Excerpt from the Handbook of the Chemical Review Committee

**Working paper on preparing internal proposals and decision guidance documents for banned or severely restricted chemicals**

## 1.2 Working paper on preparing internal proposals and decision guidance documents for banned or severely restricted chemicals

|  |
| --- |
| *Reference: UNEP/FAO/RC/CRC.14/10*  *This document provides guidance to intersessional drafting groups of the Chemical Review Committee (CRC) in the preparation of decision guidance documents for banned or severely restricted chemicals. It is designed to clarify the purpose of each section of the decision guidance document and to characterize the information to be included.*  *The working paper, originally developed by the interim CRC, was adopted at the first meeting of the CRC. Subsequent meetings of the CRC have reviewed and amended this working paper based on the experience gained in drafting decision guidance documents. This most recent version was approved by the fourteenth meeting of the CRC with the understanding that it would continue to evolve in the light of future experience.* |

**Purpose**

This working paper is to serve as guidance to drafting groups established by the Chemical Review Committee for the preparation of decision guidance documents for banned or severely restricted chemicals in accordance with Article 5 of the Rotterdam Convention.

This working paper is intended:

1. To clarify the purpose of each section of the decision guidance document;
2. To characterize the information to be included;
3. To define acceptable sources of information for each section.

This working paper is expected to evolve as further experience is gained in the preparation of decision guidance documents. It is to be used by drafting groups preparing decision guidance documents for both pesticides and industrial chemicals. In this version of the working paper those sections which are potentially different for industrial chemicals and pesticides have been highlighted. If required, future versions of the working paper may be split into two separate working documents, one for pesticides and one for industrial chemicals.

A separate working paper has been developed for the preparation of decision guidance documents for severely hazardous pesticide formulations in accordance with Article 6 of the Rotterdam Convention.

In order to further facilitate the work of the drafting groups an electronic template of a draft decision guidance document has been prepared as a companion document to this working paper.

**General guidance**

In preparing each decision guidance document a standard cover/title page will be added as will a version of the standard introductory text developed at the fourth session of the interim Chemical Review Committee. This text provides a brief summary of the process through which the individual decision guidance document was developed and includes three separate sections an introduction, purpose and disclaimer.

In cases where a decision guidance document includes more than one chemical (*e.g*. asbestos), a table of contents will facilitate the use of the document. Similarly the insertion of footers identifying the chemical should be included on each page.

A standard list of “core” abbreviations has been prepared based on experience in drafting decision guidance documents to date. It is intended that this core list should serve as the basis for decision guidance documents for both industrial chemicals and pesticides and that it should be augmented by abbreviations used in the individual decision guidance documents relevant to the chemical(s) in question. This core list of abbreviations is appended to this working paper (appendix 1). As a general rule it is preferable that acronyms used only once in the text be spelled out rather than included in the list of abbreviations.

In preparing a decision guidance document, it may be that not all sections are relevant to the chemical under consideration. It is preferable, in this case, to include a phrase along the lines of ‘not applicable’, rather than deleting the section or leaving it blank. This clearly indicates that the drafting group had considered that section.

**1. Identification and uses**

**Purpose:** To provide an unequivocal identification of the chemical subject to the PIC procedure and its use as either a pesticide or an industrial chemical, or both.

1. This basic information should be obtainable from the submitted notifications and the supporting material available to the Committee prior to its decision to develop a decision guidance document.
2. CAS numbers for all forms of the chemical covered in the relevant notifications of final regulatory action should be included here. The scope of the chemical identified in this section (chemical description and associated CAS numbers) must be consistent with the recommendation by the Chemical Review Committee (CRC) for inclusion of the chemical in Annex III of the Convention. Should additional CAS numbers be found during the development of the decision guidance document, they should be brought to the attention of the CRC. If they do not broaden the scope of the original notification, they could be included here.
3. Chemical structural formula should be included if practicable. Structural formula may be found in standard references documents on pesticides *e.g*. The Pesticide Manual.

**Notes:** Updated or additional information on trade names, formulation types and basic manufacturers for products moving in international trade may be identified through the responses to the call for information on on-going manufacture, use and trade of the chemical.

