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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Chemical Review Committee
Thirteenth meeting
Rome, 23–27 October 2017
Item 6 of the provisional agenda*

Updates to the Handbook of Working Procedures and Policy Guidance for the Chemical Review Committee

Comments and further information related to the draft revision of the Handbook of working procedures and policy guidance for the Chemical Review Committee

Note by the Secretariat

As referred to in document UNEP/FAO/RC/CRC.13/18, the annex to the present note sets out comments and further information related to the draft revision of the Handbook of working procedures and policy guidance for the Chemical Review Committee. The present note, including its annex, has not been formally edited.

* UNEP/FAO/RC/CRC.13/1.

Annex

Comments and further information related to the draft revision of the sections 1.7 and 2.5 of Handbook of working procedures and policy guidance for the Chemical Review Committee Comments

Mandate

As requested by the CRC at its 12th meeting, the intersessional Task Group (ITG) is expected to revise the following sections of the Handbook of Working Procedures and Policy Guidance for the Chemical Review Committee:

1. Revise pp36-42, Section 1.7 Guidance to intersessional Task Groups on reviewing notifications of final regulatory actions, in order to include the SHPFs for which when the current CRC7 version was drafted there had been limited experience, and
2. Revise pp56-63, Section 2.5 Working paper on the application of criteria (b) of Annex II, for which further examples should be added to the current CRC8 version.

The ITG is not expected to revise other parts of the Handbook such as Bridging Information (pp47-50), which have also been the subject of discussion at recent CRC meetings. It was agreed that the Secretariat should take into account the discussions regarding bridging information in the ongoing technical assistance activities."

Comments on the Second Drafts

Over the period 4 April to 8 May comments were received from seven (7) members of the Intersessional Task Group (ITG), as well as from three (3) Observers. Six of these comments were substantive; these are detailed in the Tables below together with the drafters' proposed responses. The following comments were also received:

1. Antigua and Barbuda: I have perused the revised draft documents and I am in general agreement with the adjustments. I have not found anything further to add or subtract. My commendations to the intercessional task group chair Ms. Randall and vice-chair Mr. Holland, for their hard work in effecting the relevant changes.

2. Argentina: I went through the revised documents and agree with the addenda and adjustments. No further comment (*see previous comment on Section 1.7 in Table below*). My acknowledgement to Marit and Mr. Holland for the careful job done.

3. Canada: Thank you for this opportunity to review the updated handbook sections. The Chairs have clearly done a great job and my earlier comments are all addressed. The only comment I have is a trivial one (*see Section 2.5 of the Tables below*). (

4. Germany: I do not have any other comments and suggestions on the final (*second*) draft. With this I would like to congratulate the co-chairs for their excellent work!

5. Tonga: After revising the proposed addition and changes, I am pleased to inform you that I have no further comments. Therefore, I would like to acknowledge the work done so far but especially the chair Ms. Randall and vice-chair Mr. Holland.

