high production volume (HPV) chemicals). SIARs are also used for expanded assessments of categories that have been previously prepared to meet all SIDS endpoints. OECD member countries and companies may also submit targeted assessments or reports from other programmes that assess a subset of SIDS endpoints or other hazard endpoints. For these limited endpoints, an Initial Targeted Assessment Report (ITAR) is prepared. Where an assessment report has been prepared in coordination with a national or regional programme, some of the guidance in this chapter may not be appropriate depending on the requirements of these other programmes.

This chapter and its annexes are organised as follows:

- ***Section 5.2****:* General guidance for preparing an assessment report
- ***Section 5.3****:* Endpoint-specific guidance for preparing a report
- ***Annex 1:*** Assessment report template with focus on the SIAR and appropriate modifications for the ITAR
- ***Annex 2:*** Notes file to accompany the template, with descriptions of the cover page and options for formatting within Word version 97-2003.

Because other chapters focus on gathering data for SIDS endpoints (Chapter 2), grouping chemicals (Chapter 3) and data assessment (Chapter 4), Chapter 5 focuses primarily on overall scope, content, and structure of the assessment report, with reference to these other topics only as needed.

5.2 GENERAL GUIDANCE FOR PREPARING AN ASSESMENT REPORT

There are several guiding principles for member countries and industry to consider when preparing reports. These principles are also useful when reports are prepared within the context of national or regional programmes.

5.2.1 Overall Scope and Length

For a given chemical or category, the assessment report provides key scientific data on relevant hazards as well as endpoint-specific conclusions for technical review and discussion. The report typically contains limited exposure information, which helps put hazard conclusions into context. Reports should generally be long enough for the reader to fully understand the reasoning and data used to reach conclusions on the assessed hazard endpoints but not repeat all study details reported in the dossier. As an example, the length of the SIAR for a single chemical is recommended to be about 30 pages. Category assessments for full datasets by necessity will be longer, and targeted assessments for single chemicals would likely be shorter.

5.2.2 Extent and Availability of Data

Statements about the nature and extent of the data available should be provided. Where data are limited, the report should state that only one or a few studies were available. In contrast, where data are extensive for a given endpoint, emphasis should be placed on describing several key studies and only briefly mentioning the supporting data. The extent of the database including a brief description of the study and the reference can be captured in a table, in additiona to a more detailed description of findings in the text. Key studies are often those studies for which detailed methods and results are reported and those that follow OECD test guidelines or other accepted guidelines. See Chapter 2, Section 4.2 for more information on choosing key studies.

Also, when multiple studies are given for physical-chemical and fate properties, recommended values for inputs to models should be chosen and indicated within the assessment report. Such recommended values are also helpful in the context of full SIDS assessments even when assessing non-SIDS endpoints. For example, Log K_{ow} is often used to classify substances for bioaccumulation potential and therefore, choosing a recommended value with an accompanying discussion of the validity of the data is critical.

Tables should be used to present details regarding experimental design and study results when there are multiple studies for a given endpoint. Use of tables ensures that the text of the assessment report is brief and focuses on the interpretation of the presented data rather than the experimental design and results. Ideally, any tables that are used should be placed in the body of the document rather than in an annex. The template in Annex 1 to this chapter presents an example table in the physical-chemical properties section that can be replicated in other sections as needed. Section 5.2.4 discusses presentation formats and use of tables for analogue and category assessments.

Where no data are available for a SIDS element where a full SIDS assessment is being prepared, a brief statement such as "No data were found for developmental toxicity" should be included with a reason as to why a new study should not be required. Such a statement, however, is not needed for the ITAR.

Also in the SIAR, when reliable and relevant studies are available on non-SIDS elements, the results should be presented and discussed. However, there is no obligation to generate, *de novo,* data on non-SIDS elements. For ITARs, on the other hand, there is more flexibility in the use and presentation of data; however, certain endpoints (e.g., physical-chemical properties, limited exposure data) can be included to give context to the targeted endpoints.

