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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
First meeting
Geneva, 11–18 February 2005
Item 6 (a) (iii) of the provisional agenda*

Operational procedures for the Chemical Review Committee: working procedures and policy guidance forwarded from the Conference of the Parties: working paper on preparing internal proposals and decision guidance documents for severely hazardous pesticide formulations

Working paper on preparing internal proposals and decision guidance documents for severely hazardous pesticide formulations

Note by the secretariat

1. A working paper on preparing decision guidance documents for severely hazardous pesticide formulations, originally considered by the interim Chemical Review Committee at its third session, was used by an inter-sessional drafting group in preparing a decision guidance document considered at the fourth session of the interim Chemical Review Committee (UNEP/FAO/PIC/ICRC.4/7). It was agreed that the co-chairs of the drafting group would work intersessionally to develop a further draft of the working paper (UNEP/FAO/PIC/ICRC.4/18, para. 34).

* UNEP/FAO/RC/CRC.1/7.

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2. At its fifth session, the interim Chemical Review Committee considered a revision of the working paper (UNEP/FAO./PIC/ICRC.5/7). The document was further revised by the Committee and the amended version posted on the Rotterdam Convention web site.

3. The working paper sets out the format and content for decision guidance documents for severely hazardous pesticide formulations. The interim Chemical Review Committee agreed to refer the paper to the Conference of the Parties for consideration at its first meeting, in order that the chemical review committee set up by the Conference of the Parties might consider it as part of procedures to be used by it in developing its own procedures for preparing decision guidance documents (UNEP/FAO/PIC/ICRC.5/15, para. 30).

4. At its first meeting, the Conference of the Parties agreed to forward the paper on preparing internal proposals and decision guidance documents for severely hazardous pesticide formulations to the Chemical Review Committee for its consideration. The working paper is annexed to the present note.

5. The Committee is invited to review the paper, and consider its adoption as part of the working procedures for the Committee

Annex

WORKING PAPER ON PREPARING INTERNAL PROPOSALS AND DECISION GUIDANCE DOCUMENTS FOR SEVERELY HAZARDOUS PESTICIDE FORMULATIONS CAUSING HUMAN HEALTH PROBLEMS

Introduction/purpose

1. This working paper is to serve as guidance to drafting groups established by the Interim Chemical Review Committee for the preparation of decision guidance documents for severely hazardous pesticide formulations in accordance with Article 6 of the Rotterdam Convention.

2. This working paper is intended:

- To clarify the purpose of each section of the decision guidance document
- To characterize the information to be included
- To define acceptable sources of information for each section

3. This working paper is expected to evolve as further experience is gained in the preparation of decision guidance documents. A separate working paper has been developed for the preparation of decision guidance documents for banned or severely restricted chemicals in accordance with Article 5 of the Rotterdam Convention.

General guidance

4. 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 and amended by the Intergovernmental Negotiating Committee at its tenth session. This text provides a brief summary of the process through which the individual decision guidance document was developed and includes three separate sections, *introduction, purpose and disclaimer*.

5. 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 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. As a general rule it is preferable for acronyms used only once in the text to be spelled out rather than included in the list of abbreviations.

6. In preparing a decision guidance document, it may be that not all sections are relevant to the chemical under consideration. It is preferable, in that 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 has considered that section.

1. Identification

Purpose: To clearly identify the pesticide formulation(s) subject to the PIC procedure.

- This is basic information for the formulation and should be obtained directly from part A of the submitted report form on severely hazardous pesticide formulations.

- It should include as much information as possible on the composition of the formulation. As a minimum: the type of formulation, concentration of the individual active ingredients and the CAS numbers.

1.1 Name or trade name of the hazardous pesticide formulation
1.2 Name of the active ingredient or ingredients in the formulation
1.3 Relative amount of each active ingredient in the formulation
1.4 Type of formulation
1.5 Name(s) of the producer(s), if available

2. Reason for inclusion in the PIC procedure

Purpose: To provide a generic statement that clearly identifies category within which the chemical is included in the Rotterdam Convention, in this case the specific formulation(s) of a pesticide as a result of problems under conditions of use in a developing country or country with economy in transition.

