UNITED NATIONS

RC

UNEP/FAO/RC/CRC.7/INF/6

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

Distr.: General
15 December 2010

Original: English

Chemical Review Committee
Seventh meeting
Rome, 28 March–1 April 2011
Item 4 (b) of the provisional agenda*

Technical work: consideration of the draft decision guidance document for azinphos-methyl

Comments and further information related to the draft decision guidance document for azinphos-methyl

Note by the Secretariat

1. In accordance with the process for the development of decision guidance documents set out in decision RC-2/2 of the Conference of the Parties to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, an internal proposal for azinphos-methyl was circulated to the Chemical Review Committee and its observers for their information and comments. The annex to the present note contains a tabular summary of the comments received thereon and how they were taken into account in preparing the draft decision guidance document on azinphos-methyl. It has not been formally edited.

2. The draft decision guidance document for azinphos-methyl has been made available as document UNEP/FAO/RC/CRC.7/12.

* UNEP/FAO/RC/CRC.7/1.

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Annex

Azinphos-methyl: comments by Chemical Review Committee members and responses thereto

Country	Section	Comment/Suggestion	Response
Argentina		The control of pear and apple maggot or codling moth (*Cydia pomonella* main pest of pome fruit), is a complex issue that involves socio-productive, commercial and environmental aspects.	Noted. No change.
		The management of the Experimental Site INTA Alto Valle has made progress in the research and the development of alternatives to the use of Azinphos-methyl through an integrated pest program for pome fruits; some of these alternatives have been adopted by the pears and apples productive sector, and are of common use in this region.	Noted. No change.
		The use of Azinphos-methyl has been significantly reduced, restricting its application only at the beginning of the season; the result was a successful plant protection program implementation, being the pest control as expected.	Noted. No change.
		In this context, INTA identified heterogeneity of fruit producers linked basically to socio-productive strategies, the ability of taking risks and the different technologies adopted. In some cases, productive structural problems can hinder the implementation of the proposed techniques in relation to a new phytosanitary plan.	Noted. No change.
		As for the proposed alternatives to Azinphos-methyl, we have to highlight that these have a higher cost and, in some cases, are not registered in all countries importing pears and apples.	Noted. No change.
Austria	Section 2.2 Norway Environment	For earthworms, the estimated chronic Toxicity Exposure Ratio (TER) is ~~well~~ below the trigger value, …	Agree. Changed.
		~~A~~ TER value<u>s</u> for invertebrates ~~is well~~ <u>are</u> below the trigger values ….	Agree. Changed.
	Section 3.3	Countries should consider promoting, as appropriate, integrated pest management (IPM) <u>and organic</u> strategies as a means of reducing or eliminating the use of hazardous pesticides.	Agree. Changed.
		Advice may be available through National IPM focal points, the FAO, IFOAM (<u>International Federation of Organic Agriculture Movements</u>) …	Agree. Changed.