5.2.3 Data Quality and Interpretation

Data Quality Considerations

Although in principle only reliable information should be used to describe the hazards of a substance, studies that contain limited details or experimental flaws might be mentioned in rare circumstances. Such data might referenced, for example, if they support other reliable results or if they can play a role in making conclusions in the absence of reliable studies (e.g., by a weight-of-evidence assessment). In addition, there might be a situation where the study identifies significant results not seen in the key study AND there is a legitimate reason why the study cannot be obtained. Results from these less reliable studies should always be accompanied by caveats that describe their limitations. See Chapter 3 for detailed guidance on data reliability, relevance and adequacy, including definitions of Klimisch codes.

Adequacy of the data should be discussed. For example, the report should provide information on how closely the studies conform to test guidelines. Also, Klimisch codes available for individual studies in the dossier should be mentioned within the assessment report, preferably in endpoint-specific tables when data are extensive or within the text when there are only a few studies per endpoint among which some studies are just supporting (reliability 4, exceptionally 3) the key study. When Klimisch codes are not given, some mention of data quality should still be provided. Discussions of data quality are particularly important in cases where the data described in the assessment report are extensive and of variable quality.

Data Interpretation

The assessment report should provide interpretation of the results of studies for each SIDS or other data element. Discussion and interpretation is especially important when there are multiple studies available that might vary in their methods or results. In particular, the assessment report should discuss the concordance of results across the studies, and if results diverge, a plausible basis for such divergence, if any, should be presented.

Also, when the author of the assessment report has a different interpretation of a study than that of the study author, the report should contain sufficient information describing the alternative interpretation and a narrative supporting the reason(s) for a difference in interpretation.

Such discussion can be placed in the body of the report as necessary to explain the individual studies. However, it is especially important to provide a clear discussion and reasoning within the final conclusion sections for each of the endpoints.

Final Conclusions

Furthermore, as noted in Annex 1, the human health and aquatic toxicity sections should include brief (i.e. 2-3 lines) bolded final conclusion sections that match the wording in the profiles. For SIARs, this section should address the human health or ecotoxicity endpoints. Further, for the ecotoxicity endpoints, additional information on biodegradation and bioaccumulation should be added. The conclusion should be accompanied by standard language stating that the SIDS endpoints have been met. Similar sections can be included for ITARs without stating that all SIDS endpoints have been met. See more details in Section 6.3 regarding possible criteria (e.g., GHS) for judging toxicity.

5.2.4 Reporting Analogues and Categories Information

OECD's *Guidance on Grouping of Chemicals* contains information on building analogue or category assessments, types of category and analogue approaches as well as suggested formats for presenting data. Some key points are discussed below and in appropriate sections within Section 5.3.

Use of Single Assessment Report for Analogue or Category Approach

When analogues are used to address data elements for chemicals that lack information or when a category of chemicals is being evaluated, only one assessment report should be prepared. For example, if an assessment of butyl acetate uses data for butanol for some endpoints, all data should be integrated within the butyl acetate assessment report.

It is possible, however, that an analogue or one or more category members already have published SIARs, in which case, reference to the earlier assessment should be included within the SIAR or ITAR that relies on the earlier assessment.

Use of a Data Matrix for chemical category

When a SIAR is elaborated for a chemical category, a data matrix should be included to illustrate the extent to which data for tested chemicals are used to read-across or establish a trend analysis for untested chemicals. The data matrix of all SIDS endpoints should be placed in an annex to the SIAR and include qualitative or quantitative values for all sponsored chemicals using the key toxicity study (usually the study resulting in adverse effects at the lowest dose) or recommended value (for physical-chemical or environmental endpoints) when multiple studies are available for an endpoint for a given chemical. Chapter 7 of OECD's *Guidance on Grouping of Chemicals* discusses the use of data matrices and Appendix 1 to the grouping guidance presents an example of a completed data matrix for phosphonic acids and alkali metal salts.