The list of trade names, formulation types and manufacturers should, where possible, distinguish old products from those that are known to be moving in international trade.

It is clear that a list of both manufacturers and trade names will be constantly changing, for this reason a generic disclaimer along the following lines should be considered:

1. Under trade names:
2. This is an indicative list of trade names. It is not intended to be exhaustive.
3. Under basic manufacturers:

*This is an indicative list of current and former manufacturers of XXX. It is not intended to be exhaustive*.

In accordance with article 7, when a chemical may be used as both a pesticide and an industrial chemical (a dual-use chemical), the decision guidance document should provide information on uses in both categories. A statement on “reported use in X category” or “no reported uses in X category” should be given (where X is either an industrial chemical for a pesticide decision guidance document or a pesticide for an industrial chemical).

**2. Reasons for inclusion in the PIC procedure**

**Purpose:** To provide a generic statement that clearly identifies the use category (pesticide or industrial chemical) and whether the chemical is subject to a **ban** or **severe restriction** in the notifying countries.

1. References to any previous listing(s)under the PIC procedure should also be included, where relevant.
2. For dual-use chemicals, it will also be important to note when the PIC obligations do not apply to the use category that was not regulated.

**Example:** *[Chemical X]* is included in the PIC procedure as a pesticide. It is has been listed on the basis of the final regulatory actions to severely restrict its use, notified by *[Country 1]*, and to ban its use, notified by *[Country 2]*.

No final regulatory actions relating to industrial chemical uses have been notified.

List notifying countries alphabetically.

**2.1. Final regulatory action**

**Purpose:** To provide a brief statement/summary of the final regulatory action(s) as reported by the notifying countries and the reasons for the actions taken (*e.g*., occupational health concerns, environmental concerns).

1. The text should reflect the reasoning used by the regulatory authority to underpin the national regulatory action(s) – for example, as presented in national law, regulation, gazette, legal journal, code.
2. Specific reference to the relevant directive or regulation for the reported regulatory action(s) should be included in annex 2.
3. The reason(s) stated should set the stage for the subsequent description of the underlying risk evaluation.

National authorities should ensure that any technical legal references, if they are used, are accurate.

**2.2. Risk evaluation**

**Purpose:** To provide a brief summary (no more than 1-2 pages) highlighting the key reported finding(s) of the national risk evaluation(s) that led to the regulatory action(s).

1. The text should reflect the reason(s) identified in the final regulatory action(s) by the notifying countries and include information on the uses that were permitted prior to the regulatory action.
2. In the interests of brevity, the text may include references to Convention Annexes I and II for additional details.

**Note:** Depending on the chemical and the finding(s) of the national risk evaluations, this section may provide information on an individual country basis, or, where there are multiple country notifications based on common human health or environmental concerns, the information may be summarized and combined. It would also be useful to highlight the differences in regulatory actions, if they are not already obvious.

**3. Protective measures that have been applied concerning the chemical**

**Purpose:** To highlight measures taken to reduce exposure, in the first instance through *regulatory* controls or measures and secondly through *other* measures (administrative, non-legal/voluntary codes of practice, field practice, etc.) recalling that:

1. A **ban** in the regulated category of use eliminates all exposure (occupational or environmental); and
2. A **severe restriction** in the regulated category of use allows continued use in a manner that reduces risk to an “acceptable” level.

**3.1. Regulatory measures to reduce exposure**

**Purpose:** To provide information on the *regulatory* measures taken to **ban** or **severely restrict** the chemical and associated products.

1. for **bans**, the risk has been eliminated and therefore a simple explanation of the risk management strategy to deal with existing stocks may be enough; and
2. for **severe restrictions**, briefly describe the regulatory measures taken/set in place to reduce the risk to acceptable levels - *e.g*. by restricting access to trained/certified applicators or requiring purchasers to be licensed.

**3.2. Other measures to reduce exposure**

***This section is primarily intended for additional information from the notifying country(ies) on chemicals that have been severely restricted e.g. chemicals where for which virtually all use has been prohibited.***

***For most banned chemicals this section would not be completed. The exception is where there was relevant chemical specific information from either the notifying country or international sources on possible risk mitigation measures.***

**Purpose:** To provide information about *non-regulatory* measures (including technical and field-level arrangements) for severely restricted chemicals taken/set in place to reduce exposure and ensure that risk remains at an acceptable level for the uses that are permitted to continue. Information could include, for example changing the type of formulation or application equipment used, specifying the personal protective equipment or clothing required.

