CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 6a

CX/PR 12/44/05-Add.1
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

44th Session

Shanghai, P. R. China, 23-28 April 2012

COMMENTS ON THE DRAFT AND PROPOSED DRAFT MAXIMUM RESIDUE LIMITS IN FOODS AND FEEDS AT STEPS 7 AND 4, submitted by Australia, Brazil, Canada, China, Costa Rica, European Union, United States of America and Croplife International

STEPS IN THE CCPR-CODEX PROCEDURE

Step 1	Recommendation of priority compounds by CCPR, involving the Ad Hoc Working group on Priorities
Step 2	First evaluation of the compound by the Joint FAO/WHO Meeting on Pesticide Residues; estimation of an ADI and of MRLs (draft MRLs or proposed Codex MRLs)
Step 3	Submission of the proposed Codex MRLs to governments for a first round of comments
Step 4	First discussion of the proposed MRLs by the CCPR in the light of the comments received
Step 5	Submission of the proposed Codex MRLs to the Codex Alimentarius Commission in the light of the CCPR-discussion, for consideration
Step 6	Submission of the proposed Codex MRLs to governments for a second round of comments
Step 7	Final discussion of the proposed Codex MRLs by the CCPR in the light of comments received
Step 8	Consideration by the CAC in view of adoption of the proposal as Codex MRL (CXL)
Step 5/8	The proposed codex MRL is submitted to the Commission at Step 5; as there seems to be no controversy and no need for further discussion at Steps 6 and 7, omission of these Steps is recommended to the Commission

Guideline Levels (GLs) will not proceed beyond Step 4 of the procedure.

General

Brazil

Brazil supports the work done by JMPR and its advance for consideration by the 44th Session of the Codex Committee on Pesticide Residues.

Canada

Canada has no objections to the JMPR MRLs at Step 7 and 4. Canada has no further comments on the EMRLs. Guazatine (in Part 3) is not registered for use in Canada, nor have any import MRLs been established.

Canada has no objection to the proposed commodity codes for edible orange oil (OR 004) and ginseng processed products (DM 0604). Canada also agrees with the recommendation to exclude dried ginseng from this code and place it in group 055, provided the drying process is clarified.

Costa Rica

Costa Rica does not have any comments in relation to the document and considers that the proposals in the document are well elaborated.

United States of America

The US supports the JMPR's use of proportionality to recommend MRLs for five chemical/commodity combinations that otherwise would not receive MRL recommendations. These recommendations include dicamba in soya bean (dry) at 5 mg/kg, etofenprox in grapes at 4 mg/kg, diflubenzuron in almonds hulls at 1.15 mg/kg, flutriafol in grapes at 0.8 mg/kg and hexythiazox in strawberry at 6 mg/kg. The US encourages the Committee to endorse the application of proportionality for use by JMPR for these five chemical/commodity combinations and in future work where this concept would apply. This approach will give greater flexibility to JMPR in the use of residue field trial data and will allow MRL estimates to be made in more situations. The US believes that acceptance of the proportionality concept will be another important tool for the establishment of Codex MRLs.

Chorpyrifos-methyl (90):

Canada

As a result of re-evaluation, Canada has revised its MRLs for apples, grapes and tomatoes to 0.01 ppm based on a revised Canadian use pattern. For further information, please consult the Health Canada website (Phase 2 of the Re-evaluation of Chlorpyrifos - Proposed Acceptability for Continuing Registration - PACR2003-03).

Acephate (95)

Australia

Australia supports advancement of the MRLs for rice to Step 5/8.