Country	Section	Comment/Suggestion	Response
	Annex I Section 4.2.3	Azinphos-methyl is harmful to parasitoids, predatory mites, ladybirds, ~~chrysopala~~ lacewings, ~~syrphus~~ hoverflies and ~~group~~ beetles (EU Pesticide Monograph, 1996; NAIS, 2002).	Agree. Changed.
	Annex I Section 5.2	This conclusion was also supported by actual measured concentrations in Norway, …	Agree. Changed.
	Annex I Section 5.3	**Norway** A risk assessment based on ~~L~~ laboratory tests ~~using~~ and application rates of 1.5 kg a.i./ha on tree fruit gave Hazard Quotients of 15000 by both the contact and oral route.	Agree. Changed
	Annex I Section 5.6	**Norway** Azinphos-methyl poses a high risk to terrestrial and aquatic organisms. TER values are ~~well~~ below the ~~T~~trigger value for birds, mammals, fish, *Daphnia* and invertebrates.	Agree. Changed.
	Annex II Norway Section 3	For earthworms, the estimated chronic Toxicity Exposure Ratio (TER) is ~~well~~ below the trigger value, indicating a high risk to earthworms (for all uses except fruit trees).	Agree. Changed.
		Azinphos-methyl is extremely toxic to several aquatic organisms. TER values for invertebrates ~~exceed~~ are below the trigger values (even with buffer zones of 30 metres) indicating high risk to the aquatic environment. underlined text : Added words strikethrough text: Deleted words	Agree. Changed.
Brazil		Brazil informs about the absence of registers of production, use or trade of azinphos-methyl.	Noted. No change.
Canada	Section 1 use	Registered uses on outdoor ornamental crops including nursery plants, forest trees and shade trees.	No change. Wording is correct.
	Section 2.2 Norway	In the last paragraph the sentence "When comparing this value to NOEC values from chronic fish test (0.18-0.39 µg/L)" should be replaced by "When comparing this value to NOEC values from chronic fish test (rainbow trout 0.18-0.39 µg/L)".	Agree. Changed.
	Annex I Section 3.4	Delete Occupational risk assessments associated with application, mixing and loading for current label uses exceeded the level of concern for most exposure scenarios, even after consideration of maximum feasible engineering controls and personal protective equipment and clothing (PMRA, 2003)	Agree. Deleted.

Country	Section	Comment/Suggestion	Response
	Annex I Section 4.1.2	change (PACR, 2003) to (PMRA, 2003)	Agree. Changed.
	Annex I Section 4.2.1	change (PACR, 2003) to (PMRA, 2003)	Agree. Changed.
	Annex II Canada Section 6	Please insert in Annex II under Canada as section 6 - Waste management: Production limits have been put in place to minimize potential disposal issues resulting from phase out of Azinphos-methyl.	Agree. Inserted.
Chile	Abbreviations	Add NOEC and its meaning, "No Observe Effect Concentration".	Agree. Inserted.
	Section 4.1: IARC: Not evaluated	In Page 15, Annex I item 2.2.4, Long term toxicity and carcinogenicity, indicate about Carcinogenicity "Azinphos-methyl does not appear to have any carcinogenic potential (JMPR, 2007)". I suggest adding in item 4.1, that this parameter was measured by JMPR and azinphos-methyl does not appear to have any carcinogenic potential.	No change. Only positive classifications are required under this section.
	Annex I Section 2.2.7	Second paragraph says "However, azinphos has a Hazard Classification…" I suggest indicate "However, azinphos-methyl has a Hazard Classification…"	Agree. Changed.
	Annex I Section 3.4, Occupational exposure, Canada	In first paragraph says "Occupational risk assessments associated with application, mixing and loading for current label uses exceeded the level of concern for most exposure scenarios, even after consideration of maximum feasible engineering controls and personal protective equipment and clothing (PMRA, 2003)". This is repeated in the second paragraph. I suggest eliminating one of them.	Agree. Deleted.
	Annex I Section 3.7, Summary overall risk evaluation	Second paragraph, says "…current label uses exceed the level…". I suggest reviewing this phrase, may be is better to indicate "…current label uses exceeded the level…".	Agree. Changed.