Section 1.7

Source	Section	Comment and further information related to the amendment of Section 1.7 of the CRC Handbook – 2nd draft	Response
Argentina	General, but appears to refer specifically to **5. Points to be considered by the CRC,** at the end of Annex II.	The revision proposed for pp 36-42 Section 1.7 is more troublesome. Specially those regarded to severely hazardous pesticide formulations (SHPF) have a more difficult scope and I believe that perhaps they would require a more careful discussion, in a case by case analysis, because of the extended formulations that can be found. I do hope that in the CRC13 we will have the opportunity of a more clarifying discussion.	This comment was made on the first draft, but has been retained here as a flag for possible discussion at CRC13.
Poland	General	Comments made on both Sections 1.7 and 2.5	Noted.
	p2, start of final paragraph of **Role of Intersessional Task Groups**	It ~~should~~ has to be noted that the work of Task Groups is not to initiate a debate on whether or not there is agreement with the national regulatory action taken for a chemical, (*Proposed to amend asindicated because*) That sentence should be more stressed.	Not accepted. This is already in the text agreed by CRC7. If this is to be changed the word "must" may be more appropriate.
	p2, 2nd sentence of third paragraph of **Operations of Intersessional Task Groups - *Prior to a CRC meeting***	Proposed drafters' amendment in 2nd draft They may also circulate a completed analysis table (for which an Excel template is provided by the Secretariat), which may be used as a tool to organise the information found in the notifications and supporting documents, and which may serve as a means for each Task Group member to become familiar with the information. Comment: if in opinion of other CRC members the table is useful that sentence should remain. However, I have some doubts if that is used and if it really facilitates the work. I would suggest to cancel that sentence.	Comment noted – the ITG's views were sought as to whether they would find the retention of this analysis table useful – see Table for third draft below.
	p2, 2nd last sentence of ***During the CRC meeting***	Proposed amendment to amended words in 2nd draft ...the Committee shall recommend to the Conference of the Parties to make ~~whether~~ the chemical or the severely hazardous pesticide formulation ~~in question should be made~~ subject to the Prior Informed Consent procedure and ~~accordingly~~ be listed in Annex III. Reasons for proposal: Committee recomends only that chemical or SHPF that fulfills criteria of relevant annexes. That is why in my opinion whether is not necessary here.	Not accepted. Following a comment by Canada on the first draft, to make it clearer this (new) sentence was amended to combine the wording from Article 5 clause 6 and Article 6 clause 5 of the Convention. Thus the word "whether" and the other words/phrases proposed to be deleted should be retained. However, the sentence following was amended to remove superfluous text.
	p3, last sentence 2nd paragraph of ***Undertaking the preliminary review by an intersessional Task Group***	The analysis should also highlight those areas that the Task Group considers need particular attention by the CRC. Is it possible to make that sentence more simple, basic? I know that its present form is in perfect English, but CRC members do not always have perfect	Not accepted as the purpose of the comment is unclear – does it refer to the last sentence only as appears to be indicated, or the whole paragraph. See also **5. Points to be considered by the CRC** at the end of Annex II.

Source	Section	Comment and further information related to the amendment of Section 1.7 of the CRC Handbook – 2nd draft	Response
		English so maybe simpler form of some sentences would be more useful.	
	p3, **Step 1 - Organize information**	Four comments in first three paragraphs re use of the analysis table.	Noted - The retention or revision of the text will depend on whether the ITG feels use of this analysis table is helpful – see above.
	p3, first paragraph of **Step 2 – Analysis of information available for individual notifications or SHPF proposals**	Based on the information available to the Committee the Task Group should, for each notification or for SHPF proposal, establish whether or not the individual criteria of, respectively, Annex II or Part 3 ~~for SHPFs the individual criteria of Part 3~~of Annex IV, have been met.	Not accepted. It is not clear why the different requirements for chemicals and SHPFs is now proposed to be combined, compared with their previous clear separation which has been consistently used (and not proposed to be changed). However, the word chemical is proposed to be added before notification, and also below.
	p4, last sentence of final paragraph of **Step 2 – Analysis of information available for individual notifications or SHPF proposals**	Where there are two notifications from two PIC regions for the same chemical, or in the case of SHPFs one proposal, that are found to meet the requirements of the Convention, ~~or one proposal in the case of SHPFs~~ and which the Committee decides to recommend to the Conference of the Parties that it be listed in Annex III, the individual rationale will accompany the recommendation.	Not accepted for same reasons as immediately above.
	p4, first sentence of first paragraph under **Task Group Reports**	The Task Group report should include a cover page that sets out a list of the information available to the Task Group, a brief summary of the principal conclusions clearly stating which, if any, criteria of Annex II are met by the notifications of chemical and which ~~meet the~~ criteria of Part 3 of Annex IV are met by ~~Annex II, or for~~ (the) SHPF proposal ~~the criteria of Part 3 of Annex IV~~.	Not accepted for same reasons as immediately above. In the drafters' opinion the proposed revising of the text makes it less clear compared the originally proposed simple addition.
	p4, first sentence of second paragraph under **Task Group Reports**	The main body of the report should consist of the detailed analysis outlining, for each notification, whether or not the criteria contained in Annex II have been met and whether or not the criteria contained in, ~~or for SHPFs the criteria of~~ Part 3 of Annex IV for SHPFs have been met ~~of the Convention~~.	Not accepted, as again the proposed change makes it less clear compared the originally proposed simple addition.
	p4, last paragraph under **Task Group Reports**	The completed tables do not need to be annexed to the final version of the Task Group report as the text of the report summarizes the information and conclusions of the Task Group.	The completed tables refer to the analysis table for which the ITG needs to decide whether or not they are useful to retain – see above.
United States of America	p3, second paragraph of **Step 2 – Analysis of information available for individual notifications or SHPF proposals**	At the start … For each notification: "Like the following paragraph, I would add "for chemicals" here to distinguish from SHPF".	Accepted – this has also been added a number of other times as appropriate – see track changes in draft
	p4, third last line of final paragraph of **Step 2 – Analysis of information available for individual notifications or SHPF proposals**	SPHF "typo"	Corrected
Croplife International	General	We limit our comments to the proposed changes in section 1.7.:	Noted.