Methamidophos (100)

Australia

Australia supports advancement of the MRLs for rice husked, rice polished and rice straw and fodder dry to Step 5/8

Phorate (112):

Canada

As a result of the re-evaluation, the uses of phorate on corn, lettuce, beans and rutabaga for which alternatives exist, were phased out at the end of 2003. For potatoes, where available pest management alternatives are limited (especially for wireworms), Canada proposed that the use be phased out by the end of 2004, however, this date has been extended to 2015 due to a continuing extensive wireworm problem and the lack of adequate alternative management strategies. There are currently no MRLs specified for phorate. Consequently, any residues on imported or domestic commodities must not exceed the default MRL of 0.1 ppm. For further information, please consult the Health Canada website (Re-evaluation of Phorate - Proposed Acceptability for Continuing Registration - PACR2003-01 - Health Canada Consultation Document and Re-evaluation Note: Update on the Use of Phorate on Potatoes (REV2008-05, 26 March 2008)

Cypermethrin (118)

Australia

Australia supports advancement of the MRLs to Step 5/8.

Canada

Alpha and zeta-cypermethrin are not registered for use in Canada, however, an application for promulgation of zeta-cypermethrin MRLs in/on various imported commodities has recently been completed. Cypermethrin is registered in Canada and is currently undergoing re-evaluation.

Diflubenzuron (130)

Australia

Australia supports advancement of the MRLs to Step 5/8.

Triazophos (143)

Canada

Please note that triazophos and esfenvalerate are not registered for use in Canada, nor have any import MRLs been established. Therefore, registrants are encouraged to submit information to Canada to resolve any potential trade irritants.

Glyphosate (158)

Australia

Australia supports advancement of the MRLs to Step 5/8.

Profenofos (171)

Australia

Australia supports advancement of the MRLs for chili peppers and chili peppers dry to Step 5/8.

Hexythiazox (176)

Australia

Australia supports advancement of the MRLs to Step 5/8.

Bifenthrin (178)

Australia

Australia notes that MRL recommendations for mango, okra and papaya are held at step 5 pending confirmation of authorised GAPs. Australia supports retaining the MRLs at Step 5 until submission of relevant official GAP to CCPR and consideration by the 2012 JMPR.

European Union

JMPR confirmed in its response that the MRL is indeed not safe and that there are no alternative GAPs. In the report of the 43rd session of the CCPR it is noted that: "*Due to the short term intake concern identified by JMPR, the Committee decided to retain the proposed draft MRL for strawberry at step 4, awaiting data from the manufacturer to support a review of alternative GAP by JMPR in 2014.*" The EUMS agree with this decision.

Etofenprox (184)

Australia

Australia supports advancement of the MRL for apples to Step 5/8.

Tebuconazole (189)

Australia

Australia supports advancement of the MRLs to Step 5/8.

China

China notes that the GAP considered by JMPR for banana and cucumber is quite different with the authorized GAP in China. China will submit the GAP information, as well as the supervise field trial data, for JMPR evaluation and therefore suggests retaining the MRLs of banana and cucumber at Step 5.

Haloxyfop (194)

European Union

The EU submitted a concern form in 2011 on the basis of consumer risks but JMPR has not yet responded to this concern. The EU is requesting JMPR to review this concern due to the exceedance of the ADI driven mainly by the consumption of milk from cattle ingesting feeds containing residues of Haloxyfop. Until this can be clarified the EU is unable to incorporate this CXL into the EU legislation.

Spinosad (203)

Australia

Australia supports advancement of the MRLs to Step 5/8.

Esfenvalerate (204)

Canada

Please note that triazophos and esfenvalerate are not registered for use in Canada, nor have any import MRLs been established. Therefore, registrants are encouraged to submit information to Canada to resolve any potential trade irritants.

Pyraclostrobin (210)

Australia

Australia supports advancement of the MRLs to Step 5/8.

Indoxacarb (216)

European Union

JMPR confirmed that there was insufficient data to recommend a MRL based on an alternative GAP for indoxacarb on leafy lettuce. Hence the EUMS are seeking the revocation of the original MRL of 15 mg/kg which is based on EU use.

Difenoconazole (224)

Australia

Australia notes that the MRL recommendation for papaya is held at Step 5 pending confirmation of authorised GAP. Australia supports retaining the MRL at Step 5 pending submission of relevant official GAP to CCPR and consideration by the 2012 JMPR.

