



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

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**Conference of the Parties to the Rotterdam Convention
on the Prior Informed Consent Procedure for Certain
Hazardous Chemicals and Pesticides in International Trade
Ninth meeting**

Geneva, 29 April–10 May 2019

Item 5 (b) of the provisional agenda*

**Matters related to the implementation of the
Convention: listing of chemicals in Annex III
to the Convention**

**Comments and further information related to the draft decision
guidance document for phorate**

Note by the Secretariat

1. At its fourteenth meeting, the Chemical Review Committee finalized the text of the draft decision guidance document for phorate, as set out in the annex to document UNEP/FAO/RC/COP.9/8/Add.1, and agreed to forward it, together with the related tabular summary of comments received and how they were taken into account in the preparation of the draft decision guidance document, to the Conference of the Parties for its consideration.
2. The tabular summary of comments is set out in the annex to the present note. The present note, including its annex, has not been formally edited.

* UNEP/FAO/RC/COP.9/1.

Annex

Comments and further information related to the draft decision guidance document for phorate

Source	Section	Comment and further information related to the draft decision guidance document for phorate	Response
Brazil	p24, Section 4.1.1, 2 nd paragraph	<p>The Secretariat asked the notifier to comment on the following paragraph: <i>“Field studies indicate that leaching is very low in soils high in clay and organic matter content, and lower in sandy soils.”</i></p> <p>It is well known fact that in sandy soils leaching potential of such substances as phorate is higher than in soils with clay and organic matter content. The drafting group chairs asked the Secretariat to double check with you whether this could be an editorial/ translation error and, if so, suggested to replace “lower” by “low” if you agree.</p> <p>Brazil’s response: Please, change the word if the experts suggest it.</p>	“Lower” has been replaced by “low”.
CRC member Jeffery Goodman (Canada)	Throughout	Typos, formatting and minor editorial suggestions provided in marked-up version, for consideration.	Generally accepted.
	p7, Section 1, Trade names, line 2	Modify “Trade names listed by Canada” to “Trade names listed by Canada <u>at the time of regulatory action...</u> ”	Accepted
	p8, Section 2.1, paragraph 2, line 6	Change last sentence of paragraph to “It also put particular obligations on obligated companies that held stocks of products based on phorate <u>to provide adequate final disposal</u> ”.	Accepted
	p9, Section 2.1, Canada FRA section, footnote #4.	Having this information as a footnote buries the information too much. It makes it look like this is a ban when really it is a severe restriction. This section should make that as clear as possible.	Modified accordingly. The text in the footnote moved to the main.
	p9, footnote #4, line 1	Change the term “ <u>approval</u> ” to “ <u>use on potato</u> ”.	Agreed, but footnote deleted and location of text changed in response to comments immediately above & below.
	p10, Section 3.1, paragraph 2, after line 3	Additional text provide regarding registration status similar to text in footnote 4 above: <u>The use on potatoes was subsequently extended to August 2015. A new phorate product, paired with application equipment to reduce environmental exposure, was registered in 2015.</u>	Modified accordingly.
	p11, Section 3.1, paragraph 1, after line 3	Additional references to re-evaluation notes added: <u>- REV2008-05: Update on the Use of Phorate on Potatoes.</u> <u>- REV2012-01: Update on the Use of Phorate on Potatoes.</u>	The suggested additional references have been added in full in section 2.1 where the references are cited for the first time. Reference to section 2.1 added here.

