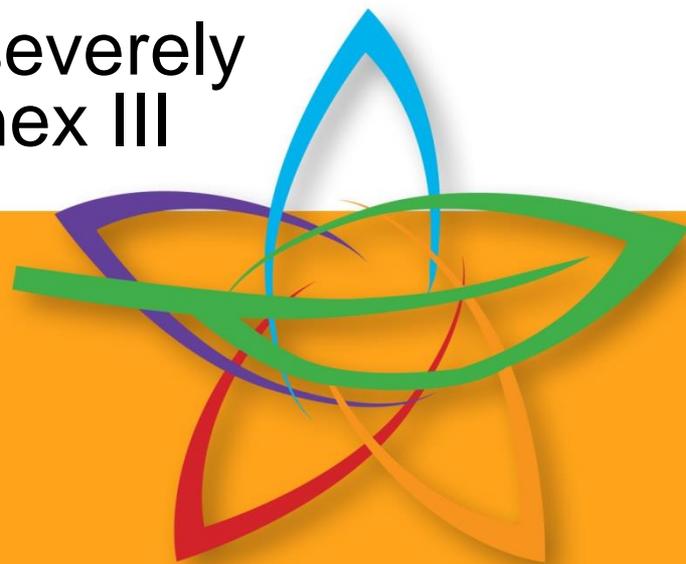


CRC - Policy Guidance

Annex II

Criteria for listing banned or severely restricted chemicals in Annex III



How the CRC applies the CRITERIA

When reviewing the notifications forwarded by the Secretariat pursuant to paragraph 5 of Article 5, the Chemical Review Committee shall check whether criteria (a) to (d) of Annex II have been met

Criterion (a)

- **Confirm that the final regulatory action has been taken in order to protect human health or the environment**
- ➔ Information is generally contained in the text of the regulatory decision itself (section 2.2 of the notification) and presented in more detail in the underlying risk evaluation (section 2.4 of the notification)

Criterion (b)

- **Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:**
 - (i) Data have been generated according to scientifically recognized methods;
 - (ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;
 - (iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action.
- ✓ **Please note: criterion (b) is met if all three sub-criteria are met.**

Working procedures

- ➔ ***Risk evaluation: working paper on the application of criterion (b) of Annex II***
 - includes practical examples where the Committee has determined that these criteria have been met
 - guidance on (b) (i) and (ii) was linked to COP guidance on risk evaluations from other MEAs – helps ensure a consistent approach to the application of these criteria



Reminder

A risk evaluation considers
information on

hazard (toxicological properties of chemical)

and

exposure (contact of organism with the chemical)

Criteria (b) (i) and (ii)

- ➔ **Hazard** information is usually not generated nationally, but drawn from international sources;
- ➔ Information from such sources is considered to have met criteria (b) (i) and (ii).
- ➔ **Exposure** information is usually, but not necessarily, generated at national level;
- ➔ Whether information meets the criteria is considered on a case-by-case basis.



Scenario 1: Data are not provided and there is no reference to a source of data in the notification or in the supporting documentation

Criteria (b) (i) and (b) (ii) would not be met.

Scenario 2: Data are provided but the source of the data is not referenced in the notification or in the supporting documentation.

Criteria (b) (i) and (ii) would not be met as it would not be possible to verify that the data have been generated according to scientific principles and procedures or that the data reviews have been performed and documented according to generally recognized scientific principles and procedures.



Scenario 3: Data are not provided but there is a reference to a source of data in the notification or in the supporting documentation.

Criteria (b) (i) and (ii) would be met where the notifying country merely references a source document, without drawing out the specific information which they have used to make their decision, provided that the reference is to an internationally recognized source including a risk evaluation undertaken under the Stockholm Convention or the Montreal Protocol. Other documents, such as national or regional assessments, would need to be examined on a case-by-case basis.

Scenario 4: Data are provided and the source of the data is referenced in the notification or in the supporting documentation.

Criteria (b) (i) and (b) (ii) would be met, provided that the data are from an internationally recognized source including a risk evaluation undertaken under the Stockholm Convention or the Montreal Protocol. Other documents, such as national or regional assessments, would need to be examined on a case-by-case basis.