Country	Section	Comment/Suggestion	Response
CropLife		CropLife informs that they have no comments	Noted. No change.
Ecuador	Annex I Section 2.2.2	Instead of: A no observed adverse effect level (NOAEL) of 20 mg/kg bw/day was identified as brain cholinesterase activity was not reduced (JMPR, 1991). Consider: A no observed adverse effect level (NOAEL) of 20 mg/kg bw/day was identified <u>that</u> brain cholinesterase activity was not reduced (JMPR, 1991).	Changed to “was identified because”.
	Annex I Section 5.4,	Instead of: *Taking the toxicity (NOEC from a reproduction test) and comparing it with the exposure (calculated soil PEC), there is a high risk to earthworms* Consider: Observing the toxicity value of NOEC (from a reproduction test) and comparing it with the exposure value, (the calculated soil PEC value), it reveals a high risk to earthworms.	Agree. Changed.
Germany	Page. 5 (list of abbreviations):	the entry "Kow" should be listed under "K".	Agree. Changed.
	Section 1, (other numbers):	Please consider whether "EEC", "STCC" and "RTECS" should be spelled out, as they only occur once in the DGD and are not explained in the list of abbreviations.	Agree. Changed.
	Section 2.2 (risk evaluation from Norway) sentence 1:	Add "a" to read "poses a high risk"; sentence 5: "trigger" should be lower case.	Agree. Changed.
	Section 4.1 (hazard classification from EU):	The risk phrases should be mentioned right after the classification symbol which triggers them. Otherwise, if "T+" and "T" are listed next to each other without further explanation, one may wonder if both symbols are necessary or even mutually exclusive.	Agree. Changed.
	Section 4.1.1, 3rd sentence	The correct unit for vapour pressure in this case should be mPa, not Pa (see also sect. 1.8.1 of the Canadian notification: "vapour pressure is 5 x 10-4 mPa (from The Pesticide Manual)").	Agree. Changed.

Country	Section	Comment/Suggestion	Response
Netherlands	Abbreviations	There are many abbreviations used in the draft DGD that are not explained by the Standard Core Set of Abbreviations. I propose to insert a specific list of abbreviations after the standard set and to see which should be inserted in the standard set and keep the rest as specifics. In my view the DGD should be readable as a separate document and should give no rise to unclearities. This means that the logic of the reasoning to take regulatory action for a substance or formulation should be clear. In the draft DGD this logic is to my opinion sometimes missing. If for instance a specific LOAEL is used by the notifying country for standard setting this value should also be available in the list of studies described in the DGD. Under item 3.1 (Food, Canada, 1st section) a LOAEL was set at 2 mg/kg bw/d based on an acute neurotoxicity study in rats. Under the short term studies (section 2.2.2) there is no study referring to an acute neurotoxicity study with rats. The same occurs for the EC15 for *Chironomusriparius* in section 5.2 and the NOEC for earthworms established in a reproduction study. I suggest including these essential studies as a short summary in the text of the relevant items. Under specific comments I have made this comment as well.	Agree. Abbreviations inserted.
	Page 5, under “m”	ml should read mL.	No change. ml is used in the template.
	Page 5, under “p”	Kow not under “p”.	Agree. Changed to K.
	Annex I, Section 2.2.2	The LOAEL mentioned in section 3.1 of 2 mg/kg bw/d is missing.	Agree. Inserted, but study in JMPR is confusing.
	Section 2.2.2, 3rd study	This is not a short term study, but not a long term study either.	No change. Dog studies of 1 year are usually considered to be short-term.
	Section 2.2.2, 4th study	No study duration is mentioned, the use by JMPR for determining an ARfD suggests that it may be a short term study.	No change. The study cites a single dose.
	Annex I Section 3.1, 1st paragraph	The study summary establishing a LOAEL of 2 mg/kg bw/d is missing in section 2.2.2.	Agree. Inserted.