Source	Section	Comment and further information related to the amendment of Section 1.7 of the CRC Handbook – 2nd draft	Response
(CLI)	Page 1 – Membership and composition of intersessional Task Groups:	Current text: *Following POPRC's experience, a new approach has been agreed to by the CRC Bureau where one of the co-coordinators that is not from the notifying party would serve as a 'chair', while the other could be from the notifying party and would act as a 'drafter', as the expertise of the member for the chemical at hand is important.* CLI comment: In the past, some CRC members and observers viewed critical if the task group was chaired by a member from the notifying parties as a conflict of interest could not be excluded. We therefore appreciate that the intersessional task group addressed this issue. However, we do not believe that that the concern related to conflict of interest can be resolved with the proposed approach as the drafter may have a similar or even more influential role within the task group than the chair. We therefore suggest that neither the chair nor the drafter should be from the notifying party.	Comment noted, but this would involve the formulation of new policy which is outside the above mandate given by CRC12 to the ITG; ie Revise pp36-42, Section 1.7 Guidance to intersessional Task Groups on reviewing notifications of final regulatory actions, in order to include the SHPFs for which when the current CRC7 version was drafted there had been limited experience. However, the opportunity has been taken to include into Section 1.7 some previously agreed policy changes of which this is one example.
	Page 2 – Prior to a CRC meeting – para. 3 with regards to timelines:	Comment CLI: We appreciate that the intersessional task group suggested to extend the commenting period on draft group reports to 3 weeks. Unfortunately, there is now some inconsistency with the overall timelines which need to be resolved: • 2 months prior to CRC meeting: TG is established • 4 weeks prior to CRC meeting: Preliminary review report to TG members • **2 weeks** prior to CRC meeting: TG members to provide comments • **3 weeks** prior to CRC meeting: Draft TG report on website / start of commenting period for members and observers	It is agreed there clearly is a problem here which has arisen from CRC's agreed change from 2 to 3 weeks before the meeting to put the final ITG report on the website. It has been modified to indicate the Preliminary review report is circulated to ITG members for comment at least 5 weeks before the meeting. See also to comments from PAN Asia Pacific.
	Page 2 – Prior to a CRC meeting – para. 3 last sentence:	Current text: …*Comments from CRC members and observers will be collected by the Secretariat and made available at the Task Group meeting.* CLI comment: Experience has shown that there is nearly no consideration of observer comments by the task groups at their meetings immediately prior to the CRC meeting. In order to stimulate a more substantial discussion on observer input, we suggest that all comments available already 3 days before the CRC meeting	Comment noted, but again this would involve the formulation of new policy which is outside the ITG's mandate – see comments above.