A data matrix would also be helpful when an ITAR is being prepared for a chemical category.

Presentation within sections of the assessment report for use of analogue data

When analogue data are used for a full SIDS assessment, the endpoint-specific sections within the report should clearly state that no data are available for the sponsored chemical and that the endpoint is being addressed using data from the analogue. Such clarity is also of course needed in the ITAR when analogues are used.

Presentation of information within sections of the assessment report for a chemical category

For categories, discussion of each chemical for which data are available should be presented separately within each endpoint element section. As an example, for the section on repeated-dose toxicity, if five chemicals form the category and three chemicals have data, the three chemicals with data should first be described separately (e.g., in separate paragraphs). Then the section should continue by noting how these data can be extrapolated (extended) to the two remaining chemicals, along with a discussion of similarities and differences in the data for the three chemicals. Then the conclusion section for repeated-dose toxicity can include a data summary and an overall conclusion for the whole category.

When differences in data among chemicals are noted, explanations should be given to characterise the difference (e.g., "minor differences in the NOAELs of each study might be related to an increase in molecular weight of the substance and the ability of the substance to be available for consumption" or "differences in effects may be due to different routes of exposure.")

Tables can be a very useful when organizing assessments that rely on either an analogue or category approach. These tables are distinct from the data matrix (see above) and would be presented within the specific endpoint sections and are used primarily to assist in readability of the report when there are many studies.

Presentation of Subcategories

In some instances a specific category of chemicals may be acceptable for one set of endpoints but not for others. As an example, chemicals may have similar physical-chemical and environmental fate properties and react similarly in the aquatic environment but may have different human health-related toxicities. In such cases, the sponsor should thoroughly evaluate the chemicals proposed for the category to determine if possible subcategories may be required for specific endpoints. Alternately, the sponsor may evaluate one set of endpoints as a category and another set of endpointsseparately for each chemical in the category.

Another situation where sub-categories may be formed is when hazard conclusions vary within the category because of increasing carbon chain length of its members - the chain length reaches a breaking point where the size of the chemical prevents crossing membranes, hence toxicity is no longer observed. The hazard conclusion is not necessarily the same for all chemicals across the category, depending where chemicals are in relation to the cut-off value (i.e. number of carbons on the linear chain). The conclusion 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.

References to Published OECD and Other Reports

It is important to take into consideration conclusions that have already been made either in published OECD assessments or in other peer reviewed assessments of any chemical presented as an analogue or within a category. Conclusions in the analogue or category that use the existing OECD or other assessments should match the conclusions of existing assessments whenever possible, unless other newer data are available, or unless a clear and thorough explanation is provided that would make the published conclusions obsolete. For example, if a chemical from SIAM 20 was considered to be a mutagen and is being used as an analogue for a chemical presented at SIAM 32, the chemical presented at SIAM 32 should also be considered a mutagen if no new data suggest otherwise.

Hydrocarbon Solvents

As a result of discussions at SIDS Initial Assessment Meetings, several specific items of information were agreed to include in assessments conducted on hydrocarbon solvents. A list of identifiers is included in section 5.3 below, along with information on adding a caveat about the CAS number coverage, if needed. These identifiers and the caveat should be used whether taking a single “substance” or a category approach. These identifiers are essential so that the category can be easily understood and evaluated. In addition to the identifiers noted in Section 5.3, it is essential that for the category as a whole, the carbon number range should identify at least 80% of the chemical constituents. For example, if the category is identified as a category of C10-C13 aromatic hydrocarbon solvents, at least 80% of the constituents of the category members should be within this range.

5.3 SECTION-SPECIFIC GUIDANCE FOR PREPARING AN ASSESSMENT REPORT

To ensure a harmonised format among assessments drafted by different member countries, a template that focuses primarily on preparation of the SIAR can be downloaded from Annex 1. Annex 2 contains tips on formatting the document within Word and describes what to enter in the cover page sections.