Generic text may include:

The following formulations of +++++ are subject to the Rotterdam Convention:

- (name active ingredient(s) and relative concentrations, and specific formulation(s))

- This severely hazardous pesticide formulation is subject to the Rotterdam Convention as it was found to cause problems under conditions of use in line with Article 6 and Annex IV of the Convention.

Note: The specific formulation identified in a proposal submitted in accordance with Article 6 is the basis for including a severely hazardous pesticide formulation in the PIC procedure. However, formulations containing the active ingredient or ingredients at or above the specified concentrations and in the same formulation type would also be included if supported by the technical documentation supporting the proposal.

- As many differing formulations may be called by the same or similar names, a disclaimer that clearly defines the formulations that are subject to the PIC procedure should be included.

1. Description of common and recognized pattern of use of the formulation in the reporting country

Purpose: To provide a clear description of how the formulation is typically used in the reporting country (should include description of degree to which individual formulations are regulated).

- This is a key section of the decision guidance document as it will help countries that use the formulation to determine how closely the reported incident reflects their own patterns of use. This would be useful information to countries when making import decisions.

- This information should be available to the drafting group from the incident report form on severely hazardous pesticide formulations and/or from additional information collected by the secretariat in line with part 2 of Annex IV.

3.1 Permitted uses of the formulation

- Space fumigation, seed treatment, crops treated etc.
- Application method – how it is used
- Pests controlled
- Rate and frequency of application

3.2 Restrictions in handling or use

- Relevant to worker exposure or environmental exposure

3.3 Availability/applicability of protective clothing

3.4 Actual uses

- Description of how the formulation is typically used, e.g. crops treated, pests controlled, application methods, rate and frequency of application etc., particularly where such use differs from the officially permitted uses.

4. Description of the incident(s), including adverse effects and way in which the formulation was used

Purpose: To briefly describe the incident and the resulting adverse effects, and to relate how the formulation was used to the common and recognized patterns of use.

Note: The description of the incident and the adverse effects should be based on the information in part B of the submitted incident report form. Reference should also be made to the completed incident report forms appended as annex I and the data sheets in annex II.

4.1 Description of the incident – summary of key points could include the following:

- Where the incident occurred
- Main activity at the time of exposure
- Application method
- Route of exposure
- Conditions of use when the incident occurred, e.g. prevailing climatic conditions

4.2 Description of the adverse effects

- Summary of key points described in the incident report form (annex I)

4.3 Relationship of the adverse effects observed to recognized acute toxicological effects of the active ingredient(s)

- The simplest approach is to reference/quote from the relevant sections of the data sheet included in annex II

4.4 Extent of incident (e.g. number of people affected for human health incidents)

- Summary of information in the incident report form (annex I)

5. Any regulatory, administrative or other measure taken, or intended to be taken, by the Party in response to the incidents

Purpose: To briefly outline any administrative/regulatory action that may have been taken by the reporting country

- This information could be taken directly from part A of the submitted incident report form.

6. WHO hazard classification of the formulation

Purpose: This section should provide an internationally recognized baseline from which countries can better understand the potential concerns with the formulations in question relative to others that they may be using

- This should be calculated based on the best available information. The values and possible hazard classification should be based on the principal routes of exposure (e.g. dermal, oral) and presented in tabular format.

- The WHO recommended classification of pesticides by hazard should be used as the primary reference for oral LD_{50} values. Where several LD_{50} values for other routes of exposure, e.g. dermal, have been published, the lowest deemed reliable is used (and referenced). This is in line with the approach used by WHO in compiling the oral LD_{50} values.

- Where a formulation consists of more than one active ingredient, the fact that the calculated hazard classification cannot account for possible synergistic effects or the potentiation of toxicity as a result of interaction among the active ingredients should be noted.

7. Alternative pest-control practices

Purpose: To provide countries with brief information about alternatives that have been identified by the country submitting the proposal or others.

- Where available, information on the pests controlled should be included in order to ensure that appropriate alternatives may be identified.