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	p11, Section 3.3, Alternatives	Based on the working paper, add standard text such as “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) and organic strategies as a means of reducing or eliminating the use of hazardous pesticides.”	Checking reveals the proposed text is an example of standard text for this section related to <i>pesticides</i> . Hence the proposed text has been added (to a new subsection “General”) but before that a more generic text found in the current template was inserted.
	p13, Section 4.3, Packaging and labelling	Based on the working paper, add standard text such as “Further specific guidance on appropriate symbols and label statements for phorate products may be available in the FAO <i>Guidelines on Good Labelling Practice for Pesticides</i> ”.	Reference to the latest version of the FAO Guideline added.
	p14, Section 4.4, Safety Data Sheet of Central Pollution Control Board of India (2017)	Consider removing as we question whether it is internationally recognized.	Based on the comment the IPCS safety datasheet text related to first aid now included on top of the text. The Indian information and the reference is kept as it is of similar level of recognition as Pubchem, also included in the text.
	p15, Section 4.4, Safety Data of Sigma-Aldrich (2015), line 1 General advice	Consider adding a hyperlink to the reference to the safety data sheet .	Added
	p16, Annexes	Changes to titles as per working paper guidance. I.e: Annex 1: Further information on the substance-chemical Annex 2: Details on final Final regulatory actions reported	Again the “working paper” refers to the “Handbook of working procedures and policy guidance for the Chemical Review Committee”. The text used in the current draft is as per those included in p9 of the current (April 2012) DGD template. However, it is noted that on p17 and 18 the heading for Annex 1 refers to the actual chemical, ie Further information on phorate . The proposed change also reflects the heading for Annex 2 on p28 of the current draft. Therefore the proposed change has been agreed.
	p26, Section 4.2.2, last line	Remove “ Algae - Acute 72 hour EC50, growth 0.13 mg/L Unknown species “, as not part of Canadian NFRA or supporting information.	Not accepted, as this result (and those above it) is actually from the Pesticide Properties DataBase as noted 8 lines above.
	p29, Section 5.6, paragraph 2, last line	Add the following footnote “ The use on potato was subsequently extended to August 2015. Furthermore, it should be noted that a new phorate product, paired with application equipment to reduce environmental exposure, was registered in 2015 ”.	Added.
	p31, Annex 2, Canada, section 4.2	Remove “human health” from the criteria used.	Accepted.
	p34, Annex 4, Supporting documentation	Update to the following references – Health Canada (2008): Re-evaluation Note REV2008-	References have been added

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	provided by Canada, 1 st reference (PMRA)	<p>05: Update of the Use of Phorate on Potatoes.</p> <ul style="list-style-type: none"> - Pest Management Regulatory Agency, 26 March 2008 - Health Canada (2012): Re-evaluation Note REV2012-01: Update of the Use of Phorate on Potatoes. Pest Management Regulatory Agency, 28 May 2012. <p>To access these documents, they must be requested at the following link: https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates.html#revnote.</p>	
	Page 34, Annex 4, Other documents, 1 st reference (Goodman J))	<p>Change reference to: PMRA: Evaluation Report to Register a new granular insecticide end-use product. http://pr-rp.sc.gc.ca/1_1/view_label?p_ukid=96999729</p> <p>This reference provides additional information about the current Canadian status of the authorisation of phorate as pesticide</p>	Reference has been changed.
CRC member Juergen Helbig (Spain)	General	Typos, formatting and minor editorial suggestions	Generally accepted.
	p7, Section 1, Trade Names	Modify to: <i>This is an indicative list of trade names. It is not intended to be exhaustive.</i>	Accepted, while not included in the current (April 2012) DGD template, it is consistent with the wording for Basic manufacturers below it in this same section.
	p9, Section 2.1, Canada , Relevant regulatory documents are:	This para might not be necessary if the documents are cited in the list of references at the end of the DGD.	Not accepted, text has been amended based on the notifier Canada's wishes.
	p10, Section 2.2, Brazil, Human health	Editorial changes proposed to first and third para & also top of p11, Section 3.1.	Accepted as they improve the English but don't change the meaning expressed in the Brazilian notification
	p10, Section 3.1 Canada , Relevant regulatory documents are:	See first comment: This para might not be necessary if the relevant documents are cited in the list of references at the end of the DGD.	Reference list added to section 2.1, see comments on p9, Section 2.1 above.
	p11, Section 3.3 General	<u>None?</u>	Text has been added based on comments from Canada and PAN
	p13 Section 4.2, reference used for US State Drinking Water Guidelines	Only short citation here, move complete source to list of references at the end of the DGD?	Text deleted at this point as it was not possible to verify the values.
	p15, Section 4.5, delete line after: Disposal Methods (Pubchem 2017b)	Disposal methods for this chemical	Proposed change has been made.

