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INTERIM CHEMICAL REVIEW COMMITTEE

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Item 5 (b) (iii) of the provisional agenda*

INCLUSION OF CHEMICALS IN THE INTERIM PRIOR INFORMED CONSENT PROCEDURE
CONSIDERATION OF DRAFT DECISION GUIDANCE DOCUMENTS:

GRANOX TBC and SPINOX T

Note by the Secretariat

1. In line with the process for the development of decision guidance documents set out in decision INC-7/6, the internal proposal for Spinox T /Granox TBC was circulated to the Interim Chemical Review Committee and its observers for information and comment. Annexed to the present note is a tabular summary of the comments received on the internal proposal and how they were addressed in preparing the draft decision guidance on Spinox T /Granox TBC.
2. The draft decision guidance document for SPINOX T /GRANOX TBC is available to the Committee in document UNEP/FAO/PIC/ICRC.4/13.

* UNEP/FAO/PIC/ICRC.4/1

Tabular summary of Comments on the Internal Proposal for Granox TBC and Spinox T

Received from	Abstract of Comments	Suggestions for Follow up
CropLife	<p><u>Section 2. Reason for Inclusion in the PIC Procedure. page 5.</u> We note the last paragraph clearly identifies only the two specific formulations notified by the government of Senegal as being subject to the PIC procedure. This is consistent with the Convention and we commend the drafting group for such clarity.</p>	<p>Noted. Amended to reflect guidance from INC.9</p>
Australia	<p><u>Section 4. Relationship of observed adverse effects to recognized acute toxicological effects of the active ingredient(s): page 7.</u> Add to the 3ed parag.: No incidents were reported in surrounding peanut-growing regions where the formulations were not available.</p>	<p>Agree</p>
Australia	<p><u>Section 4. (iii). Thiram. page 8</u> change “early symptoms of poisoning may include....” to “Symptoms of poisoning are dose dependent but may include”.</p>	<p>Noted: Text is direct quote from Section 4.4.1 of the WHO/FAO Data Sheet on Thiram included in Annex II in its original form.</p>
CropLife	<p><u>Section 4. Page 8. (iii). Carbofuran. para 1</u> The first sentence should read "Carbofuran is a carbamate pesticide that in technical form is considered highly hazardous according to WHO classification." This wording is consistent with the information in Section 6,page 9.</p>	<p>Noted: Text is direct quote from section 4.4.1 of the WHO/FAO Data Sheet on Carbofuran included in Annex II in its original form.</p>
CropLife	<p><u>Section 4. (iii). Carbofuran. para 2</u> The wording of sentence 5 seems to have two verbs as written. It is unclear whether it should read as a supposition "were maybe related " or " may be related"(were is a typo) or an assertion "were related" (may be is a typo).</p>	<p>Agree: to delete “were”and keep “may be related” to reflect supporting rationale for the recommendation to include Spinox/Granox see Annex IV to report of ICRC 3.</p>
CropLife	<p><u>Section 4. (iii). Carbofuran. para 2</u> In any case, whether a supposition or an assertion, the comment that lung oedema is normally a symptom of severe carbamate poisoning is unsupported by any of the scientific data specific to carbofuran. The statement should be deleted unless there is credible scientific evidence that the comment is specific to carbofuran.</p>	<p>Noted: text reflects supporting rationale for the recommendation to include Spinox/Granox see Annex IV to report of ICRC 3.</p>
CropLife	<p><u>Section 4. (iii). Carbofuran</u> The intoxication occurred days to months following a short-term use of these products is not consistent with carbofuran intoxication.</p>	<p>See above.</p>