- It may 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 pesticide formulations 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.

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 specific chemicals on the Rotterdam Convention web site. Such new sources of such information could be included in a series of updates 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:

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) strategies as a means of reducing or eliminating the use of hazardous pesticides.

Advice may be available through national IPM focal points, FAO 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 web site www.pic.int.

It is essential that before a country considers substituting alternatives for a given formulation, it ensures that the use is relevant to its national needs and the anticipated local conditions of use.

Annex I Rationale for the recommendation by the Chemical Review Committee to include the severely hazardous formulation in the PIC procedure

Part 2 of Annex IV of the Convention refers to a range of information that is to be collected by the secretariat. This information will need to be considered by the Chemical Review Committee. In order to assist countries in better understanding the reason why a particular formulation has been included in the PIC procedure, this section will contain the rationale prepared in support of the recommendation of the Chemical Review Committee for inclusion of the formulation in the PIC procedure.

Annex II Information on reported incident from incident report

This should include specific information submitted by the notifying country:

- Summary of completed incident report form(s) (e.g., part B for a human health-related incident);
- Name of the country
- Designated national authority contact information

Annex III Safety data sheet(s) on pesticide active ingredient(s)

The relevant data sheet(s) for the individual active ingredients should be inserted in their entirety.

Safety data sheets typically contain the following key headings:

1. Chemical product identification and company identification
2. Composition of and other information on ingredients
3. Hazard identification
4. First aid measures
5. Accidental release measures
6. Handling and storage
7. Exposure controls and personal measures
8. Physical and chemical properties
9. Stability and reactivity
10. Toxicological information
11. Ecological information
12. Disposal considerations
13. Transport information
14. Regulatory information
15. Other information

Other examples of readily available information that might be used to complete this annex include the IPCS International Chemicals Safety Cards, summaries from environmental health criteria documents etc. These documents are freely accessible at www.inchem.org.

Annex III Summary of toxicological properties

Purpose: Summarize key elements in the toxicological profile of the formulation (*where available*)

For mammalian toxicological end points, the primary data generated for a pesticide formulation are limited to a set of six acute toxicity studies. The most common and those that might be expected to be available for a given formulation are the following:

- Rat LD_{50} oral
- Rat LD_{50} dermal
- Rat LC_{50} inhalation
- Skin irritation
- Eye irritation
- Skin sensitization (test method used and result)

Where there is a risk or hazard evaluation on the formulation either from a national Government or an international source it may be summarized here.

- Where this information is not available for a given formulation, consideration should be given to including:
  - The material safety data sheet (MSDS) for the formulation;
  - A reference to the risk or hazard information in annex II on the active ingredient(s) from an internationally recognized source such as the INCHEM database, the EXTOXNET Profile, IPCS International Chemical Safety Cards, summaries from environmental health criteria documents etc.

Appendix. Standard core set of abbreviations

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
>>	much greater than
µg	microgram
µm	micrometre
ArfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
ADP	adenosine diphosphate
ATP	adenosine triphosphate
b.p.	boiling point
bw	body weight
°C	degree Celsius (centigrade)
CA	Chemicals Association
cc	cubic centimetre
CHO	Chinese hamster ovary
cm	centimetre
DNA	deoxyribose nucleic acid
EC	European Community
EC_{50}	effect concentration, 50%
ED_{50}	effect dose, 50%
EEC	European Economic Community
EHC	environmental health criteria
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
IC_{50}	inhibition concentration, 50%
ILO	International Labour Organization
IPCS	International Programme on Chemical Safety
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	organic carbon-water partition coefficient
l	litre
LC_{50}	lethal concentration, 50%
LD_{50}	lethal dose, 50%
LOAEL	lowest observed adverse effect level
LD_{LO}	lowest lethal dose
LOEL	lowest observed effect level
m	metre
m.p.	melting point
mg	milligram
ml	millilitre
mPa	millipascal
MTD	maximum tolerated dose
ng	nanogram
NOAEL	no-observed-adverse-effect level
NOEL	no-observed-effect level
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
PCM	phase contrast microscopy
Pow	octanol-water partition coefficient
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	standardized mortality ratio
STEL	short term exposure limit
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
WHO	World Health Organization
wt	weight