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	p15, Section 4.5, first three paragraphs, 2 sets of references given at the end of paragraphs	Only short citation here, move complete source to list of references at the end of the DGD?	Not accepted. The text in the 3 first paras is in line with DGD on carbofuran. It is a common practice to directly refers to guidelines with their names.
	pp15-16, Section 4.5, following Disposal Methods, 3 sets of references given at the end of paragraphs	Only short citation here, move complete source to list of references at the end of the DGD?	Not accepted. It is a common practice to refer in the text to the guidelines with their names.
	p19, Section 2.1.3, inchem web address at end of 2nd paragraph	Only short citation here, long source only in list of references?	Amended, now reads IPCS INCHEM (undated), with the web link now in the reference list.
	p20, Section 2.1.3, inchem web address at end of 1st paragraph	Only short citation here, long source only in list of references?	Amended, now reads IPCS INCHEM (undated), with the web link now in the reference list
	p20, Section 2.2.4, Extoxnet web address at end section	Only short citation here, long source only in list of references?	Amended, now reads Extoxnet (2017), with the web link now in the reference list
	p26, Section 4.2.2, PPD database web address cited	Only short citation here, long source only in list of references?	Amended, now reads PPDB (2018), with the web link now in the reference list
	p26, Section 4.2.4, PPD database web address cited	Only short citation here, long source only in list of references?	Amended, now reads PPDB (2018), with the web link now in the reference list
CRC member Nuansri Tayaputch (Thailand)	Section 4.1.1, 2 nd paragraph	"Field studies indicate that leaching is very low in soil high in clay and organic matter, and lower in sandy soils". I doubt whether this statement is correct or error, because leaching of many pesticides are higher in sandy soil.	"Lower" has been changed to "low", see response to Brazil's clarification above.
USA	General	Typos, formatting and minor editorial suggestions	Generally accepted
	p9, Section 2.2, Human health , first paragraph	Consider adding a transition statement here to say " the following is a summary of information presented in the Brazilian notification " given some of these statements are not widely agreed upon. If not, need to be clear in the following paragraphs that these are things Brazil concluded based on the data they reviewed.	Not accepted. It is not clear why there should be doubt that the paragraph summarises information Brazil concluded based on the data they reviewed, since it starts with "Brazil's risk evaluation of phorate..." and the paragraphs following summarise the "extensive review of relevant data undertaken." It is also not clear why "some of these statements are not widely agreed upon." It should be noted that CRC 13 concluded by consensus that the notifications made by Canada and Brazil meet all the criteria of Annex II. CRC 13 recommended that the Conference of the Parties should list phorate in Annex III to the Convention as a pesticide and adopted a workplan for preparing a draft decision guidance document for phorate. (see Decision CRC-13/4: Phorate, page 23 of the CRC13 meeting report UNEP/FAO/RC/CRC.13/19)