Country	Section	Comment/Suggestion	Response
	Annex I Section 3.4	The last sentence of the 1st paragraph and the first sentence of the 2nd paragraph are exactly the same.	Agree. Paragraph deleted.
	Annex I, Section 3.5	It seems to me that the first 2 paragraphs refer to the same study.	No change. There is no definite way of checking this.
	Annex I, Section 4.1.1, line 4	The value for vapor pressure (1.8×10^{-4} Pa) is different from the value in 1.6 of Page 13 (1.8×10^{-4}mPa).	Agree. Changed to mPa.
	Annex I, Section 4.1.1, line 5	The unit Pa m^3/mol for Henry's Law constant is preferred (SI-units).	Agree. Changed.
	Annex I, Section 4.1.4, 2nd para	The unit of Kd is missing.	Agree. Inserted.
	Annex I, Section 4.2	The study duration of the ecotoxicity studies should be added to the endpoints, where applicable: birds, Rainbow trout, Bluegill sunfish, bees, earthworms.	Agree. Inserted where available.
	Annex I, Section 4.2.2, line 2	The NOEC-range stated is not correct. It should be 0.18 – 0.39 µg/L.	Agree. Changed.
	Annex I, Section 4.2.2	The study summary establishing an EC15 = 0.3 µg/L is missing in this section. (see section 5.2).	Agree. Inserted.
	Annex I, Section 4.2.2	The study summary establishing an NOEC = 0.32 µg/L in a mesocosm study is missing in this section. (see section 5.2).	Agree. Inserted.
	Annex I 19, Section 5.2	The text part from "**General**" to the end of Page 19 should be placed on top of this section 5.2 or this part should be deleted entirely as in the text of section 5.2 3rd para the specific values for Norway are given. Therefore the EU results are redundant.	Agree. Moved to the top of the section.
	Annex I, Section 5.2, 2nd para	In the 2nd line the value of 0.18 is given while in section 4.2.2 a value of 0.8 is mentioned. The notification gives 0.18.	Agree. Changed.

Country	Section	Comment/Suggestion	Response
	Annex I, Section 5.2, 2nd para	The values EC15 = 0.3 µg/L and NOEC = 0.32 µg/L are not mentioned in section 4.2.2. To me this is required for the logic of the reasoning of the document.	Agree. Inserted.
	Annex I, Section 5.2, 3rd para	The last sentence of this para is written to describe a PEC/PNEC ratio. I propose to write it also as a TER to be consistent with the rest of the text.	Agree. Changed.
	Annex I, Section 5.2	The heading for Canada is missing.	Agree. Inserted.
	Annex I, Section 5.4	The reproduction study with earthworms is not mentioned under section 4.2.2.	Agree. Inserted.
	Annex I, Section 5.6, last line	For consistency reasons (see Annex 2, Norway, point 3) add “under Norwegian conditions”.	Agree. Inserted.
New Zealand	Section 1. Identification and uses,	The CAS name is incorrect. The CAS name listed is the CAS name quoted in Alanwood Compendium but a check of the CAS STN Easy site gave the following name: Phosphorodithioic acid, O,O-dimethyl S-[(4-oxo-1,2,3-benzotriazin-3(4H)-yl)methyl] ester Trade names: I cannot find a reference to gusathion M. In the Norwegian notification it has gusathion without the M.	No change. Name used as per the Pesticide Manual. Agree: M deleted.
	Section 2.2,	The second and third paragraphs are very confusing and if you didn’t understand that being well below the trigger value was a bad thing this would not make sense. Could these possibly be reworded? A suggestion would be: *“For earthworms, the estimated chronic Toxicity Exposure Ratio (TER) indicates high risks to earthworms (for all uses except fruit trees).”* TER is well explained in Annex 1.	Agree. Changed.
	Section 3.1,	Suggestion only: Information on specific mitigation measure may be of high value to some countries when reviewing this document. Would it be useful to add a sentence saying *“refer to (reference to specific document) for specific mitigation measures adopted in Canada”.* This would make it easier to find the relevant information in a large document.	No change.
	Section 3.3, Alternatives Canada	It says there are alternatives for some crops but not what they are. Would it be useful to add these or at least give a reference to the section and Page number in the Canadian documentation?	No change. Further information on alternative is not available.