Azoxystrobin (229)

Australia

Australia supports advancement of the MRLs to Step 5/8.

Spirotetramat (234)

Australia

Australia supports advancement of the MRLs to Step 5/8.

Clothianidin (238)

Australia

The 43rd CCPR noted that the manufacturer would provide new data to the 2011 JMPR in support of a minor reconsideration of the residue definition for clothianidin (also a metabolite of thiamethoxam). The 2011 JMPR reviewed the data and clarified the residue definitions for both clothianidin and thiamethoxam, thereby resolving the uncertainty regarding the relationship between clothianidin (the E-isomer of CGA 322704) and CGA 322704, both metabolites of thiamethoxam.

The E and Z isomers exist in equilibrium at room temperature with the E-isomer dominant such that CGA 322704 is equivalent to clothianidin. Australia supports the advancement of all MRL recommendations to Step 8.

Dicamba (240)

Australia

Australia supports advancement of the MRLs for soya beans and soya bean oil to Step 5/8.

Etoxazole (241)

Australia

Australia supports advancement of the MRL for pome fruits to Step 5/8.

Acetamiprid (246)

Australia

Australia does not support the recommendation for spinach, as based on the calculations of the 2011 JMPR the ARfD is exceeded for this commodity. Australia proposes that the MRL recommendation for spinach be held at Step 4 pending alternative GAP and residue trial data to support a different MRL recommendation.

Australia supports the advancement of all other MRL recommendations (other than spinach) to step 5/8.

China

China notes that the GAP considered by JMPR for tomato and cucumber is quite different with the authorized GAP in China. China will submit the GAP information, as well as the supervise field trial data, for JMPR evaluation and therefore suggests retaining the MRLs of tomato and cucumber at Step 5.

Emamectin benzoate (247)

Australia

Australia supports advancement of the MRLs to Step 5/8.

Croplife International

With reference to CL 2011/22-PR dated November 2011, Syngenta Crop Protection AG, the manufacturer of emamectin-benzoate, would like to comment on the acceptable daily intake (ADI) and acute refeference dose (ARfD) established at the Joint FAO/WHO Meeting on Pesticide Residues held in Geneva from 20 to 29 September 2011.

The endpoints selected in the JMPR review are:

- ADI = 0-0.0005mg/kg/day based on 1 & 2 year rat study, 14 week & 1 year dog study (NOAEL = 0.25mg/kg/day) with a 500x UF
- ARfD = 0.03mg/kg/day based on acute rat neurotoxicity study (NOAEL = 5mg/kg/day) with a 200x UF

These endpoints are lower than those proposed in the Syngenta submission, and lower than those agreed in recent external regulatory reviews (eg. EU 91/414 review).

Comment

The dog is the most sensitive of the species tested to emamectin neurotoxicity, with neuropathological lesions being seen after repeat dosing, as summarised below:

Table 1: Summary of neuropathological effects in the dog following repeat dosing

Study duration	Neuropathology effects at LOEL	LOAEL mg/kg	NOAEL mg/kg	Reference
5 week – 7 day kill	No effects at highest dose tested	-	1.5	Lankas, 1992 89-014-0
5 week – 13 & 33 day kills	Brain – neuronal & white matter degeneration Spinal cord – neuronal & white matter degeneration Peripheral nerve – degeneration Effects more severe at 33 days than at 13 days	1.5	0.5	
14 week	Brain – white matter degeneration in 4/8 dogs Spinal cord – multifocal degeneration in 1/8 dogs Skeletal muscle atrophy – 2/8 dogs	1.0/0.5*	0.5/0.25*	Lankas, 1994 88-060-0
1 year	Brain – axonal degeneration in 3/8 dogs Spinal cord – axonal degeneration in 2/8 dogs Peripheral nerve – axonal degeneration in 4/8 dogs Muscle – focal fibre degeneration in 1/8 dogs	0.5	0.25	Gillet, 1992 90-612-0 90-612-1

*dosed at the higher level for first 2 weeks of study, then lower level for remaining period

These data show that there is both a time and dose response, with extended exposure for longer periods producing more marked effects. In the 14 week study, animals were dosed at 2 different levels, but a conservative assumption is made that the received dose level is the lower of the 2 doses given; however there is likely to have been some contribution from dosing at the higher dose level for the first 2 weeks.