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			<p>It should be noted that the text for this sub-section has been taken directly from information considered by CRC13, ie the document Phorate: Supporting documentation provided by Brazil (UNEP-FAO-RC-CRC.13-INF-29.En.pdf), Section 2.4.2.1 of Brazil's FORM FOR NOTIFICATION, p8; Section 2.1. Key findings of the national risk evaluation, p19; and in particular Section 2.4. A summary of actual or potential human exposure and/or environmental fate presented in the Technical Note of ANVISA, p21.</p> <p>Importantly much of the information is also included in the Rationale for the conclusion by the CRC, see the Annex to decision CRC-13/4, pp47-51 of the CRC13 meeting report UNEP/FAO/RC/CRC.13/19.</p>
	p10, Section 2.2, Human health , first paragraph	Please change “ shows this pesticide as more toxic to humans” to “ ANVISA considered as evidence that this pesticide is more toxic to humans... ”	Text modified based on the comment with slightly different wording.
	p10, Section 2.2, Human health , 2 nd paragraph	I think it would help to add in the literature references that were cited in the notification here. It's a transparent way to show how Brazil made this conclusion	<p>No changes. References are not included elsewhere in this sub-section and from p8 and p19 of the document Phorate: Supporting documentation provided by Brazil (UNEP-FAO-RC-CRC.13-INF-29.En.pdf) four references would need to be added since none of them are currently in the document.</p> <p>Please note the Comment [PJ5] p33 of the draft circulated to CRC members and observers which indicates “Background info for the CRC. Only these references contained in the supporting documentation of the Brazilian notification are listed here specifically, as they were cited in this document specifically. Based on SECR advice, there is no need to include full list of the references included in the notification and supporting documentation as default.”</p>
	p10, Section 2.2, Human health , 4 th paragraph	<p>The notification wording for the basis of their action is the following:</p> <p>ANVISA concluded this active ingredient has the potential to cause hormonal disturbances in humans and is more toxic to humans than demonstrated in tests with laboratory animals, which are prohibitive criteria for registration of pesticides in Brazil.</p> <p>Suggest changing this paragraph to this wording or at the very least adding this wording into the paragraph so it's transparent how they came to their decision.</p>	Agreed and added at the end of the paragraph noting that they are the exact words found on p9 of the document Phorate: Supporting documentation provided by Brazil (UNEP-FAO-RC-CRC.13-INF-29.En.pdf), Section 2.4.2.1 of Brazil's FORM FOR NOTIFICATION .

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	p12 Section 4.1 US EPA I – Highly toxic classification	Which route/study is this referring to of the EPA acute toxicity studies?	Not possible to verify. Text deleted. US observers kindly asked to support in finding direct formal reference to hazard classification of acute oral, derman and inhalation toxicity.
	p12 Section 4.1	Add after JMPR Report 2004, JMPR Report 2012 (included in the Brazilian notification)	Not agreed. While the JMPR reports are referenced in the document Phorate: Supporting documentation provided by Brazil (UNEP-FAO-RC-CRC.13-INF-29.En.pdf), acute reference dose (ARfD) and acceptable daily intake (ADI) are only included on p185 of this document. Together with the preceding page this text seems to be a summary of the Brazilian conclusions of the toxicological evaluation, even though the ADI and ARfD values are the same as those of the JMPR.
	p13 Section 4.2, reference used for US State Drinking Water Guidelines	I couldn't verify these values in the FSTRAC documents I searched.	Thanks for the comment. Text now deleted.
	p13, Section 4.4 <i>NOTE:</i> at beginning of section	The citations on pubchem are not for WHO and the following information (including the safety data sheet information) does not appear to be in the notifications.	Agreed and modified accordingly. While the <i>NOTE:</i> is contained in on p9 of the current (April 2012) DGD template, the only reference in the draft Phorate DGD to the WHO is in the reference to the IPCS/WHO safety data sheet . First aid instructions are often not included in the notification and need to be sourced separately, as was the case here.
	p17, last paragraph	Information from pubchem also appears to be considered.	The text has been amended to reflect Pubchem and other sources which were needed to be consulted in this case due to the limited information in a number of areas in the notifications
	p20, Section 2.2.1	Recommend delete: Rat, LD₅₀ dermal for male and female 6.2 mg/kg bw and 2.5 mg/kg bw, respectively , as this appears to be a duplication of some of the information presented below from the Canadian notification.	Agreed, these values seem to have been included in error as they are not located in the Brazilian submission.
	p20, Sections 2.2.2, 2.2.3 and 2.2.4.	Add? Taken from JMPR information cited in Brazilian notification.	That this comes from the Brazilian notification has been added.
	p20, Section 2.2.2, 3rd sentence	Add at end: (Canadian notification)	Added accordingly.
	p20, Section 2.2.2, final sentence.	Add at end: based on signs consistent with acetylcholinesterase inhibition (Taken from JMPR information cited in Brazilian notification.)	The text modified based on the comment as a direct copy paste from the supporting documentation of the Brazilian notification
	p20, Section 2.2.3	Add Taken from JMPR information cited in Brazilian notification.	(Brazilian notification) has been added
	p20, Section 2.2.4	Not classifiable as a human carcinogen. (notifications). Which notification is this from?	Thank you for the comment. The text must have been included mistakenly.

