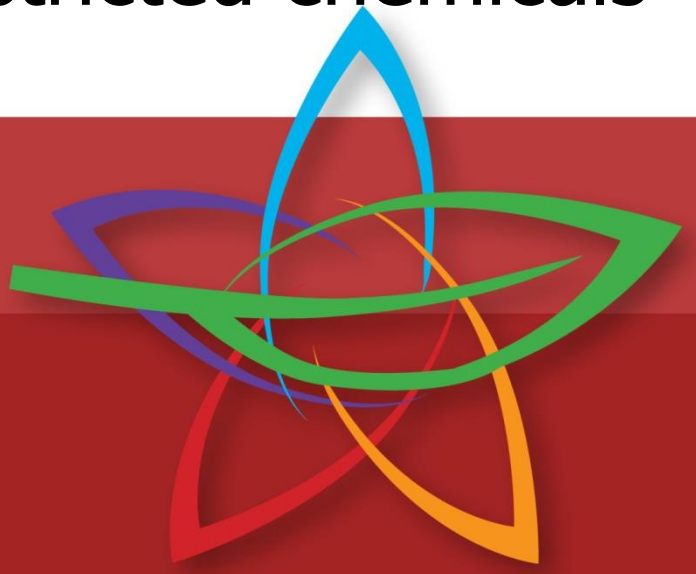
Content of Decision guidance document (DGD) for banned or severely restricted chemicals

- Content + Structure
- Review examples
- Lessons learned



Introduction

- For every chemical that is listed in Annex III a DGD has been approved by the Conference of the Parties (COP).
- The draft DGD prepared by the CRC is part of the decision process when the COP decides upon including a chemical in annex III.
- The DGD reflects the information contained in the two or more notifications of final regulatory action provided by two or more Parties. The notifications have previously been approved by the CRC.
- Handbook of working procedures for the CRC: chapter 1.2 guides the CRC in the development of a DGD for banned or severely restricted chemicals.

http://www.pic.int/TheConvention/ChemicalReviewCommittee/GuidancetotheExperts/tabid/1060/language/en-US/Default.aspx

Guidance for preparing a DGD

Objective of the guidance:

- 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.

The guidance is a living document, it evolves as further experience is gained.

- The Co-chairs of the DGD drafting group receive an *electronic template.* It has a standard structure.

STANDARD CORE SET OF ABBREVIATIONS

JECFA	Joint FAO/WHO Expert Committee on Food Ad
JMPR	Joint FAO/WHO Meeting on Pesticide Residues on Pesticide Residues in Food and the Environm Residues)
k	kilo- (x 1000)
kg	kilogram
Koc	organic carbon normalized partition coefficient (
Kow	octanol-water partition coefficient
kPa	kilopascal

Structure of the DGD

Sections 1 – 4

1. Identification of the chemical and uses
2. Reasons for inclusion in the PIC procedure
3. Protective measures
4. Hazards and risks to human health and/or the environment

Annex 1 Further information on the substance

Annex 2 Details on the final regulatory actions

Annex 3 Addresses of designated national authorities

Annex 4 References

1. Identification and uses

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.

- CAS, IUPAC names and numbers, structural formula
- Category (pesticide / industrial chemical)
- Trade names, formulation types, basic manufacturers
- Uses in the notifying parties

Additional information may be included but only if it is within the scope of the notifications.

Identification: example

Identification:

Identification can be challenging especially when notified chemical is a complex mixture of substances.

Example

Notification of Short-Chain Chlorinated Paraffins (SCCP):

- Canada: chloroalkanes C10-13 and a non exhaustive list of CAS numbers.
- Norway: chloroalkanes C10-13, one CAS number and a degree of chlorination.

- Consultation of the notifying Parties to find out common scope.

2. Reasons for inclusion in the PIC procedure

2.1. Final regulatory action

- brief summary of the FRA and reasons for the action taken (human health concerns / environmental concerns) for each notifying party.
- legal background of the decision (more details in annex 2).

2.2. Risk evaluation

- summary highlighting the key reported finding(s) of the national risk evaluation(s) that led to the regulatory action (more details in annex 1).

Final regulatory action: example

Example of tributyltin compounds:

Canada: Registrations of all TBT-based anti-fouling paints, active ingredients and concentrates were phased out. The registrant agreed to recall all unsold stocks.

Reason: concerns with regard to non-target aquatic organisms, persistence in the environment and bioaccumulation in aquatic organisms.