Where available, information from the notifying country or international sources of information on chemical specific risk mitigation measures may also be referenced. Examples may include publications from the International Labour Organization or International Standards Organization.

It is not intended that generic information on handling hazardous chemicals would be included in this section.

**Note:**  In order to maintain the timeliness and accuracy of this information, it is preferable to include references to additional sources of information (electronic links, etc) for a specific chemical on the Rotterdam Convention website. New sources of such information could also be included in a series of up-dates that could be distributed to designated national authorities along with the PIC circular.

**3.3. Alternatives**

**Purpose:** To provide countries with brief information about alternatives that have been identified by the notifying country or countries and others where available.

It is not be feasible for the decision guidance document to contain a comprehensive list of specific pest crop complexes and recommended pesticides or non-chemical alternatives, particularly for pesticides that have a broad spectrum of activity. As the available alternatives are constantly evolving, identifying sources of information is likely to be more useful and more reliable than a list of specific recommendations.

1. Notifying countries may provide information about chemical and non-chemical alternatives that are being used within their jurisdictions. Detailed information can be included in annex 2.
2. Information from sources other than the notifying country might be referenced here with details on where the information might be found provided to DNAs through the PIC Circular and the Rotterdam Convention website (see following note).

**Note:** While recognizing that a range of chemical and non-chemical alternatives may be available, this section should include a generic statement on the need for caution in considering them or using them and should remind parties of the need to ensure that they are appropriate to national circumstances.

In order to maintain the timeliness and accuracy of this information, it is preferable to include references to additional sources of information (electronic links, etc.) for a specific chemical on the Rotterdam Convention website. Such new sources of such information could be included in a series of up-dates that could be distributed to designated national authorities along with the PIC circular and also used in workshops.

The following is an example of standard text for this section related to ***pesticides.***

There are a number of alternative methods involving chemical and non-chemical strategies, including alternative technologies available, depending on the individual crop-pest complex under consideration. Countries should consider promoting, as appropriate, integrated pest management (IPM) and organicstrategies as a means of reducing or eliminating the use of hazardous pesticides. SAICM’s Fourth International Conference on Chemicals Management recommended that in replacing highly hazardous pesticides the focus should be on agroecologically-based practices.

Advice may be available through National IPM focal points, the FAO, IFOAM (International Federation of Organic Movements) and agricultural research or development agencies. Where it has been made available by governments, additional information on alternatives to XXXX may be found on the Rotterdam Convention website [www.pic.int](http://www.pic.int).

Information on such agroecologically-based practices can be found at the following websites:

FAO Agroecology hub: http://www.fao.org/agroecology/en/

IPAM (International Peoples Agroecology Multiversity): http://ipamglobal.org/

OISAT (Online Information Service for Non-Chemical Pest Management in the Tropics): http://www.oisat.org/

Replacing Chemicals with Biology: Phasing out Highly Hazardous Pesticides with Agroecology: http://panap.net/2015/11/replacing-chemicals-biology-phasing-highly-hazardous-pesticides-agroecology/

*It is essential that before a country considers substituting alternatives, it ensure that the use is relevant to its national needs and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.*

For ***industrial chemicals***, the final paragraph above should be used, to indicate the need to consider the hazards associated with possible alternatives. National alternatives should be included, and if international organizations have discussed alternatives in reviews etc. this information could also be included.

**3.4. Social and economic effects**

***This section would only be completed where Notifying Countries have undertaken specific studies of the social and economic effects related to their final regulatory action(s) and wish to report on their findings.***

**Note:** Most countries do not undertake rigorous social and economic studies that are relevant beyond their own jurisdictions, but they may provide information on alternatives when a country took an action to restrict a chemical.

This information is optional. When reported, there will need to be a caveat that countries consider the results of this information in the context of their own national conditions.