Other formats can be accepted in place of a SIAR if they comply with the objectives of the SIAR, i.e. to outline the rationale for the hazard conclusions. For example, European Union Risk Assessments have been submitted as SIARs (see http://ecb.jrc.ec.europa.eu/esis/). Data in these reports was evaluated both for its adequacy and its completeness with respect to the SIDS endpoints.

Formats for targeted assessments will vary depending on the endpoints assessed and on whether they have been prepared within other programmes. Annex 1 can be adjusted as needed when preparing an ITAR. For example, an assessment that targets genotoxicity and carcinogenicity data could present these data in the order specified in the Annex 1 template, along with any other sections (e.g., physicochemical properties) that may be needed.

The following sections are organized according to the assessment report sections that may be used (with numbering to match the sections as they should appear in the SIAR), and discuss situations specific to the SIAR or ITAR as appropriate.

5.3.1 Cover Page

A cover page should be included and should designate the SIDS contacts, shared partnerships, prior history and details of the quality check process. The quality check process is particularly important to maintain superior reports and therefore, the process used should be fully described. For a targeted assessment, the comments section can be used to note the endpoints that have been assessed.

5.3.2 Identification of the chemical(s)

This section of the assessment report should include basic chemical information such as CAS number(s), name(s), structural and molecular formula. When a category is assessed, each member should be clearly identified, using consistent nomenclature in this section and the rest of the report.

With respect to the composition of the chemical(s) being assessed, Chapter 2, Section 2.1, Substance Information lists data that should be reported for s*ingle chemicals, mixtures, class 2 substances* and *streams*. The assessment report should generally include the same descriptors as those in the dossier.

Justifications for analogue or category approaches are included in Section 1.4. The justification should be described in adequate detail and relevant data upon which the rationale was based – such as similarities in chemical structures, physical-chemical and environmental fate properties, and toxicity data – should be presented. Generally a few paragraphs should be used; however, this section might be longer for large categories. See guidance on the grouping of chemicals for information on building a category or analogue assessment and developing hypotheses and justifications. Subsections within Section 1.4 can be used when both category and analogue justifications are needed.

Hydrocarbon Solvents

As a result of discussions at SIAMs, several specific identifiers were agreed as necessary to include in the profiles for hydrocarbon solvents. These are:

- CAS number
- Carbon number range

  - The range should include at least 80% of the chemical constituents found in the UVCB;
  - Further, the percent of indicated carbon number range should be specifically noted (e.g., C10-C13 > 90%)
- Content of: benzene, n-hexane, sulphur or other components with specific toxicities
- PINA (paraffins, isoparaffins, naphthenes [cyclics] and aromatics) distribution
  - Indicate first three if between 10-80% and indicate aromatics as < or > 2%
- Boiling point range

Because CAS numbers used for hydrocarbon solvents may include a wider range or higher percentages of certain constituents for other uses (e.g., fuel vs. solvent uses), a note should also be added for any hydrocarbon solvents to indicate that other streams with the same CAS number might not be covered in the assessment if they don't meet the identification criteria described in the assessment. Similar considerations should be made for other UVCBs or complex mixtures produced from variable feedstocks.

5.3.3 Physical-chemical Properties

The SIAR or ITAR includes a section where these properties are presented in a table (see Annex 1). Endpoint values should be specified as to whether they have been estimated (e.g., via (Q)SARs) or measured experimentally, and the reference or model used and version. Temperature- and pressure-dependent physical/chemical data should be reported preferentially for standard ambient temperature (i.e. 298.15 K, 25°C) and pressure (i.e. 1013 hPa) conditions. For substances that may dissociate in aqueous environments, the dissociation constant (e.g., pKa for acids) should be mentioned. Also the predominant form/species of the substance in neutral pH environment should be indicated for clarity.

Certain physical-chemical properties may not be measured depending on the nature of the chemical (e.g. octanol-water partition coefficient for inorganic chemicals) and this can be reported in the table as "Not applicable".