Source	Section	Comment and further information related to the amendment of Section 1.7 of the CRC Handbook – 2nd draft	Response
		be forwarded to all task group members.	
	Page 12 – Section 2.2.3 (a):	CLI comment: The example provided appears to be a summary of information provided in the documentation of the proposing party. We are missing here a guidance how to assess the reliability of the evidence. The quality of data and surveys need to be considered as misclassification cannot be excluded. The CRC should have in front of it detailed information on the individual incidents and confirm the association between the effects reported and alleged exposure to the SHPF. A scheme as used by UK poison centers could be used. By doing that, the severity of the incidents should also be determined to conclude whether or not the SHPF in question meets the definition of an SHPF according to Art. 2(d). A widely used scheme is available[1]. If the severity of poisonings is not considered, essentially all pesticide formulations could be affected by the Convention which is in contrast with the aim of the authors of the Convention to limit the scope to formulations the use thereof had reliably shown to produce severe acute effects under conditions of use. [1] Persson HE, Sjöberg GK, Haines JA, Pronzcuk de Garbino J. Poisoning severity Score. Grading of acute poisoning. Clin Toxicol 36: 205-213, 1998	Comment noted, but again this would appear to involve the formulation of new policy which is outside the ITG's mandate – see comments above.
	Page 12 – Section 2.2.3 (a), para. 3:	Current text: *… All reported symptoms in 95% of the reported poisoning incidents can clearly be linked to intoxication with the acutely toxic SHPF Y as the symptoms…* CLI comment: We suggest to delete "acutely toxic", "intoxication with the SHPF" is sufficient.	Accepted.
	Page 13 – Section 2.2.3 (d):	CLI comment: In our view, the significance of the reported effects should be put in relation to the quantity of the formulation used in the territory of the notifying party or a sub-territory surveyed, and not solely in relation to a volume handled by an individual. If a proposing party experiences problems with a pesticide formulation, it would certainly consider the frequency of reported effects and the severity grade of these effects when suggesting risk mitigation measures or even a regulatory action. If a small volume handled would result in a serious problem in the proposing party, an over-proportionate incidence rate would result which may satisfy criterion Annex IV part 3(d), however, a small volume unrelated to an incidence rate	Comment noted, but again this would involve the formulation of new policy which is outside the ITG's mandate – see comments above.

Source	Section	Comment and further information related to the amendment of Section 1.7 of the CRC Handbook – 2nd draft	Response
		does not. We also suggest for this criterion to develop guidance to the CRC considering the incidence rate in context with the volume used in a territory and the application rate (the combination of these parameters would provide a kind of normalization to similarly assess high- and low volume pesticides). Also the severity of effects should be considered as severe effects should only tolerate a relatively low incidence/volume ratio, while a higher ratio could be applied to minor effects.	
Pesticide Action Network (PAN) Asia Pacific	General	Please find attached comments from PAN Asia Pacific on the draft (Section) 1.7 of the CRC handbook. We have no comments on (Section) 2.5.	Noted
	p1, first sentence under **Membership and composition of intersessional Task Groups**	*Proposed addition underlined in red.* For each chemical or SHPF scheduled for review by the CRC, an intersessional Task Group is established by the Secretariat in consultation with the Bureau. Task Groups consist of one to two coordinators and a representative group of members of the CRC, and observers. (*Comment taken from covering E-mail of 4 April 2017)* You will notice that we have added observers to members of the CRC, as members of intercessional Task Groups. We requested, at the Intersessional Rotterdam Convention Workshop in Latvia last year, that observers be permitted to participate in the Task Groups in the intersessional period. We believe that we can contribute usefully in this phase, and that to do so would able us to be more familiar with the candidate chemicals and SHPF, enabling us to make more targeted contributions at the CRC meeting. I trust that consideration will be given to this request.	Not accepted. The Report of the workshop referred to held in Riga Latvia on 3-5 July 2016 on the intersessional work on the process of listing chemicals in Annex III to the Convention was in the COP8 papers as **UNEP/FAO**/RC/COP.8/INF/. The issues of observers being involved in the intersessional work comes up a number of times in this report, first on p22 under section 2.2.2 on the outcome of the discussions of Group 2 of the Cluster group II, but the following is the most pertinent. **In Appendix IV, Compilation of Proposals and Options** on p34 under **III CRC STAGE** **E. OBSERVERS** Observers should also be welcome to participate in the CRC's intersessional work and task groups, like the Persistent Organic Pollutants Review Committee (POPRC) under the Stockholm Convention (ACPMA, IPEN, PAN AP). This is largely repeated on p63 where the USA comments on this proposal/option as part of their comprehensive comments. This Report was one of the most discussed topics at COP8, but without substantive outcomes. At the end the COP agreed to continue intersessional work and took a decision on the process of the intersessional work through an informal open-ended contact group of parties and non-party states. The Secretariat has been mandated to undertake an online survey, to prepare a report analysing the legal and operational implications.