**4. Hazards and risks to human health and/or the environment**

**4.1 Hazard Classification**

**Purpose:** To provide a brief summary of internationally recognized classifications applied to the chemical(s) for which the decision guidance document has been prepared.

1. This section should focus on internationally recognized standards such as IARC, WHO/IPCS classification systems.
   1. The standard reference for LD50 values is the most recent edition of the WHO/IPCS publication, *recommended classification of pesticides by hazard and guidelines to classification*. The WHO classification schemes for pesticides as well as its formulations are based on oral or dermal toxicity. According to the WHO guideline, the route which indicate greater hazard would be chosen for its classification.
   2. As far as possible, information on the WHO hazard classification of liquid and solid formulations should be included.
2. The US EPA and European Union classification systems have been included as they are widely used by many countries as a reference.
3. All references should include the date when they were established.

**Note:** It is not intended that national standards be included here, notifying countries should include their national classification schemes in Annex 2.

The following is an example of how this information might be presented:

|  |  |  |  |
| --- | --- | --- | --- |
| **4. Hazards and Risks to human health and the environment** | | | |
| **4.1 Hazard Classification** | | | |
| **WHO / IPCS** | Technical product  a.i.: | Insert classification *e.g.* Class Ia (extremely hazardous) Classification based on oral or dermal toxicity in rats LD50: (WHO reference) | |
| Formulations | a.i. (%) | Hazard class |
| Liquid |  |  |
| Solid |  |  |
| **IARC** | Group 3: the agent is not classified as to its carcinogenicity to humans. (IARC reference) | | |
| **European Union** | Classification of the active substance is (Commission Directive reference):  T (toxic)  Xi (Irritant)  N (dangerous for the environment)  R 24/25 (Toxic in contact with skin/ if swallowed)  R 36 (Irritating to eyes)  R 50/53 (Very toxic to aquatic organisms / may cause long-term adverse effects in the aquatic environment) | | |
| **US EPA** | Toxicity Class I (formulation) (EPA reference) | | |

**4.2. Exposure limits**

**Purpose:** To provide a brief summary of internationally recognized exposure limits as applied to the chemical(s) subject to the decision guidance document.

1. This section should focus on those exposure limits that are internationally recognized, *e.g*., Codex levels in food, WHO drinking water guidelines, etc.
2. All references should include the date when they were established and the date of any subsequent review by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR), etc.
3. It is not intended to capture occupational exposure limits such as Threshold Limit Values (TLVs) for pesticides largely because of the widely differing ways in which they may be calculated

**Note:**  It is not intended that national standards be included here as their applicability to other countries is limited without a good understanding of how the limits were derived. Notifying countries could include them in Annex 2 if they feel it is appropriate and necessary.

If no international exposure limits are available, the words ‘not applicable for this chemical’ could be inserted.

**4.3 Packaging and labelling**

**Purpose:** To provide a quick reference to existing standards for packaging and labelling of the chemical.

This section should focus on internationally recognized classifications established by the United Nations Committee of Experts on the Transport of Dangerous Goods, and on the Globally Harmonized System of Classification and Labelling of Chemicals (if used), the International Maritime Dangerous Goods Code, etc., along with relevant explanatory text if applicable (*i.e.* for specific requirements).

**Note:**  In the case of pesticides, this section should include a generic statement on the availability of further specific guidance on appropriate symbols and label statements for individual pesticides and formulations in the FAO *Guidelines on Good Labelling Practice for Pesticides*.

|  |  |
| --- | --- |
| **4.3 Packaging and labelling** | |
| The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in: | |
| Hazard Class and Packing Group: |  |
| International Maritime Dangerous Goods (IMDG) Code |  |
| Transport Emergency Card |  |

**4.4. First aid**

**Purpose:** To provide a quick reference to internationally recognized information on the treatment of chemical poisoning (pesticides and industrial chemicals) available at the time of publication of the decision guidance document.

1. Reference should be generic and include the most recent WHO/IPCS recommendation.
2. It should note any aspects specific to the chemical cited in the decision guidance document.
3. A reference to the WHO website for other relevant information might also be included www.inchem.org

**Notes:** For chemicals that are not acutely toxic, this section may not be relevant and could be completed with the statement “*not applicable to this chemical*”.