Country	Section	Comment/Suggestion	Response
Norway	Abbreviations	Five additional abbreviations that should be included in the list of abbreviations have been identified: DT_{50} – degradation time, 50 % PEC – predicted environmental concentration PPE – personal protective equipment RQ – Risk Quotient TER – Toxicity Exposure Ratio	Agree. Inserted.
	Annex 1 Section 4.1.2:	The correct reference after the sentence “Azinphos-methyl has been found in creeks and rivers in Norway on several occasions” is: *Use and findings of the insecticide azinphos-methyl in the JOVÅ-programme*. Memorandum from GroHegeLudvigsen and Olav Lunde, Jordforsk to Kristin Espeseth, Norwegian Agricultural Inspection Service (Statenslandbrukstilsyn). September 4, 2002. This reference should also be included in Annex 4 – References.	Agree. Inserted.
	Annex 1 Section 5.2	The above mentioned reference should also be included in this chapter after the sentence “This conclusion was also supported by actual concentrations in Norway, in that concentrations detected in the monitoring program were twice as high as the acceptable concentration for the protection of aquatic species”, in addition to the reference to the EU Pesticide Monograph.	Agree. Inserted.
	Annex 1 Section 5.2	To clarify the point, we suggest to rewrite the sentence “Using the calculation method used at the time of the evaluation, a maximum predicted environmental concentration (PEC) in surface water, taking into account a 30 metres buffer zone, of 1.53 µg/L was calculated.” to read “Using the calculation method used at the time of the evaluation, a maximum predicted environmental concentration (PEC) of 1.53 µg/L in surface water was calculated when taking into account a 30 metres buffer zone.”	Agree. Changed.
Peru	Section 2.2	To standardise the writing of "trigger values"	Agree. Changed.
	Annex I Section 3.4	To delete the last sentence in the first paragraph, since it is repeated later.	Agree. Changed.
	Annex I Section 1.1.2	The abbreviation "Kow LogP" is not coherent with "Log Kow" used in section 4.1.4.	Agree. Changed.

Country	Section	Comment/Suggestion	Response
Poland	Section 4.2 Page 10	Canada established an ADI of 0.0015 mg/kg bw/day. **Acute Reference Dose** Canada established an Acute Reference Dose (ARfD) of 0.007 mg/kg bw/day. (Taking into account "Working Procedures" I would cancel information tagged with yellow.)	Agree. Yellow marked text removed.
	Annex I Section 4.1.4	In the first paragraph it should read "Log Kow is 2.96"	Agree. Changed.
Sri Lanka	Section 2 Page 7	Reasons for inclusion in the PIC procedure), sub section2.1, in the second line Canadian Pest Control Product Regulations **Comment-** Canadian Pest Control Product (PCP) Regulations	Agree. Inserted.
	Section 4.2 Page 10	http://www.codexalimentarius.net/mrls/pestdes/pest_ref/MRLs_Spices_e.pdf **Comment**- http://www.codexalimentarius.net/pestres/data/pesticides/details.html?id=2	Agree. Changed.
	Annex I, Section 2.2.2 Page 14	of 20 mg/kg bw/day was identified as brain cholinesterase activity was not reduced **Comment**- of 20 mg/kg bw/day was identified for brain cholinesterase activity.	Changed to "was identified because of".
	Annex I, Section 2.2.2 , 3rdpara Page 14	Plasma and erythrocyte cholinesterase was depressed in the mid and top dose groups and in the brain in the top dose group. **Comment**- Plasma and erythrocyte cholinesterase inhibition occurred in mid and top dose test groups and brain cholinesterase inhibition at the top dose test group.	Agree. Changed.
	Annex I, Section 2.2.4, Page 15	A NOAEL of 0.15 mg/kg bw/day was identified and used in the Canada (Canadian?) risk evaluation (PMRA, 2003). However, the JMPR document identifies the NOAEL at 25 ppm (0.74 mg/kg bw/day) based on reduced weight gain and inhibition of cholinesterase in brain bw/day (0,5,15,45 ppm) for one or two years. Brain cholinesterase was reduced in the mid and top dose groups. A NOAEL of 0.9 mg/kg bw/day ……. **Comment-**bw/day (0,5,15,45 ppm) for two years. Brain cholinesterase was reduced in the mid and top dose groups. A NOAEL of 0.9 mg/kg bw/day (15 ppm)…..	Agree. First part changed.
	Annex I, Section 2.2.7, 2ndpara, 2nd line Page 15	and dermal routes, and moderately toxic via the inhalation route. However azinphos **Comment-** and dermal routes, and moderately toxic via the inhalation route. However azinphos-methyl	Agree. Inserted.