Source	Section	Comment and further information related to the amendment of Section 1.7 of the CRC Handbook – 2nd draft	Response
			Given that it is an ongoing COP project, it would be premature at this stage for this ITG to agree to formally include observers in the first sentence of the revised Section 1.7, noting that observers already participate in the work of the intersessional task groups as outlined in the end of the third, as well as the fourth, paragraphs of **Operations of Intersessional Task Groups - *Prior to a CRC meeting*** on p2 of Section 1.7.
	p2, final paragraph of **Role of Intersessional Task Groups**	*Proposed addition underlined in red.* It should be noted that the work of Task Groups is not to initiate a debate on whether or not there is agreement with the national regulatory action taken for a chemical or SHPF, but rather whether the regulatory action meets the requirements set out in Annex I and the criteria set out in Annex II of the Convention. It is also not the aim of the Task Group to discuss whether or not there is agreement with the outcome of the risk evaluation of a chemical or SHPF performed by the notifying Party in support of the national decision.	Not accepted – there is no need to add SHPF here as there is no criterion in Part 3 of Annex IV of the Rotterdam Convention which asks for the proposing party to have taken any regulatory action for the SHPF. Part 1 (h) of Annex IV asks for documentation of "Any regulatory, administrative or other measure taken, or intended to be taken, by the proposing Party in response to such incidents," for which a clear description is sought in Part 1 (g) above it.
	p2, third paragraph of **Operations of Intersessional Task Groups - *Prior to a CRC meeting***	There is a problem here with timing: if the draft report is circulated 4 weeks before the meeting and members have 2 weeks to review and comment, then the final cannot be made available on the website 3 weeks before the meeting. Suggest that the draft report is circulated at least 5 weeks before the meeting, but preferably 6 weeks to allow for the second 2 timeframes to be met.	It is agreed there clearly is a problem here which has arisen from CRC's agreed change from 2 to 3 weeks before the meeting to put the final ITG report on the website. It has been modified to indicate the Preliminary review report is circulated to ITG members for comment at least 5 weeks before the meeting. See also Croplife's comments.
	p2, paragraph under ***During the CRC meeting***	Minor edits, "which" to "that", and SHPF for severely hazardous pesticide formulation.	Both not accepted. The first is in the agreed CRC7 text, and the second is from text taken directly from the Convention (see response to Poland's comment below) and thus in this one instance will not be abbreviated.
	p7, Annex I, paragraph under **2.3 ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures.** *Example of i) and ii):*	Current text *Country 1 undertook research studies prior to the regulatory action and published the results in an internationally peer reviewed scientific journal: Review of the Persistence, Bioaccumulation, and Toxicity of Country X in Aquatic environments in relation to Country 1's toxic substances management policy, (Reference: R. James Maguire, Water Qual. Res. J. Canada, 2000, volume 35 (4), 633-679.* If that is the full title of the paper, need consistency in use of capitals and this would make a very difficult sentences easier to read. Suggest also removing the italics from the title or use ' '.	Accepted. Capitals are now used consistently in the Title, and the italics removed from it to make the Title stand out more clearly from the remaining italicised text.