Recognizing that a range of first-aid treatments may be available, this section should include a generic statement on the need for caution and should remind parties of the need to ensure that this information is in compliance with any national standards that may exist.

**4.5. Waste management**

**Purpose:** To ensure that countries are aware of the need for appropriate management of wastes and to provide references to relevant guidance and other sources of information.

1. This section should include references to appropriate internationally recognized guidelines such as those developed by FAO for pesticides.
2. Particular attention should be drawn to the relevant terms of international agreements – the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal.
3. Notifying countries may wish to note specific actions taken to avoid the creation of stockpiles, including arrangements to permit use of existing stocks during a phase-out period.

**Annex 1. Further information on the chemical**

***Annex 1 contains information submitted by the notifying countries based on the national assessments which were used to support the reported final regulatory action. The results of international reviews such as those of WHO/IPCS/JMPR/IARC should also be included in this section where available and considered relevant. Subsequent evaluations or reviews of the chemical from Parties, other than those that submitted the notifications of final regulatory actions may be submitted to the secretariat for posting on the Rotterdam Convention website.***

**Purpose:** To provide an overall summary of information on the chemical for which the reported regulatory action(s) have been taken, including physico-chemical properties of the substance and/or product(s) and the results of toxicological and ecotoxicity studies. The decision guidance document is not intended to be a scientific treatise on a chemical. The emphasis should be on the concerns that formed the basis of the reported final regulatory action(s). For example, if the sole basis of the reported regulatory action(s) is unacceptable occupational exposure, this annex section should focus on human health effects rather than environmental aspects.

The principal headings in this annex generally reflect those used by OECD countries and the European Union in their monographs. This approach will assist all countries, especially developing countries, which may have used an OECD/European Union monograph as the basis for the risk evaluation supporting their final regulatory action(s). The generic headings and general guidance on content should facilitate consistency in the format and content of decision guidance documents.

1. The introduction to the annex should describe its content. This should include reference to any relevant international reviews (*e.g*. those of OECD, IPCS/WHO or IARC) and how this information has been incorporated into the document. For example whether or not the results of an international assessment (toxicological or ecotoxicological) are substantively different from those of the notifying countries should be noted. In the case of mammalian toxicity a summary of the two evaluations highlighting the similarities or differences as appropriate may be included in section 2.2.7 of this annex (see below).
2. The level of detail within the subheadings may be adjusted to accommodate the information used to support the notified regulatory action and available to the drafting group. (See appendix 2 to the present note for a list of the headings and subheadings and an indication of the points that may be included under each.)
3. Specific sections on exposure/risk evaluation have been included for both human health and environmental fate and effects. These sections should include specific information from notifying countries on the basis for their final regulatory action.

**General comments**

Tabular summaries of information should be used wherever possible; this should not, however, be at the expense of a clearly stated analysis that explains how the data were used in the risk evaluation that formed the basis for the reported regulatory action.

The level of detail will be a function of the information that is available and will need to be determined on a case‑by‑case basis. As a guiding principle, however, the focus should be on those end points that were the basis for the risk evaluation underlying the notified final regulatory action. For example, in those instances where a chemical was found to be a reproductive toxin and this was the basis for the regulatory action, greater detail would be expected on the supporting studies *e.g*. NOEL/NOAEL/LOEL, than on end points for which the results may have been negative (*i.e.*, simply stating “was not carcinogenic”). In the case of universally recognized regulatory guidelines or limits such as the acceptable daily intake (ADI) or acute reference dose (ARfD), details on the supporting studies on which they are based should be included.

LD50 and LC50 data can vary widely for a chemical. In order to avoid apparent discrepancies in the information reported, it may be better to report a range of values wherever possible, particularly where the results from more than one source are combined.

In reporting toxicity data reference should be made to the duration of exposure for all studies reported, including acute toxicity studies, where it is available or known.