ADI

The most logical endpoint on which to set the ADI is the NOAEL of 0.25mg/kg/day from either the 2 year rat or the 1 year dog. This value is a very clear no adverse effect for neuropathology in the dog, which is the most sensitive species following repeat dosing. The use of a standard 100 fold uncertainty factor would give an ADI value of 0.0025mg/kg. The use of this ADI value would still give a difference of 200 fold between an acceptable human intake level and an effect level in the dog, which is considered to be sufficient.

ARfD

The most logical acute study on which to set the ARfD is the rat acute oral neurotoxicity study, as outlined in our original submission.

Table 2: Summary of acute effects in the rat

Study, species, dose levels (mg/kg/day)	NO(A)EL (mg/kg/day)	LO(A)EL (mg/kg/day)	Effects relevant to acute exposure	Reference
Acute oral; rat; 0, 0.5, 2.5, 5.0, 10, 25	5.0 (clinical effects) 10 (neuropathology)	10 (clinical effects) 25 (neuropathology)	Tremors and irritability neuronal degeneration in CNS and PNS	Manson, 1992f IIA 5.7.1/02

The NOAEL for neuropathology is 10mg/kg, and the NOAEL for clinical signs of neurotoxicity is 5mg/kg. Although the clinical signs were reversible within a few days, this endpoint can be used to set a conservative ARfD of 0.05mg/kg, using the standard 100x uncertainty factor. This provides a difference of 200 fold between an acceptable human acute intake level and an effect level for clinical effects, and a difference of 500 fold between an acceptable human acute intake level and an effect level for neuropathology in the rat.

Uncertainty factors

For all these endpoints a standard uncertainty factor of 100 has been used. We believe there is no need for any higher uncertainty factor, for the following reasons:

- Even though effects at the LOAEL may be quite severe, each endpoint is set using a very clear NOAEL
- The standard 100 fold uncertainty factor comprises 10 fold for uncertainty around intraspecies variation and 10 fold for uncertainty around interspecies variation. These factors are inherently very conservative.
- These standard factors already provide very large differences of several hundred between the adverse effect level in animals and the acceptable human exposure level.

Flutriafol (248)

Australia

Australia supports advancement of the MRLs to Step 5/8.

Isopyrazam (249)

Australia

Australia supports advancement of the MRLs to Step 5/8.

Propylene Oxide (250)

United States of America

The US notes that no MRLs were recommended for propylene oxide. The US would like to submit additional information for JMPR to consider regarding a MRL for residues of propylene oxide on tree nuts and will ask JMPR reconsider the establishment of a MRL for propylene oxide on tree nuts. Accordingly, the US expects to submit a concern form for propylene oxide.

Saflufenacil (251)

Australia

Australia supports advancement of the MRLs to Step 5/8.

Spices

Australia

Recommendations for omethoate MRLs in spices based on an analysis of available monitoring data by the 2010 JMPR have been retained at Step 5 by CAC. Australia notes that all CXLs for omethoate, together with the ADI/ARfD have been withdrawn. It is therefore not appropriate to set MRLs for omethoate. At CCPR43, Australia supported advancement of all the MRLs for spices to Step 5/8, except those for omethoate. Australia proposes that the MRL recommendations for omethoate in spices be deleted.

Australia notes that there are MRL recommendations for carbosulfan in spices, however there are no recommendations for carbofuran. Australia requests that the 2012 JMPR consider whether associated MRL recommendations are required for carbofuran.

Canada

Canada has no objection to assigning the recommended codes for spices, to allow inclusion of this commodity in the Codex MRL Database. However, Canada supports the position of deferring any MRLs pertaining to the “Entire Group 028” until this group is completed as part of the revision of the Classification of Food and Feed.