5.3.4 Rationale for Targeting the Assessment (ITAR Only)

This section should be added for any single chemical or category assessment that targets certain endpoints. The rationale will vary depending on the purpose of the assessment. If the targeted endpoints are evaluated within a certain regulatory context, some background on the regulatory programme can be added. Examples of this type of rationale are those for assessments conducted for certain human health endpoints under the Japanese Chemical Substances Control Law (see CAS Nos. 5460-09-3 and 27676-62-6 from SIAM 31 in OECD's Existing Chemicals Database). Alternately, a rationale could simply be that the targeted endpoints/related effects are the primary toxicities of concern for a given chemical or category. In all cases, the endpoints targeted in the assessment should be listed in this section.

5.3.5 General Information on Exposure

To maintain high output and make the best use of data and assessments offered by the International Council of Chemical Associations (ICCA), the Cooperative Chemicals Assessment Programme focuses primarily on screening level hazard conclusions for human health and/or the environment. Therefore, when a SIAR is being prepared, it should include only general information on exposure to put hazard(s) into context, and due to its limited scope, the exposure data is not intended as a basis for risk assessment.

As a general rule, exposure information within the SIAR should include production volume and use data. It is not necessary to conduct exposure modelling or monitoring of concentrations in workplaces, homes or the environment, although if available, this type of information can be referenced in the

assessment report with additional details within the dossier. Regardless of the type of assessment report, the source of exposure information should always be provided, whether a peer-reviewed journal article, unpublished company data or personal communication.

If exposure data are more extensive than simple use patterns, the following important aspects should be addressed whether it is presented in a SIAR (in Sections 2.1-2.3) or ITAR:

- Any information available on sources of exposure (workers, consumers, environment) should always be specified as to whether it is related to a given site or whether it is generic for a given use.
- Similarly, any information on exposure reduction measures should be specified as to whether this is related to a given site or whether it is considered generic for a given use.
- The extent to which information provided is based on actual measurement of releases or exposures, modelling or other estimation methods, or expert judgment should be clearly indicated.
- The specific producers and/or users to which any information provided applies should be identified.
- Because the industry partners that participate in the preparation of full SIDS assessments are usually chemical manufacturers rather than processors and users (unless processing and use are supplemental activities of the manufacturer), care should be used when making conclusions on downstream uses.
- Likewise, care should be taken not to make overreaching conclusions when data are not available to support such conclusions.

If an ITAR has been prepared within the context of another programme, a variety of exposure data (possibly with extensive results) might be included in the report. In general, however, the focus of chemical assessment within the Cooperative Chemicals Assessment Programme is on hazard assessment. Therefore, ITARs, like the SIAR, would often likely only include limited exposure information.

5.3.6 Production Volumes and Use Pattern

At a minimum, the following information must be provided when preparing a SIAR to put the human health and environmental hazard information into context:

- Estimated production/import volume in the sponsor country (in tonnes per year) or, for assessments prepared under voluntary industry programmes, in the country where the lead company is located (section 3.2 in IUCLID 5).
- Use categories and/or functions in the sponsor country or, for assessments prepared under voluntary industry programmes, in the country where the lead company is located (section 3.5 in IUCLID 5).

The OECD guidance document, ENV/JM/EA(2010)3[B1] on use descriptors can be used when determining and describing the uses of a chemical or category.

The following supporting information, if reported and verified, would significantly improve the usefulness of the SIAR:

- The percentage of the production volume associated with each use in the sponsor country or, for assessments prepared under voluntary industry programmes, in the country where the lead company is located
- The OECD and global annual production quantities
- Number of producers in the sponsor country or, for assessments prepared under voluntary industry programmes, in the country where the lead company is located
- Number and production capacities of producers in other countries
- Brief general description of manufacturing/production processes

- Physical form of product(s) as transported or as purchased and used by the consumer
- The use pattern in other countries

This information can also be presented in ITARs as needed to put the hazard data into context.