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Operational procedures for the Chemical Review Committee: working procedures and policy guidance forwarded from the Conference of the Parties: working paper on preparing internal proposals and decision guidance documents for severely hazardous pesticide formulations

Working paper on preparing internal proposals and decision guidance documents for severely hazardous pesticide formulations

Note by the secretariat

1. A working paper on preparing decision guidance documents for severely hazardous pesticide formulations, originally considered by the interim Chemical Review Committee at its third session, was used by an inter-sessional drafting group in preparing a decision guidance document considered at the fourth session of the interim Chemical Review Committee (UNEP/FAO/PIC/ICRC.4/7). It was agreed that the co-chairs of the drafting group would work intersessionally to develop a further draft of the working paper (UNEP/FAO/PIC/ICRC.4/18, para. 34).

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3. The working paper sets out the format and content for decision guidance documents for severely hazardous pesticide formulations. The interim Chemical Review Committee agreed to refer the paper to the Conference of the Parties for consideration at its first meeting, in order that the chemical review committee set up by the Conference of the Parties might consider it as part of procedures to be used by it in developing its own procedures for preparing decision guidance documents (UNEP/FAO/PIC/ICRC.5/15, para. 30).

4. At its first meeting, the Conference of the Parties agreed to forward the paper on preparing internal proposals and decision guidance documents for severely hazardous pesticide formulations to the Chemical Review Committee for its consideration. The working paper is annexed to the present note.

5. The Committee is invited to review the paper, and consider its adoption as part of the working procedures for the Committee

Annex

WORKING PAPER ON PREPARING INTERNAL PROPOSALS AND DECISION GUIDANCE DOCUMENTS FOR SEVERELY HAZARDOUS PESTICIDE FORMULATIONS CAUSING HUMAN HEALTH PROBLEMS

Introduction/purpose

1. This working paper is to serve as guidance to drafting groups established by the Interim Chemical Review Committee for the preparation of decision guidance documents for severely hazardous pesticide formulations in accordance with Article 6 of the Rotterdam Convention.

2. This working paper is intended:

- To clarify the purpose of each section of the decision guidance document
- To characterize the information to be included
- To define acceptable sources of information for each section

3. This working paper is expected to evolve as further experience is gained in the preparation of decision guidance documents. A separate working paper has been developed for the preparation of decision guidance documents for banned or severely restricted chemicals in accordance with Article 5 of the Rotterdam Convention.

General guidance

4. 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 and amended by the Intergovernmental Negotiating Committee at its tenth session. This text provides a brief summary of the process through which the individual decision guidance document was developed and includes three separate sections, *introduction, purpose and disclaimer*.

5. 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 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. As a general rule it is preferable for acronyms used only once in the text to be spelled out rather than included in the list of abbreviations.

6. In preparing a decision guidance document, it may be that not all sections are relevant to the chemical under consideration. It is preferable, in that 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 has considered that section.

1. Identification

Purpose: To clearly identify the pesticide formulation(s) subject to the PIC procedure.

- This is basic information for the formulation and should be obtained directly from part A of the submitted report form on severely hazardous pesticide formulations.

- It should include as much information as possible on the composition of the formulation. As a minimum: the type of formulation, concentration of the individual active ingredients and the CAS numbers.

1.1 Name or trade name of the hazardous pesticide formulation
1.2 Name of the active ingredient or ingredients in the formulation
1.3 Relative amount of each active ingredient in the formulation
1.4 Type of formulation
1.5 Name(s) of the producer(s), if available

2. Reason for inclusion in the PIC procedure

Purpose: To provide a generic statement that clearly identifies category within which the chemical is included in the Rotterdam Convention, in this case the specific formulation(s) of a pesticide as a result of problems under conditions of use in a developing country or country with economy in transition.