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	p21, Section 2.2.5 and 2.2.6.	Change (Brazilian notification) to: <u>Taken from JMPR information cited in Brazilian notification.</u>	Not agreed, Brazilian notification is used throughout the draft DGD.
	p22, Section 3.4 Brazil.	The notification wording for the basis of their action is the following: ANVISA concluded this active ingredient has the potential to cause hormonal disturbances in humans and is more toxic to humans than demonstrated in tests with laboratory animals, which are prohibitive criteria for registration of pesticides in Brazil. Please change this paragraph to this wording so it's transparent how they came to their decision.	As for the end of the 4 th paragraph of Section 2.2, Human health , p10, these words have been added to the end of this subsection.
	p23, Section 3.7 Summary-overall risk evaluation	The notification wording for the basis of their action is the following: ANVISA concluded this active ingredient has the potential to cause hormonal disturbances in humans and is more toxic to humans than demonstrated in tests with laboratory animals, which are prohibitive criteria for registration of pesticides in Brazil. Please change this paragraph to this wording or at the very least adding this wording into the paragraph so it's transparent how they came to their decision	Not agreed, as these words have already been added to Section 3.4 (see response immediately above) as well as at the end of the 4 th paragraph of Section 2.2, Human health , p10. There is no need to repeat them in this short summary paragraph.
	p28, Annex 2 Brazil , sub-section 4	The notification wording for the basis of their action is the following: ANVISA concluded this active ingredient has the potential to cause hormonal disturbances in humans and is more toxic to humans than demonstrated in tests with laboratory animals, which are prohibitive criteria for registration of pesticides in Brazil. Please capture the basis as presented.	Not agreed, as these words have already been added to Section 3.4 (see response immediately above) as well as at the end of the 4 th paragraph of Section 2.2, Human health , p10. Again there is no need to repeat them in this short paragraph.
	pp28-29, Annex 2 Brazil , sub-section 4.1	The notification wording for the basis of their action is the following: ANVISA concluded this active ingredient has the potential to cause hormonal disturbances in humans and is more toxic to humans than demonstrated in tests with laboratory animals, which are prohibitive criteria for registration of pesticides in Brazil. Please change this paragraph to this wording so it's transparent how they came to their decision.	Not agreed, as these words have already been added to Section 3.4 (see response immediately above) as well as at the end of the 4 th paragraph of Section 2.2, Human health , p10. Again there is no need to repeat them in this paragraph.
Croplife International (on behalf of registrant AMVAC)	p9, Section 2.2, Risk Evaluation, Brazil , Human Health , final paragraph	The conclusions drawn here in relation to respiratory tract systemic toxicity are not supported by the data set used in the evaluation. This statement should be removed from the DGD.	Not accepted. This sentence has been taken directly from information considered by CRC13, ie the document Phorate: Supporting documentation provided by Brazil (UNEP-FAO-RC-CRC.13-INF-29.En.pdf) Section 2.4. A summary of actual or potential