Source	Section	Comment and further information related to the amendment of Section 1.7 of the CRC Handbook – 2nd draft	Response
	p7, Annex I,	A number of edits have been suggested	Partially accepted where words were missing and it helps improve the English – see revised draft
	p10, Annex II, second line of **2.1 Background of the proposal:**	Replace "that" with "which".	Not accepted, this part of the text used has been taken directly from Article 6, clause 1 of the Rotterdam Convention where "that" is used

Section 2.5

Source	Section	Comment and further information related to the amendment of Section 2.5 of the CRC Handbook – 2nd draft	Response
Canada	p8	We use the acronym "EC" on page 8 of the "section 2.5" document, but the acronym is not defined. Perhaps in this case we use "European Community"?	Accepted.
India	Section 2.5 **Working paper on the application of criteria (b) of Annex II** **2. Incidents involving direct exposure of the environment (wildlife, livestock, etc.)** (i) Comparison of mammalian and environmental toxicity data with anticipated exposure levels generated using models. Case examples include the following: **(v) another example**	The example of bridging information given in the para 2 mentioned as another example. The concept of 'bridging information' holds where the risk or hazard evaluations and exposure assessments completed in one country may be used by another country in support of its notification of final regulatory action submitted in accordance with Article 5 of the Rotterdam Convention, as long as both countries have similar local conditions. As per annex II of the Rotterdam convention, the risk evaluation shall (be) based on the scientific data of notifying country. Every country has different geographical and climatic conditions. The risk or hazard value may vary with the geographical conditions of notifying countries. Bridging concept can be used for similar kind of regions. The result suggested in the said example 2 as bridging information where from three different countries having different geographical and climatic conditions. It is suggested that under the spirit of the convention the result of the risk evaluation must be carried out in the notifying country itself. The bridging information from other countries may dilute the objective of the convention and may also be expected that the Rotterdam convention may be flooded with number of notification with no specific information on risk evaluation generating from the notifying country but having only such bridging information. However that bridging information/data may be utilize as supporting information to assist notifying country to carry out the scientific studies in their own country. The use of bridging information used as scientific evidence may not serve the	Comments noted. The use of the bridging information in this specific example was accepted by CRC5. However, the suggestion to formulate a methodology/mechanism/procedure for generation of information required by the para 3 (scientific information - *note it is assumed this should read as criteria (b)*) of annex II, so that parties are benefitted by the Convention, is outside the mandate of this Intersessional Task Group, as outlined at the start of this document.

Source	Section	Comment and further information related to the amendment of Section 2.5 of the CRC Handbook – 2nd draft	Response
		purpose of the convention. Therefore it is suggested to formulate a methodology / mechanism / procedure for generation of information required by the para 3 (scientific information) of annex II, so that parties are benefitted by the convention.	
Poland	p3, paragraph 14 – phrase "according to generally recognized scientific principles and procedures"	If I well remember during workshops there was said what is meant by that part of text of criteria b. Would it be possible to mention it here as well? That would be helpfull mostly for some observers but even for CRC members would leave some clarity.	Not accepted as the comment needs clarification – which workshop is being referred to? Is it the one held in Riga Latvia on 3-5 July 2016 on the intersessional work on the process of listing chemicals in Annex III to the Convention? Or was it during Contact Groups at CRC meetings? Could it please be clarified and preferably some proposed text provided?
	p6, heading of new insertion under **(c) Other examples**	Other examples of what? Could it be added clarified?	Corrected, the **(c) Other Examples** heading has been removed and it has been made clear that the new addition is the sixth (vi) example added to those already accepted by CRC
	p9, start of new insertion (v) Another example is the Sahelian notification for endosulfan….	See comment (above). Are there some mistakes with paragraphs numbering. It is a bit confusing.	Corrected, this has now aligned with the text above and it has been made clear that the addition is the fifth (e) example added to those already accepted by CRC
United States of America	p6, fifth entry under (b) **Expected or anticipated exposure**	(vi) Why (has this been) updated from v to vi?	This has been corrected back to (v)
	p6, heading of new insertion under **(c) Other examples**	Why is this example being added and put under its own subheading of "other examples"? The others have characterization text above to indicate the circumstances. Can the same be done with this and keep with other examples above?	Corrected, as noted above the **(c) Other Examples** heading has been removed and it has been made clear that the addition is the sixth (vi) example added to those already accepted by CRC
	p9, last sentence of paragraph b of former (v) Another example….	Rephrase to say was not authorized at the time. As written, implies that we may currently have authorized uses when, at this point, we (USA) have no registered uses of endosulfan at all.	Accepted and corrected – see also other changes made to this sub-Section above
	p9, fourth line of paragraph c of former (v) Another example….	Add "were" before required	Accepted