5.3.7 Environmental Exposure and Fate

Sources of potential releases to the environment as well as the compartments into which the chemical is likely to be released ~~(see section 1.7 of the SIDS Dossier)~~ can be discussed qualitatively in this section if information is available in enough detail to make such statements. When making these judgements, the whole life-cycle of the substance should be taken into consideration. Available information on amounts released into the environment or monitoring data on environmental concentrations can be summarised in this section and used as a basis for conclusions. Physical-chemical and fate properties can also help to make conclusions about the likely compartments into which chemicals might be released and distributed.

Information on environmental fate parameters is provided in the SIAR under this section, with brief summaries of the available data as well as recommended values. Details of endpoints to cover and discuss include:

- Degradation endpoints
  - Abiotic in water (hydrolysis):
    - half-life, temperature and pH conditions
    - if measured, note the hydrolysis products
  - Air (photodegradation):
    - half-life
    - type of photolysis (direct; indirect by reaction with OH radicals and/or ozone)
  - Biodegradation (aerobic/anaerobic):
  - classification (e.g., readily or not readily biodegradable)
  - extent of biodegradation - percent of initial amount at the end of the test (and number of days associated with the result)
  - if readily biodegradable, indicate whether the 10-day window was met

- Distribution and transport between environmental compartments
  - Indicate the modelled transport values as well as the model used.
  - Henry's Law Constant, although not a required SIDS endpoint, is useful for determining the likelihood of volatilization. Therefore, it should be reported, with a statement on the likelihood of volatilisation from water.
  - log K_{oc} is a useful measure to help estimate adsorption to organic matter in soil and sediment, and should also be discussed in most cases even though it is not a SIDS endpoint.
  - When using distribution models, the percentages distributed to various compartments should be stated according to the example in the Annex as well as the model used.
  - For Level III models: inputs used should be at least for equal and continuous release to all three compartments, and in addition release to the compartment most likely to receive the substance in the environment (if applicable)
  - Environmental fate models should be used only for substances that are within the applicability domain of the model. If the training set for the model does not include the type of chemical sponsored or only a limited number in its training set, and so if the model has limitations for that type of chemical, a disclaimer should be added in the SIAR/ITAR and SIAP/ITAP.

- Bioaccumulation

- If there is a bioaccumulation potential expected (estimated using the Log K_{ow} or measured), then information related to the possibility for adverse effects attributed to secondary/long-term accumulation (poisoning) should be included in this section of the profile.
- Bioconcentration factors (BCF) - either measured or estimated values using the partition coefficient (log K_{ow}) may be useful here as well.
- When reporting the measured BCF, the basis of the result should be given (i.e., kinetic or steady state, whole fish or lipid, etc.) as well as the method used and any extra important details, such as whether the result was based on measurement of radioactivity (in case radiolabelled material was used) or on analytical measurement of the actual chemical, and whether results are normalised to a set lipid content (for whole body BCF) or if, for kinetic BCFs, the result has been corrected for growth dilution.

Regardless of whether a SIAR or ITAR is prepared, the assessment report should clearly note the specific model and version of any models used to estimate some of these endpoints. Input values to the models are more appropriately placed in the dossier.

Information that should routinely be discussed in the assessment report (SIAR or ITAR) for environmental fate endpoints includes identified degradation products from hydrolysis and biodegradation tests and from photodegradation tests, if available.

5.3.8 Human Exposure

Although not required, any information available to characterize human exposure is useful and can assist in reaching conclusions on the potential for overall exposure to humans.

Thus, it is recommended that available information on occupational and consumer populations be presented in the assessment report if not too extensive. When presenting occupational exposure information, existing relevant workplace exposure limit values (e.g. TLV, MAK) may be presented, along with job tasks associated with the highest potential exposure.