CropLife	<p><u>Section 4. (iii). Carbofuran</u> WHO/FAO Data Sheet No. 56, Section 2.2.6. also recognizes in a reported mishap that "The onset of symptoms was rapid, but mild, recovery was also rapid." Section 5.1 of that same document states, "Symptoms of mild poisoning are short lasting and in case of occupational over-exposure occur without delay and at doses well below the fatal dose.</p>	<p>Noted: The case referenced in the WHO/FAO Data Sheet is not relevant to a description of the incidents in Senegal which are the basis for this DGD. As the data sheet is included in Annex II this information is available to DNAs.</p>
CropLife	<p><u>Section 4. (iii). Carbofuran</u> In the interest of scientific accuracy and information exchange, we believe it is appropriate to include a comment that the observed onset of symptoms was not consistent with carbamate intoxication so that developing countries that are being asked to make an import decision will be aware of the possibility of other causative or contributing factors.</p>	<p>Noted: The relationship between exposure and the observed onset of symptoms of carbamate intoxication is described in parag. 2 of section 4 iii) and in the rationale included in Annex IV to the report of ICRC3</p>
PANUK	<p><u>Section 4.and Annex I point 19</u> Suggested to insert the relevant information of the rational in order to avoid reopening of any discussion regarding the gap between the first exposure and the onset of symptoms</p>	<p>Noted: There are two options to reflect this comment, a) to insert the rational as an additional annex to the DGD; b) to add a short explanation in the Annex I point 19 of the DGD.</p>
Australia	<p><u>Section 4. (iii). Benomyl</u> change "Dullness" to "confusion and lethargy</p>	<p>Noted: Text is direct quote from the Acute/Hazards Symptoms listed in the WHO International Health and Safety Card on Benomyl</p>
CropLife	<p><u>Section 4. (iii). Extent of incident</u> We recommend the statement, "The 5 deaths occurred 2 days to 4 months after exposure." be added at the end of this subsection because it adds to an understanding of the extent of the incident.</p>	<p>Noted: Proposed change does not reflect the conclusions of the ICRC (Annex IV report of ICRC3). Text reformatted to better reflect the information contained in Annex I</p>
CropLife	<p><u>Section 5. Any regulatory, administrative or other measure taken, or intended to be taken, by the proposing Party in response to such incidents. page 9.</u> We propose the first sentence read, "The Government of Senegal decided to continue the use of this formulation and plans to take the following measures: ". That Senegal will continue to use these formulations despite the reported incidents is an important fact for other countries to consider in formulating an import response to the PIC listing.</p>	<p>Noted: The proposed amendment does not reflect the information provided by the Government of Senegal with their original proposal and available to the ICRC in document UNEP/FAO/PIC/ICRC3/17. The administrative measures listed include no specific mention of continued use of Spinox or Granox but identify a range of actions aimed at providing better information and training regarding the use of pesticides in general.</p> <p><i>To be clarified with DNA in Senegal</i></p>

PANUK	<u>Section 6.</u> Add: “there is no information on possible synergistic effect of the mixtures available.”	Noted: It is a general applicable statement. It will be forwarded to ICRC4 for discussion.
CropLife	<u>Section 7. Existence of handling or applicator restrictions for the formulation in other countries. page 10.</u> As the title makes clear, this section should include only information about the formulation that is the subject of the notification and not related or other formulations. The working paper also states that the purpose of the section is "To provide an understanding of how the formulation in question (emphasis added) is used in other countries and the measures in place to reduce risk associated with use of the formulation." Therefore, we recommend the first paragraph be retained and the remaining paragraphs be deleted.	Agree: Delete paragraphs 2 and 3 and move the last paragraph on handling restrictions on other formulations of the active ingredients to Section 10.
CropLife	<u>Section 9. Information on incidents related to other formulations of the pesticide. page 10.</u> The second paragraph should make clear that the EPA report refers to the liquid formulation, which is predominantly used in the USA, and not all formulations of carbofuran.	Noted: unchanged as EPA confirmed that at the time of data collection both granular and liquid formulations were still in use.
Switzerland	<u>Section 10. page 10.</u> <i>missing Switzerland:</i> “Information on other formulations of the active ingredient(s) in the country reporting the incident and in other countries -In the responses that were received by the Secretariat, 27 countriesSamoa, Switzerland , Tanzania”	Done
CropLife	<u>Section 12. Summary of toxicological properties. page 11.</u> When no data are available on the severely hazardous pesticide formulations in question, we support the inclusion of summaries on the relevant toxicological properties of the active ingredient(s). In the case of Granox/Spinox we do not believe toxicity to non-mammalian species is relevant.	Noted: section makes reference to the relevant sections of the FAO/WHO data sheets Sections 2.1 Toxicology mammals and 2.2 Toxicology man.
Australia	<u>Annex I. Page 12.</u> Proposal to summarise the information in Annex I where possible without losing useful detail.	Details listed below
Australia	<u>Annex I. Synopsis of incident reports for both Granox TBC and Spinox (Comments apply to both sections of Annex I)</u> <u>Point 7.</u> comment: give a range of dates as the original forms are not included in the DGD.	Done
Australia	<u>Point 8</u> comment: give a range of locations as the original forms are not included in the DGD.	Done
Australia	<u>Point 10</u> delete: “check one or more of the following”.	Editorial – done