Generic text may include:

The following formulations of +++++ are subject to the Rotterdam Convention:

- (name active ingredient(s) and relative concentrations, and specific formulation(s))

- This severely hazardous pesticide formulation is subject to the Rotterdam Convention as it was found to cause problems under conditions of use in line with Article 6 and Annex IV of the Convention.

Note: The specific formulation identified in a proposal submitted in accordance with Article 6 is the basis for including a severely hazardous pesticide formulation in the PIC procedure. However, formulations containing the active ingredient or ingredients at or above the specified concentrations and in the same formulation type would also be included if supported by the technical documentation supporting the proposal.

- As many differing formulations may be called by the same or similar names, a disclaimer that clearly defines the formulations that are subject to the PIC procedure should be included.

1. Description of common and recognized pattern of use of the formulation in the reporting country

Purpose: To provide a clear description of how the formulation is typically used in the reporting country (should include description of degree to which individual formulations are regulated).

- This is a key section of the decision guidance document as it will help countries that use the formulation to determine how closely the reported incident reflects their own patterns of use. This would be useful information to countries when making import decisions.

- This information should be available to the drafting group from the incident report form on severely hazardous pesticide formulations and/or from additional information collected by the secretariat in line with part 2 of Annex IV.

3.1 Permitted uses of the formulation

- Space fumigation, seed treatment, crops treated etc.
- Application method – how it is used
- Pests controlled
- Rate and frequency of application

3.2 Restrictions in handling or use

- Relevant to worker exposure or environmental exposure

3.3 Availability/applicability of protective clothing

3.4 Actual uses

- Description of how the formulation is typically used, e.g. crops treated, pests controlled, application methods, rate and frequency of application etc., particularly where such use differs from the officially permitted uses.

4. Description of the incident(s), including adverse effects and way in which the formulation was used

Purpose: To briefly describe the incident and the resulting adverse effects, and to relate how the formulation was used to the common and recognized patterns of use.

Note: The description of the incident and the adverse effects should be based on the information in part B of the submitted incident report form. Reference should also be made to the completed incident report forms appended as annex I and the data sheets in annex II.

4.1 Description of the incident – summary of key points could include the following:

- Where the incident occurred
- Main activity at the time of exposure
- Application method
- Route of exposure
- Conditions of use when the incident occurred, e.g. prevailing climatic conditions

4.2 Description of the adverse effects

- Summary of key points described in the incident report form (annex I)

4.3 Relationship of the adverse effects observed to recognized acute toxicological effects of the active ingredient(s)

- The simplest approach is to reference/quote from the relevant sections of the data sheet included in annex II

4.4 Extent of incident (e.g. number of people affected for human health incidents)

- Summary of information in the incident report form (annex I)

5. Any regulatory, administrative or other measure taken, or intended to be taken, by the Party in response to the incidents

Purpose: To briefly outline any administrative/regulatory action that may have been taken by the reporting country

- This information could be taken directly from part A of the submitted incident report form.

6. WHO hazard classification of the formulation

Purpose: This section should provide an internationally recognized baseline from which countries can better understand the potential concerns with the formulations in question relative to others that they may be using

- This should be calculated based on the best available information. The values and possible hazard classification should be based on the principal routes of exposure (e.g. dermal, oral) and presented in tabular format.

- The WHO recommended classification of pesticides by hazard should be used as the primary reference for oral LD_{50} values. Where several LD_{50} values for other routes of exposure, e.g. dermal, have been published, the lowest deemed reliable is used (and referenced). This is in line with the approach used by WHO in compiling the oral LD_{50} values.

- Where a formulation consists of more than one active ingredient, the fact that the calculated hazard classification cannot account for possible synergistic effects or the potentiation of toxicity as a result of interaction among the active ingredients should be noted.

7. Alternative pest-control practices

Purpose: To provide countries with brief information about alternatives that have been identified by the country submitting the proposal or others.

- Where available, information on the pests controlled should be included in order to ensure that appropriate alternatives may be identified.

- It may 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 pesticide formulations 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.

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 specific chemicals on the Rotterdam Convention web site. Such new sources of such information could be included in a series of updates 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:

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) strategies as a means of reducing or eliminating the use of hazardous pesticides.