European Union: The use of TBT was prohibited in anti-fouling paints and in industrial water treatment.

Reason: concerns with regard to occupational exposure, consumption of contaminated food and risks to non-target aquatic organisms.

Risk evaluation: example

Example of endosulfan:

European Union : exposure scenarios taking into account prevailing conditions lead to unacceptable exposure levels for operators.

Long term risks for local and remote environments are expected due to POPs characteristics. Unacceptable risks for the aquatic environment have been estimated even when assuming large buffer zones.

CILSS Countries: an unacceptable risk for workers and the environment is deduced by comparing the conditions of use in the Sahelian Countries with those of Australia and USA where strict risk mitigations measure are in place. Applied doses are comparable for theses countries but much lower protective measures are common in the Sahel.

3. Protective measures

Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

Complete ban or sever ban with few uses that are exempted or subject to authorization.

Complete cancellation of registrations or very few applications that remain registered.

3.2 Other measures to reduce exposure

Information as reported, general information: e.g. Risk management evaluation. developed under Stockholm Convention.

3.3 Alternatives

Alternative products as reported in notification.

General: e.g. IPM strategies, organic strategies.

3.4 Socio-economic effects

Section only completed if notifying Party has undertaken studies.

Protective measures: example

Example of trichlorfon:

3.1 Regulatory measures

European Union: trichlorfon as active ingredient is banned. All authorisations for plant protection products containing trichlorfon are withdrawn.

Brazil: the FRA establishes the definitive prohibition of registration of pesticides containing trichlorfon. Import, use, research in all stages, production, packaging, labelling, transport and export of trichlorfon is also prohibited.

3.2 – 3.4 Other measures to reduce exposure, Alternatives, Socio-economic effects

No information from notifiers, general information on alternatives.

Section 4

Hazards and risks to human health and/or the environment

4.1 Hazard Classification

- brief summary of internationally recognized classifications.
- often includes WHO, EPA and/or EU classification.

4.2 Exposure limits

- Internationally recognized sources.
- e.g. ADI, ARfD.

4.3 Packaging and labelling

- reference to existing standards for packaging and labelling.

4.4 First aid

- reference to internationally recognized information on the treatment of chemical poisoning.

4.5 Waste management

- references to appropriate internationally recognized guidelines.

Annex 1 - Further information on the substance

Annex 1 includes information submitted by the notifying parties based on the their national assessments which were used to support the reported final regulatory action.

- Sources of information:
  - **information submitted by notifying parties**
  - results of international reviews such as WHO / IPCS / POPRC

  Links to international chemical data bases:

  JMPR (pesticides): http://www.inchem.org/pages/jmpr.html

  SIDS (industrial chemicals): http://www.inchem.org/pages/sids.html

- General:
  - the introduction to the annex should clearly state references used.
  - the level of detail and focus should be on those area(s) of concern and related endpoints that were the basis of the risk evaluation underlying the FRA.
  - in order to avoid discrepancies, a range of values may be reported (e.g. "LD50: 69 – 240 mg/kg bw").

Annex 1 subsections

1. Physico-chemical properties

2. Toxicological properties

- Summary of notified toxicological studies and international studies (e.g. WHO/IPCS).
- Summary of mammalian toxicity and overall evaluation.

3. Human exposure/risk evaluation

- Focus on major exposure routes.
- Emphasis on studies that led to FRA.
- Summary of overall risk evaluation.

4. Environmental fate and effects

- Summary of notified and international studies (e.g. POPRC).
- Specific subheadings facilitate the identification of potential POPs.

5. Environmental exposure/risk evaluation

- Emphasis on studies that led to FRA.
- Summary of overall risk evaluation.

Annex 2
Details on final regulatory actions reported

- Should reflect the information provided in the notification of regulatory action form.
  - details on aspects of the regulatory decision
- Includes effective date(s) and reference to the regulatory document.

Annex 3 and 4

- Annex 3: Contact details of the DNA`s of the notifying parties.
- Annex 4: List of References
  - Sources of information cited.
  - Reference to review documents rather than to individual papers.

Lessons learned / Challenges

- Organisation and decision-making between co-chairs / members of the drafting group.
- To identify apporiate information sources.
- To include information from different sources in Annex 1 (including occasional discrepancies/inconsistencies).
- To catch the key elements of the risk evaluation.
- To take into account comments received.


Do you have any questions or comments?