Australia	Point 12 summarize use patterns, duration of exposure and level of potential exposure	Done
Australia PAN UK	Point 12 clarification whether the pesticide was used as supplied or as mixed pesticide	Editorial - text amended to indicate was single formulation containing three active ingredients.
Australia	Point 17. change icter to jaundice what is meant by modification of urine	list of symptoms are reported verbatim from incident reports – no evidence that icter means jaundice
Australia	Point 17. Include death in list of adverse effect for the appropriate individual	Original text suggests 13 rather than 10 incidents (Granox) and 14 rather than 12 incidents (Spinox) – propose to summarise list of symptoms to reflect the way in which the information is presented in section 4 ii) of the DGD e.g. three deaths (Granox) or two deaths (Spinox) with individuals showing three or more of the following symptoms.
Australia	Point 19 summarise and check the number of cases appears to be 14 instead of 12	Editorial - done
CropLife	Annex II. Page 18. We do not support the insertion of the relevant data sheets for individual active ingredients in their entirety. The sheets contain information that go well beyond that required to make an import decision on the severely hazardous formulations in question.	Noted: In line with the working paper developed by the ICRC and in the interest of scientific accuracy and information exchange the original text of the FAO/WHO pesticide data sheets have been included in Annex II for each of the active ingredients.
Germany	Annex II page 45 under a) point 2.3.1 Fish It is explained that no data were available on thiram. The sources mentioned below contain data on aquatic organisms: - Xenopus leavis: 96-h LC50 0.013 mg/l (Seuge et al.1983) - O. mykiss: 60-d LOEC 0.00032 mg/l (Van Leeuwen 1986) - D. magna: 21-d NOEC 0.001mg/l (Van Leeuwen 1986). b) The same applies to point 2.3.3 Other species. From the addendum of the EU-evaluation of active substances the following can be summed up: - Thiram is not toxic to bees up to 100 µg/ bee. - Thiram is not toxic to most beneficial arthropods when used as seed treatment tested with intended field rates but is toxic when used as foliar spray.	Noted: no change to text. Annex II is the WHO/FAO Data Sheet on Thiram, included in its original form. Information is not directly relevant to the reported human health incidents, will be forwarded to authors of pesticide data sheets.
Switzerland	Annex III page 51 last paragraph The format of the given formula should be modified for the printed form.	Editorial - done
Mexico	General observation supporting the process of the preparation of the DGD	Noted
Australia	Australia provided a number of editorial comments.	Done

Brasil	Birds mortality is not considered in the document. It is well known that some kind of birds eats seeds treated with pesticides formulations.	Noted, in the absence of supporting information and lack of relevance to the human poisoning incidents in Senegal on which the DGD is based information is not included.
South Africa	Agree with the internal proposal	Noted
Gambia	Agree with the internal proposal	Noted