Reminder

In order to establish whether criteria
(b) (i) and (ii) have been met,
information on
hazard and exposure
should be considered

Criterion b (iii)

- ➔ Meeting criterion (b) (iii), i.e. that *a final regulatory action was based on a risk evaluation involving prevailing conditions within the party taking the action*, has proven particularly difficult.
- ➔ Other than conducting risk evaluations by themselves, notifying countries may use risk evaluations and/or exposure assessments completed in another country or from an international risk evaluation. => **bridging**

Criterion (b) (iii): Examples

➔ Incidents involving direct exposure of humans

- Actual or measured exposure
 - DNOC by Peru
- Expected or anticipated exposure, e.g. by modelling
 - Methyl parathion by the EU (modelling)
 - Bis (chloromethyl) ether by Canada (non-threshold carcinogen)
 - Aldicarb by Jamaica (use of other risk evaluation)

Criterion (b) (iii): Examples

➔ Incidents involving direct exposure of humans

- Measured data + socio-economic considerations = expected or anticipated exposure

Methamidophos by Brazil

- Non-authorized use on certain crops
- Residues above legal maximum limits

Issues:

- Exposure of operators/workers (more use than allowed)
- Exposure of consumers (produce eaten raw)

Criterion (b) (iii): Examples

- ➔ Incidents involving direct exposure of the environment (wildlife, livestock, etc.)
 - Actual or measured exposure
 - Methyl bromide by the Netherlands (fish toxicity data and monitoring data)
 - Endosulfan by Thailand (comparison of fish toxicity data and effects on non-target organisms)
 - Expected or anticipated exposure
 - Methyl parathion by the EU (comparison of mammalian and environmental toxicity with modelled exposure levels)
 - Endosulfan by the Netherlands (comparison of fish toxicity to modelled exposure levels)

Criterion (b) (iii): Examples

➔ Indirect exposure via the environment (air, water, soil)

- Presence of chemical in environment in itself is not sufficient
 - Endosulfan by Jordan
- Regulatory action taken as precautionary measure, due to bioconcentration/-magnification
 - Mirex by Canada (bioaccumulation and toxicity together with (potential) exposure)
- Indirect effects (ozone depletion => increased UV)
 - CCl₄ by Canada (direct effect)
 - Indirect effect (climate change)

Criterion (c)

The CRC is requested to consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by *taking into account* the following sub-criteria:

Criterion (c)

- (i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;
- (ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

Ban: criteria met

Severe restriction: quantity; reduction of exposure;
case-by-case

Criterion (c)

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

Case-by-case basis:

- Human health concerns are usually not limited to a geographical area;
- Environment: particular conditions (endangered species) or general concerns about effects on non-target organisms

Criterion (c)

(iv) Whether there is evidence of ongoing international trade in the chemical.

- ➔ Working paper is available
- ➔ Information available to CRC may be limited
- ➔ Absence of such information is not a basis to withhold a recommendation for listing

Criterion (d)

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

➔ Guidance is available

➔ Not a basis for listing is regulatory action taken to avoid:

- intentional use for suicide
- intentional use for fishing [see Sri Lankan notification – CRC.5 (CRC5/8 and meeting report)]



Bridging information

What is “bridging” under RC in the context of criterion (b) (iii)?

“Bridging” is done when the notifying Party has used a risk evaluation from another country or international body as the basis for its national decision

Bridging: Background

- ➔ At its third meeting, the Conference of the Parties agreed that, in order to satisfy criterion (b) (iii) of Annex II to the Rotterdam Convention, bridging information providing evidence of the prevailing conditions in the notifying country would have to be submitted when using risk evaluations from other countries or international bodies.

Use of risk evaluations under other multilateral environmental agreements



- ➔ Criterion (b) (iii) of the Convention would not be met without some form of bridging information or consideration of the risks resulting from the use of the chemical within the country taking the action
- ➔ Example: for the Montreal Protocol, such bridging information could be a statement relating to the potential impact of depletion of the ozone layer on human health or the environment in the country which has taken the action

Use of risk evaluations under other multilateral environmental agreements

The CRC determines whether the conditions in

- ➔ the country which completed the original risk evaluation (including exposure assessment) or
- ➔ risk evaluations carried out under other international agreements or conventions,
 - such as the Montreal Protocol on substances that deplete the ozone layer or
 - the Stockholm Convention on Persistent Organic Pollutants (POPs)(see specific guide)

have appropriately been considered in the context of those prevailing in the notifying country.

Considering bridging information

- ➔ The CRC will consider such bridging information on a case-by-case basis.
In reviewing the information, the Committee will apply the following principles:
 - Exposure or potential exposure is a key element;
 - The information should be science-based, on the best available knowledge;
 - The information should also be sufficiently detailed to enable the CRC to make an assessment

Bridging: Information to look at

➔ Pesticides

- Form in which it was used (formulation, contaminants)
- How it was used (use pattern, climatic conditions)
- Risk mitigation

➔ Industrial chemicals

- Information on human exposure (workers, end users...)
- Information on environmental exposure (soil, air, water, wildlife...)
- Production processes, storage, use, disposal...
-



Thank you!