Advice may be available through national IPM focal points, FAO 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 web site www.pic.int.

It is essential that before a country considers substituting alternatives for a given formulation, it ensures that the use is relevant to its national needs and the anticipated local conditions of use.

Annex I Rationale for the recommendation by the Chemical Review Committee to include the severely hazardous formulation in the PIC procedure

Part 2 of Annex IV of the Convention refers to a range of information that is to be collected by the secretariat. This information will need to be considered by the Chemical Review Committee. In order to assist countries in better understanding the reason why a particular formulation has been included in the PIC procedure, this section will contain the rationale prepared in support of the recommendation of the Chemical Review Committee for inclusion of the formulation in the PIC procedure.

Annex II Information on reported incident from incident report

This should include specific information submitted by the notifying country:

- Summary of completed incident report form(s) (e.g., part B for a human health-related incident);
- Name of the country
- Designated national authority contact information

Annex III Safety data sheet(s) on pesticide active ingredient(s)

The relevant data sheet(s) for the individual active ingredients should be inserted in their entirety.

Safety data sheets typically contain the following key headings:

1. Chemical product identification and company identification
2. Composition of and other information on ingredients
3. Hazard identification
4. First aid measures
5. Accidental release measures
6. Handling and storage
7. Exposure controls and personal measures
8. Physical and chemical properties
9. Stability and reactivity
10. Toxicological information
11. Ecological information
12. Disposal considerations
13. Transport information
14. Regulatory information
15. Other information

Other examples of readily available information that might be used to complete this annex include the IPCS International Chemicals Safety Cards, summaries from environmental health criteria documents etc. These documents are freely accessible at www.inchem.org.

Annex III Summary of toxicological properties

Purpose: Summarize key elements in the toxicological profile of the formulation (*where available*)

For mammalian toxicological end points, the primary data generated for a pesticide formulation are limited to a set of six acute toxicity studies. The most common and those that might be expected to be available for a given formulation are the following:

- Rat LD_{50} oral
- Rat LD_{50} dermal
- Rat LC_{50} inhalation
- Skin irritation
- Eye irritation
- Skin sensitization (test method used and result)

Where there is a risk or hazard evaluation on the formulation either from a national Government or an international source it may be summarized here.

- Where this information is not available for a given formulation, consideration should be given to including:
  - The material safety data sheet (MSDS) for the formulation;
  - A reference to the risk or hazard information in annex II on the active ingredient(s) from an internationally recognized source such as the INCHEM database, the EXTOXNET Profile, IPCS International Chemical Safety Cards, summaries from environmental health criteria documents etc.

Appendix. Standard core set of abbreviations

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
>>	much greater than
µg	microgram
µm	micrometre
ArfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
ADP	adenosine diphosphate
ATP	adenosine triphosphate
b.p.	boiling point
bw	body weight
°C	degree Celsius (centigrade)
CA	Chemicals Association
cc	cubic centimetre
CHO	Chinese hamster ovary
cm	centimetre
DNA	deoxyribose nucleic acid
EC	European Community
EC_{50}	effect concentration, 50%
ED_{50}	effect dose, 50%
EEC	European Economic Community
EHC	environmental health criteria
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
IC_{50}	inhibition concentration, 50%
ILO	International Labour Organization
IPCS	International Programme on Chemical Safety
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	organic carbon-water partition coefficient
l	litre
LC_{50}	lethal concentration, 50%
LD_{50}	lethal dose, 50%
LOAEL	lowest observed adverse effect level
LD_{LO}	lowest lethal dose
LOEL	lowest observed effect level
m	metre
m.p.	melting point
mg	milligram
ml	millilitre
mPa	millipascal
MTD	maximum tolerated dose
ng	nanogram
NOAEL	no-observed-adverse-effect level
NOEL	no-observed-effect level
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
PCM	phase contrast microscopy
Pow	octanol-water partition coefficient
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	standardized mortality ratio
STEL	short term exposure limit
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
WHO	World Health Organization
wt	weight