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Chemical Corporation)			<p>human exposure and/or environmental fate presented in the Technical Note of ANVISA, p21.</p> <p>Note that this sentence has also been included in paragraph 12 of the Rationale for the conclusion by the CRC, see the Annex to decision CRC-13/4, pp47-51 of the CRC13 meeting report UNEP/FAO/RC/CRC.13/19.</p>
	p10, Section 2.2 Risk Evaluation, Brazil, Human Health paragraph 2	The conclusions drawn here in relation to endocrine regulation processes are not supported by the data set used in the evaluation. This statement should be removed from the DGD.	<p>Not accepted. This sentence has been taken directly from information considered by CRC13, ie the document Phorate: Supporting documentation provided by Brazil (UNEP-FAO-RC-CRC.13-INF-29.En.pdf), Section 2.4.2.1 of Brazil's FORM FOR NOTIFICATION, p8, where references are also given for this conclusion. The same sentence may also be found on p19 in Section 2.1. Key findings of the national risk evaluation</p> <p>Again note that this sentence has also been included in paragraph 14 of the Rationale for the conclusion by the CRC, see the Annex to decision CRC-13/4, pp47-51 of the CRC13 meeting report UNEP/FAO/RC/CRC.13/19.</p>
	p19, Annex 1, 2.1.2, para 6, line 1.	“At doses similar to occupational human exposure” is incorrect and should be replaced with “At doses well in excess of potential human exposure”.	<p>Not accepted. Again this sentence has been taken directly from information considered by CRC13, ie the document Phorate: Supporting documentation provided by Brazil (UNEP-FAO-RC-CRC.13-INF-29.En.pdf) Section 2.4. A summary of actual or potential human exposure and/or environmental fate presented in the Technical Note of ANVISA, p21.</p>
	p21, Annex 1, 2.2.7, Brazilian notification, para 3	The conclusions drawn here in relation to endocrine regulation processes are not supported by the data set used in the evaluation. This statement should be removed from the DGD.	Not accepted – see comments above.
	p22, Annex 1, 3.4, Brazil	The statements made in para 1 and para 2 are not related to phorate and are therefore misleading. Phorate can be /and is, used safely throughout the world. The product label provides adequate warnings and application instructions in line with global labelling practices. In addition, and more importantly, AMVAC offers the product in a closed handling system (called the Lock’N Load system) that reduces the operator exposure risk to acceptable levels.	<p>Not accepted. The first paragraph summarises the CRC13 considerations as applied to the conditions in Brazil. The second paragraph is a slightly edited version of one considered by CRC13, ie from the document Phorate: Supporting documentation provided by Brazil (UNEP-FAO-RC-CRC.13-INF-29.En.pdf) Section 2.4. A summary of actual or potential human exposure and/or environmental fate presented in the Technical Note of ANVISA, p21.</p> <p>Note that this similar wording to the second paragraph has also been included in paragraphs 16 and 27 of the Rationale for the conclusion by the CRC, see the Annex to decision CRC-</p>

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			13/4 , pp47-51 of the CRC13 meeting report UNEP/FAO/RC/CRC.13/19.
Pesticide Action Network (PAN) Asia Pacific	3.3 Alternatives, General. page 11, last line	Please consider adding the following: SAICM's Fourth International Conference on Chemicals Management recommended that in replacing highly hazardous pesticides the focus should be on agroecologically-based practices. Information on such practices can be found at the following websites: FAO Agroecology hub: http://www.fao.org/agroecology/en/ IPAM (International Peoples Agroecology Multiversity): http://ipamglobal.org/ OISAT (Online Information Service for Non-Chemical Pest Management in the Tropics): http://www.oisat.org/ Replacing Chemicals with Biology: Phasing out Highly Hazardous Pesticides with Agroecology: http://panap.net/2015/11/replacing-chemicals-biology-phasing-highly-hazardous-pesticides-agroecology/	Accepted and included as proposed