Also, it is recommended that non-occupational exposure address direct exposure from use of products that contain the chemical (e.g., via inhalation, dermal contact, etc). Indirect exposure, such as via food, water, air or naturally occurring compounds can also be noted.

In describing sources of human exposure, it is helpful to note the exposure pathway (e.g., contact with consumer products, through the diet, or through drinking water) and likely exposure route (e.g., dermal, inhalation) for each source.

Also, if there are possible high potential exposures (such as presence in certain diet constituents), this information can be highlighted in the discussion. Likewise, the report can also address whether exposure might be expected to be limited (e.g., is the chemical polymerised, bound or otherwise immobilised?).

5.3.9 Human Health Hazards

When preparing a SIAR, results of toxicity tests and other information should be summarised in separate sections for each of the SIDS elements (plus non-SIDS elements if available) and presented in the order indicated in Annex 1. The ITAR would be modified as appropriate depending on the endpoints to be assessed. A list of the SIDS endpoints as well as major non-SIDS endpoints that may be included in an assessment report are as follows:

- ***SIDS elements:***
  - Acute toxicity
  - Repeated-dose toxicity
  - Genetic toxicity (gene mutations and chromosomal aberrations)
  - Reproduction toxicity (fertility and developmental toxicity)
- ***non-SIDS elements:***
  - Toxicokinetics information (e.g., absorption, distribution, metabolism, excretion)
  - Skin and eye irritation
  - Respiratory tract irritation
  - Sensitisation
  - Carcinogenicity
  - (Developmental) neurotoxicity
  - Epidemiological studies or biomonitoring studies

It is possible, also, that non-SIDS endpoints in addition to those in the above list might be included, depending on the type of chemical(s) being assessed and the type of assessment being conducted. In particular, as integrated approaches to testing and assessment become more widely undertaken – mode of action, high throughput – may also be referenced in assessment reports for either single chemical assessments or more likely for assessments that rely on read-across for filling endpoints.

The order of additional endpoints should reflect the IUCLID format (e.g., toxicokinetics before all endpoints; skin irritation, eye irritation and skin sensitisation after acute toxicity; carcinogenicity after genetic toxicity).

When describing results, it is important to report the toxicological effects observed as well as doses that produced these effects, especially for repeated-dose toxicity and reproduction/developmental toxicity. The classification terminology of the GHS can be used as a guide for specific language regarding severity of effects (e.g., for skin and eye irritation). For each data element, information should be separated by similar study type (for example, inhalation, dermal, and oral routes of exposure). If human data are available, they should be described separately from non-human data within each relevant endpoint section.

Although there are certainly many issues to consider when preparing an assessment report, a couple of important items related to data presentation will be mentioned here. First, in cases where there is immediate and/or significant breakdown of the chemical(s) being assessed, the potential toxicological significance of breakdown products or metabolites should be discussed in the toxicokinetics section. The toxicokinetics section is also important when category/analogue justifications are based on the use of a metabolic series. More information on the types of information to consider in the toxicokinetics section is outlined in the Annex to Chapter 4.

Also, where the Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD Test Guideline 422) has been conducted, care must be taken to separately present results of systemic effects of repeated dosing and the developmental and reproductive effects. The endpoint-specific effects should be presented in the relevant sections within the assessment report.

5.3.10 Hazards to the Environment

Aquatic Toxicity

Results of ecotoxicity tests and other information are summarised and discussed in separate sections in the order described in Annex 1 to Chapter 5. Generally, acute fish and daphnid studies and algae data,

and sometimes chronic data, are available in a full SIDS assessment. However, results from tests with other aquatic species, especially micro-organisms, should also be reported if available and relevant.

Results for ecotoxicity tests and other relevant information should also be summarised and presented in this section. When multiple studies are available for the same endpoint, results are better presented in a table, followed by a discussion of key findings. Importantly, the study summaries should report the following: duration of the study and species used, test system (flow-through or (semi-)static), whether the test concentrations were measured or reported as nominal, the measurement method and what was exactly measured, any deviation from standard test method and result (L/EC_{50}, NOEC/LOEC).