In some cases, the notifying parties may reach different conclusions on individual end points related to human health or the environment. Furthermore, the situation may arise where there has been an evaluation of the chemical at the international level *e.g*. by the OECD, WHO/IPCS or IARC that has reached conclusions that differ from those of the findings of the notifying parties. In such cases the following approaches should be considered:

1. It is intended that these differences be clearly indicated in the decision guidance document, where they concern “pivotal end points” within the risk evaluation, that is those end points upon which the final regulatory action was based.
2. Where there are differences in interpretation of data concerning specific end points, but the differences do not affect the outcome of the final regulatory action or the conclusions of the international review, the degree to which these details will be reflected in the decision guidance document will need to be considered on a case-by-case basis.
3. Section 2.2.7 Summary of mammalian toxicity and overall evaluation – this section provides an opportunity to summarize the conclusions of the toxicological evaluations from the notifying countries as well as any relevant international reviews *e.g*. WHO/IPCS/IARC.

Where information from an international evaluation such as an IPCS Environmental Health Criteria document is included, the reference in the text should be to this document, rather than to the individual papers quoted therein. Where information from the risk evaluations by the notifying Parties is included, it is sufficient if this source is indicated, rather than the specific studies or reviews referred to.

**Specific comments -** *details of proposed subheading may be found in appendix 2*

***1. Physico-chemical properties***

This section characterizes the chemical, based on national evaluations and recognized information sources *e.g*. *Pesticides Manual, A World Compendium* (Crop Protection Publications - ISBN 0 948404 79 5)

***2. Toxicological properties***

***2.1. General information***

This section should provide brief information on the mode of action, symptoms of poisonings and on absorption, distribution, excretion and metabolism in mammals. It can be retrieved from the notifications as well as from internationally recognized sources such as the Pesticide Manual or WHO/IPCS/JMPR/IARC evaluations.

***2.2 Toxicity studies***

This section lays out the toxicological profile of the chemical as assessed by the notifying countries at the time of their final regulatory actions(s). It should also include a comparative summary of any IPCS/WHO international evaluations, such as those of WHO/IPCS/JMPR, where they are available and considered relevant. This summary should be included in section 2.2.7 Summary of mammalian toxicity and overall evaluation.

1. In the interests of brevity, where multiple studies for the same end point exist, the drafting group should report in a summary form, rather than report on each individual study. The level of detail will need to be considered on a case-by-case basis. It is generally accepted that where a review document has been used as the source of the information, the review document is cited rather than the individual studies.
2. Under the heading Summary of mammalian toxicity and overall evaluation (section 2.2.7), the drafting group should provide a concise summary of key end points, in order to facilitate comparisons among different evaluations and to improve understanding of those end points considered in the human exposure/risk evaluation section (see the preceding section on General comments).

**3. *Human exposure/risk evaluation***

This section highlights in greater detail those human exposure and risk factors that led to the regulatory control action(s), focusing on the major exposure routes (*i.e.* food, air, water and occupation).

1. Information concerning epidemiological studies or poisoning incidents that were considered by the notifying country in taking the reported regulatory action could be inserted under the subheading Medical data (section 3.5).

**Note:** Where the reported regulatory actions are based on environmental effects, it is anticipated that this section of the decision guidance document would be minimal.

**4. *Environmental fate and effects***

This section provides information on the environmental fate characteristics (**Fate**, section 4.1) of the chemical and the results of ecotoxicity studies (**Effects on non-target organisms**, section 4.2).

**Note**: Specific subheadings for the parameters of persistence and bio-concentration have been included to facilitate the identification of chemicals with the characteristics of persistent organic pollutants (POPs)*.*

**5*. Environmental exposure/risk evaluation***

This section highlights in greater detail those environmental fate factors that led to the regulatory control action(s) and should include a summary of the overall risk evaluation.

**Note:** Where the reported regulatory actions are based on human health concerns (*e.g*., risks to workers), it is anticipated that this section of the decision guidance document would be minimal.

**Annex 2. Details on final regulatory actions reported**

***Annex 2 reports expand upon the information presented regarding the final regulatory action(s) of each notifying country.***

This annex should reflect the information provided in the notification of regulatory action form and presented to the Chemical Review Committee for review. The annex represents an opportunity for notifying countries to provide increased detail on aspects of the regulatory decision that they may wish to include.

**Annex 3. Addresses of designated national authorities**

This annex should provide detailed information on how to contact the designated national authorities of the notifying countries, including the name of a contact person; mailing address; telephone, fax and telex numbers; and email address.