Comments on the Third Drafts

Over the period 26 May to 13 June 2017 comments on the third drafts were received from six (6) members of the Intersessional Task Group (ITG). Four of these comments were substantive; these are detailed in the Tables below together with the drafters' proposed responses. All four commented on the usefulness of the Excel Analysis table (p2, Section 1.7, 2nd sentence of third paragraph of **Operations of Intersessional Task Groups - *Prior to a CRC meeting***) with three (3) supporting its retention and one (1) its deletion as favoured by Poland – see comments on the second draft above. As a result this sentence has been retained, together with the four mentions of this table in first three paragraphs under **Step 1 - Organize information** on p3**.**

The following comments were also received:

1. **Togo**: Just to reassure you that I received your documents and have no particular comment on it.
2. **United Kingdom:** I would like to say that I have nothing to comment at this stage.

Section 1.7

Source	Section	Comment and further information related to the amendment of Section 1.7 of the CRC Handbook – 3rd draft	Response
Argentina	p2, 2nd sentence of third paragraph of **Operations of Intersessional Task Groups - *Prior to a CRC meeting***	Regarding the sentence in p-2 "Prior to the CRC meeting" . I find extremely useful the analysis table (with the Excel format) since it organizes and makes clear each piece of information, each suggested change afterwards, etc consistently, I would recommend to keep the comment by Poland. Coherently, I would also recommend to keep "analysis table" in p.3 "Step 1", and in any further mention of it.	This sentence has been retained, together with the four mentions of this Excel analysis table in the first three paragraphs under **Step 1 - Organize information** on p3.
Canada	p2, 2nd sentence of third paragraph of **Operations of Intersessional Task Groups - *Prior to a CRC meeting***	Regarding the Excel table, I can report that I do use it, and I find it quite useful when I'm a co-chair for a task group. I think it is valuable for organizing my thoughts and identifying the relevant NFRA sections when preparing a task group report. I admit that, once the TG report is drafted, this spreadsheet seems to have little use and I never return to it for any updates. My personal preference would be to keep it as a tool, even if it's not mandatory, just because I do find it useful in the early steps.	This sentence has been retained, together with the four mentions of this Excel analysis table in the first three paragraphs under **Step 1 - Organize information** on p3.
Germany	p2, 2nd sentence of third paragraph of **Operations of Intersessional Task Groups - *Prior to a CRC meeting***	Concerning the question on the need and usefulness of the analysis table, this was also one of my suggestions to delete it.	This sentence has been retained, together with the four mentions of this Excel analysis table in the first three paragraphs under **Step 1 - Organize information** on p3.
Spain	p2, 2nd sentence of third paragraph of **Operations of Intersessional Task Groups - *Prior to a CRC meeting***	I find the table useful, but suggest limiting the information put in the table since providing too much detail creates a high workload.	This sentence has been retained, together with the four mentions of this Excel analysis table in the first three paragraphs under **Step 1 - Organize information** on p3.
	p9-14, the newly drafted Annex II of the Guidance	A number of largely editorial changes	Most have been accepted, the main exceptions are noted below.

Source	Section	Comment and further information related to the amendment of Section 1.7 of the CRC Handbook – 3rd draft	Response
	p10, **Section 2.2.1, Part 1. Documentation required from a proposing Party** (g)	*A clear description of incidents related to the problems experienced by the proposing Party, including….*	Not accepted, the points that have been included are written exactly as they are in Part 1 of ANNEX IV of the Convention
	p11, Tabular format of Part 2 information requirements and Part 3 criteria	Change ";" at end of these into ".", but I have kept these ; as in parts 2 and 3 of the Convention	Not accepted, again the points are written exactly as they are in Parts 2 and 3 of ANNEX IV of the Convention. Note that this also applies to those in Section 2.2.3
	p13, last line of first paragraph under *(d) The significance of reported effects in relation to the quantity of the formulation used;*	Change "metre" to "meter"	Not accepted – the English spelling is preferred to the American spelling