It is important to indicate whether reported values represent measured or nominal concentrations. In the case of unstable test substances or substances tested as mixtures, the chemical identity on which the result is based should be clearly stated. For substances with very low solubility and difficult to test substances (e.g. substances that are not stable under test conditions), details on the preparation of the test solution is useful (e.g. type and concentration of dispersant used, loading rate, or WAF, etc.) and a discussion on the potential impact on the assay and the results is appropriate (e.g., for volatile substances one is interested to know whether test vessels were sealed or not, if so details on headspace, etc.) to understand what is happening in the test system between the chemical and the exposed organisms.

In the discussion of aquatic effects, a qualitative consideration of the following items is recommended if relevant data are available:

- The possibility to cause chronic effects based on physical-chemical properties (e.g., octanol-water partition coefficient), stability (e.g. hydrolysis half-life), relationship between acute toxicity and time, release pattern, degradation products or other relevant considerations; and
- The toxic mode of action of the chemical (especially as it may impact a chemical category or a chemical for which analogue data are used).

When presenting data that has been obtained via modelling, the assessment report should clearly state the specific model and version used. Input values are more appropriately placed in the dossier.

The results of all testing and modelling data should be clearly summarised in a final conclusion section for a clear idea of the overall toxicity of the chemical in the aquatic environment.

Predicted No Effect Concentrations (PNECs), which are derived by applying assessment factors to NOEC values from aquatic toxicity studies, are not required but may be included for information purposes. If they are included, the basis of choosing specific assessment factors needs to be stated in the assessment report. However, the ratio of the predicted environmental concentration (PEC)/PNEC is a risk-based calculation and therefore not appropriate for the SIAR (and also probably not for the ITAR). There may be exceptions, however, for assessment reports prepared in other programmes that rely on procedures specific to those programmes.

Terrestrial Effects

For the SIAR, if information is available that shows potential significant exposure to the terrestrial environment, available information on such effects (e.g., acute toxicity to earthworms and terrestrial plants, toxicity to sediment-dwelling organisms or any likely avian effects) should be provided. Other relevant data (e.g. toxicity to soil micro-organisms) should also be reported in this section, as toxicity to micro-organisms may sometimes explain lack of ready biodegradation.

Information on well-known ecological damage and/or contamination in relation to the substance and/or its metabolites should be noted (e.g. eutrophication, acidification, global warming, tropospheric

ozone formation /ozone layer depletion, potential formation of very fine particulate matter (PM 2.5), endocrine disrupting properties, etc.).

Although PNECs are not required, if a PNEC for soil is proposed within the assessment report, the underlying procedure and rationale used to derive the PNEC should be described and referenced. Targeted assessments may not have information on terrestrial effects, but if so, the same guidance should be followed.

If data are extensive, the results of all data should be clearly summarised in a final conclusion section for a clear synopsis of the toxicity.

Other Environmental Effects

Other relevant and reliable information on non-SIDS ecotoxicological elements should also be discussed in the SIAR depending on the use of the chemical. This information might include information on toxicity to sediment-dwelling organisms or any likely avian effects. Information on well-known ecological damage and/or contamination for the substance and/or its metabolites should also be noted (e.g. eutrophication, acidification, global warming, tropospheric ozone formation/ozone layer depletion, endocrine disrupting properties, etc.).

Furthermore, a discussion on the possibility of secondary poisoning (i.e., potential impact of substances on top predators due to accumulation through food chains) should be included if there is potential for bioaccumulation.

Similar guidance should be used if such environmental effects are evaluated in a targeted assessment.

5.3.11 References

References for the key studies and any other studies specifically mentioned in the assessment report should be included to ensure that it is a stand-alone document. The reference list at the end of the assessment report should contain only the studies used in the report, since the dossier provides the comprehensive reference list. Annex 2 presents a suggested format for the citations within the assessment report.