**Annex 4. References**

This annex includes a list of the sources of information cited in the decision guidance document. Where information from a review document has been used, the reference should be to the review document, rather than to the individual papers within the review. Original papers should only be cited where they have been considered individually, rather than as a component of the review.

List References under headings as appropriate. The following is an example for a reference list:

**Regulatory actions**

Decision by the Norwegian Agricultural Inspection Service (NAIS) 22.10.2002 (200200430 IP/hmo).

**Supporting documentation provided by *Country X***

Environmental Health Criteria No. 165: Inorganic Lead. IPCS/WHO 1995 (*an example of a review document)*

**Supporting documentation provided by *Country Y***

Sebastien P, Begin R, & Masse S (1990) Mass number and size of lung fibres in the pathogenesis of asbestosis in sheep. Int J Exp Pathol, 71: 1-10. *(individual paper cited if the original paper was used in the preparation of the DGD)*

**Others**

WHO (2003): Health Risk of Persistent Organic Pollutants from Long-Range Transboundary Air Pollution.

**Relevant guidelines and reference documents**

FAO/WHO Food Standards (2010). CODEX Alimentarius.

FAO (2006) Framework of FAO Guidelines on Pesticide Management in support of the Code of Conduct. <http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Guidelines/Framework.htm>

**Appendix I: Standard Core Set of Abbreviations[[1]](#footnote-1)**

| **STANDARD CORE SET OF ABBREVIATIONS** | |
| --- | --- |
| < | less than |
| < | less than or equal to |
| > | greater than |
| > | greater than or equal to |
|  |  |
| µg | microgram |
| μm | micrometre |
|  |  |
| ARfD | acute reference dose |
| a.i. | active ingredient |
| ADI | acceptable daily intake |
| AOEL | acceptable operator exposure level |
|  |  |
| b.p. | boiling point |
| bw | body weight |
|  |  |
| oC | degree Celsius (centigrade) |
| CAS | Chemical Abstracts Service |
| cc | cubic centimetre |
| cm | centimetre |
|  |  |
| DNA | deoxyribonucleic acid |
| DT50 | dissipation time 50% |
|  |  |
| EC | European Community |
| EC50 | median effective concentration |
| ED50 | median effective dose |
| EEC | European Economic Community |
| EHC | Environmental Health Criteria |
| EU | European Union |
|  |  |
| FAO | Food and Agriculture Organization of the United Nations |
|  |  |
| g | gram |
|  |  |
| h | hour |
| ha | hectare |
|  |  |
| i.m. | intramuscular |
| i.p. | intraperitoneal |
| IARC | International Agency for Research on Cancer |
| IC50 | median inhibitory concentration |
| ILO | International Labour Organisation |
| IPCS | International Programme on Chemical Safety |
| IPM | Integrated Pest Management |
| IUPAC | International Union of Pure and Applied Chemistry |
|  |  |
| JMPR | Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues) |
|  |  |
| k | kilo- (x 1000) |
| kg | kilogram |
| Koc | soil organic partition coefficient |
| Kow | octanol–water partition coefficient |
| kPa | kilopascal |
|  |  |
| L | litre |
| LC50 | median lethal concentration |
| LD50 | median lethal dose |
| LOAEL | lowest-observed-adverse-effect level |
| LOEL | lowest-observed-effect level |
|  |  |
| m | metre |
| m.p. | melting point |
| mg | milligram |
| ml | millilitre |
| mPa | millipascal |
| MRL | maximum residue limit |
| MTD | maximum tolerated dose |
|  |  |
| ng | nanogram |
| NOAEC | no-observed-adverse-effect concentration |
| NOAEL | no-observed-adverse-effect level |
| NOEC | no-observed-effect concentration |
| NOEL | no-observed-effect level |
|  |  |
| OECD | Organisation for Economic Co-operation and Development |
|  |  |
| PEC | predicted environmental concentration |
| Pow | octanol-water partition coefficient, also referred to as Kow |
| PPE | personal protective equipment |
| ppm | parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/L are used). |
|  |  |
| RfD | reference dose (for chronic oral exposure; comparable to ADI) |
|  |  |
| SMR | standard(ized) mortality ratio |
| STEL | short-term exposure limit |
|  |  |
| TER | toxicity exposure ratio |
| TLV | threshold limit value |
| TWA | time-weighted average |
|  |  |
| UNEP | United Nations Environment Programme |
| USEPA | United States Environmental Protection Agency |
| UV | ultraviolet |
|  |  |
| VOC | volatile organic compound |
|  |  |
| w/w | weight for weight |
| WHO | World Health Organization |
| wt | weight |