Section 2.5

Source	Section	Comment and further information related to the amendment of Section 2.5 of the CRC Handbook – 3rd draft	Response
Canada	General	I have minor edits to some text/punctuation for consideration by the chairs, and three comments. The comments are for consideration by the Chairs and are more questions than suggestions, based on some review of the cited documents & examples. I'd be happy to provide further details if desirable.	See responses below
	p2 first sentence of paragraph 4, ie: "Under the Rotterdam Convention, it is generally agreed that a risk evaluation is neither hazard assessment nor risk assessment but something in between (UNEP/FAO/RC/CRC1 /13)."	I notice this text is consistent with CRC.1/13 as cited. I'd offer the following thoughts for consideration: 1. A "risk evaluation" is clearly more than a "hazard assessment", but could include a "risk assessment". We have seen a "risk assessment" meeting criteria in (b) even if it doesn't quite meet the definition of "risk evaluation" here. 2. Providing toxicity endpoints alone without any review/context is not a hazard assessment or evaluation. We could consider removing this sentence. We should at least be conscious that this isn't exactly aligned with past practice.	Noted but no action has been taken. The comments and the two sets below seek to question or re-open parts of Section 2.5 which have already been agreed at CRC8 or earlier CRC meetings, and therefore are outside the Task Group's mandate of adding further examples to the current CRC8 version of Section 2.5: Working paper on the application of criteria (b) of Annex II.
	p2 second and third sentence of paragraph 4.	Risk evaluation comprises information on hazard *and* exposure. This means that risk evaluation is an evaluation of intrinsic toxicological and ecotoxicological properties *and* actual or expected relevant exposure,…. (The proposal is to italicise and underline "and" twice as shown above)	Not accepted – see comments above.

Source	Section	Comment and further information related to the amendment of Section 2.5 of the CRC Handbook – 3rd draft	Response
	p4 Whole of *Example* under **1 (a) Actual or measured exposure**	On investigation, the information from Peru on poisonings is not found in the document cited here. The NFRA in ICRC.3/16 does not contain information on poisonings. ICRC.3/16/Add.1 is a cover sheet – it seems the information was contained in a letter from Peru provided as a hard copy at the meeting. Could the Secretariat make that letter available online, given it's cited in this guidance? Without seeing the information from Peru, it's hard to say if this was "empirical" or "measured" or both.	Noted – see comments above.
	p5, Example (iii) under **(b) Expected or anticipated exposure** Proposal is to delete: **"**Pesticides with defined hazard classifications~~, *e.g.*, WHO hazard classification 1a or 1b,~~ may….."	This is a section I've pointed to at past meetings. I'd note that the example here is based on a single endpoint of the pure substance. It is unlikely to be indicative of the hazard or potency of the formulation. I don't recall any instances so far where we have come across an NFRA from a regulatory action taken as a consequence of the WHO classification and a Party's national policy. Should we consider eliminating the example and retaining the concept? Given the above, the example by itself suggests a national policy based on a hazard endpoint, rather than an analysis or risk evaluation.	Not accepted – see comments above. However, it is agreed that a specific example for this remains to be identified.
	p6, 3rd line of (vi) a.	"In most cases, the effects are ~~conditioned by~~ consistent with factors such as….."	Accepted.
Spain	p6, amend the heading for the example (vi) which has been newly added to **1 (a) Actual or measured exposure,**	A risk evaluation that takes into account socioeconomic and cultural conditions in the evaluation of exposure – the example of the Brazilian notification of methamidophos (UNEP/FAO/RC/CRC.9/11, Annex to decision CRC-9/3) Spain also recommends to make this example (v) swapping with the current one which now becomes (vi)	Accepted. The proposed amendments both explain clearly why this example has been included and why it was accepted at CRC9. Therefore it is agreed it should precede the former (v) for which no consensus could be reached at CRC5 and CRC6 that the prevailing conditions in the notifying country had been adequately taken into consideration.
	p6 2nd line of point e. of newly added example (vi).	the prevailing conditions in Brazil (workers and consumers), and the toxicological endpoints	Accepted