**Appendix 2: Headings for Annex I and a list of information points that could be included under each**

1. **Physico-chemical properties**
2. **Toxicological properties**
   1. General
      1. Mode of action
      2. Symptoms of poisoning
      3. Absorption, distribution, excretion and metabolism in mammals

* Rate and extent of absorption
* Distribution
* Potential for accumulation
* Rate and extent of excretion
* Metabolism in animals
* Toxicologically significant compounds (animals, plants and environment)

2.2. Toxicology studies

2.2.1. Acute toxicity

* Rat LD50 oral
* Rat LD50 dermal
* Rat LC50 inhalation
* Skin irritation
* Eye irritation
* Skin sensitization (test method used and result)

2.2.2. Short term toxicity

* Target/critical effect
* Oral
* Dermal
* Inhalation

2.2.3. Genotoxicity (including mutagenicity)

2.2.4. Long term toxicity and carcinogenicity

* Target/critical effect
* Relevant NOAEL/NOEL
* Carcinogenicity

2.2.5. Effects on reproduction

* Reproduction target/critical effect
* Lowest relevant reproductive NOAEL/NOEL
* Developmental target/critical effect
* Lowest relevant developmental NOAEL / NOEL

2.2.6. Neurotoxicity/delayed neurotoxicity

* Acute neurotoxicity
* Subchronic neurotoxicity
* Special studies (where available)could include human immunotoxicity studies

2.2.7. Summary of mammalian toxicity and overall evaluation

* include summary of key findings of relevant international reviews *e.g*. WHO/IPCS/IARC evaluations

1. **Human exposure/risk evaluation**

3.1. Food

3.2. Air

3.3. Water

3.4. Occupational

3.5. Medical datacontributing to regulatory decision – could include:

* Report on medical surveillance on manufacturing plant personnel
* Report on clinical cases and poisoning incidents
* Observations on exposure of the general population and epidemiological studies

1. **Environmental fate and effects**

4.1. Fate

4.1.1. Soil

* Field dissipation
* Aerobic and anaerobic degradation
* Rate of degradation
* Adsorption/desorption
* Mobility

4.1.2. Water

* Route and rate of degradation

4.1.3. Air

* Fate and behaviour

4.1.4. Bioconcentration and bioaccumulation

4.1.5. Persistence

4.2. Effects on non-target organisms

4.2.1. Terrestrial vertebrates

* Acute/chronic toxicity mammals
* Acute/chronic toxicity birds
* Dietary toxicity birds
* Reproductive toxicity birds
* Other

4.2.2. Aquatic species

* Fish
* Invertebrates
* Algal species
* Aquatic plants
* Other

4.2.3. Honey bees and other arthropods

4.2.4. Earthworms

4.2.5. Soil microorganisms

4.2.6. Terrestrial plants

**5. Environmental exposure/risk evaluation**

Specific reference as appropriate to the following

5.1. Terrestrial vertebrates

* Mammals/birds

5.2. Aquatic species

* Fish/invertebrates/algal species/aquatic plants

5.3. Honey bees

* Other arthropods

5.4. Earthworms

5.5. Soil microorganisms

5.6. Summary – overall risk evaluation.

1. This core list should serve as the basis for DGDs for industrial chemicals, pesticides and severely hazardous pesticide formulations. It should be augmented by abbreviations used in the individual DGDs relevant to the chemical(s) in question.

   Definitions and spelling should, as far as practicable, follow the IUPAC glossary of terms in toxicology and the IUPAC glossary of terms relating to pesticides in their current editions.

   As a general rule it is preferable that acronyms used only once in the text be spelled out rather than included in the list of abbreviations. [↑](#footnote-ref-1)