CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



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Agenda Item 6

CX/PR 22/53/5-Add.1 June 2022 ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDES

53th Session

Virtual

4-8 and 13 July 2022

MRLS FOR PESTICIDES IN FOOD AND FEED (AT STEPS 7 AND 4)

Comments in reply to CL 2022/20-PR

Comments of Australia, Canada, Chile, Kenya, Philippines, CropLife International

Background

 This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2022/20-PR¹ issued in May 2022. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

- 2. The comments on MRLs submitted through the OCS are hereby attached in <u>Annex I</u> and are presented in table format.
- 3. The concern forms submitted in reply to CL 2022/20-PR are presented in Annex II.

¹ Codex circular letter, including CL 2022/20-PR, are available on the Codex webpage/Circular Letters: <u>http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/</u> or on the dedicated Codex webpage/CCCF/Circular Letters: <u>https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCPR</u>

GENERAL COMMENTS

COMMENT	MEMBER / OBSERVER
Australia is grateful to the JMPR for their work on the proposed MRLs in CL 2022/20-PR (Rev 1) and provides the below response.	Australia
Considerando que es relevante que el Codex avance en el estudio y determinación de LMRs de aquellos principios activos que se usan regularmente, Chile apoya todas las recomendaciones realizadas por la JMPR como órgano científico asesor del Codex para este Comité, y por lo tanto el avance en el trámite correspondiente en miras a su adopción por la CAC45.	Chile
<u>Comment</u> : Kenya has no objection to the proposed MRLs for the Chemical compounds listed and supports this document to move to the next step in both annexes.	Kenya
The Philippines generally agrees on the proposed draft MRLs of the list of pesticide specified on CL 2022/20 (Rev1). The Philippines acknowledges the review, evaluation and recommendations made by the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) including the estimation of pesticide residue levels and dietary risk assessment conducted.	Philippines

<u>Annex I</u>

SPECIFIC COMMENTS

EXTRA JMPR MEETING

Acetamiprid (246)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs for the new uses.	Canada

Bifaxen (262)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs for the new uses.	Canada

Clofentezine (156)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRL for dry hops.	Canada

Clothianidin (238)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs for the new uses.	Canada

Cyprodinil (207)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada acknowledges that the recommended MRLs for ginseng and the new subgroups of dry peas and beans are lower than the Canadian MRLs for ginseng and legume vegetables based on different critical GAP and crop field trial data.	Canada

Difenoconazole (224)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs for the new uses. Difenoconazole was recently re-evaluated in Canada. See PRVD2021-06 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-re-evaluation-decisions/2021/difenoconazole.html) for details.	Canada

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Ethion (034)

COMMENT	MEMBER / OBSERVER
Canada supports JMPR's decision not to recommend an MRL based on the lack of residue data conducted according to the critical GAP.	Canada

Ethiprole (304)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs for the new uses.	Canada

Fenbuconazole (197)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRL for tea.	Canada

Fenhexamid (215)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs for the new uses. Fenhexamid was recently re-evaluated in Canada. See PRVD2020- 01 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest- management/public/consultations/proposed-re-evaluation-decisions/2020/fenhexamid.html) for details.	Canada

Fenpicoxamid (305)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs for the new uses.	Canada

Fluopyram (243)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs for coffee beans.	Canada

Imazalil (110)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs for the new use on citrus fruits.	Canada

Isoprothiolane (299)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRL for banana.	Canada

Isoxaflutole (268)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada acknowledges that the recommended MRL for dry soya bean is lower than the Canadian MRL based on different interpretation of the critical GAP.	Canada

Mandipropamid (231)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs.	Canada

Methoprene (147)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRL for soya bean.	Canada

Methoxyfenozide (209)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada supports the recommended JMPR MRLs.	Canada

Prothioconazole (232)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs.	Canada

Pydiflumetofen (309)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada acknowledges that the recommended MRLs for the subgroups of beans with pods and succulent peas without pods are lower than the Canadian MRLs based on different crop subgrouping approach.	Canada

Quinoxyfen (222)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada acknowledges that the recommended MRLs for the subgroup of cherries is lower than the Canadian MRL based on different data and crop subgrouping approach.	Canada

Spinetoram (233)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs.	Canada

Sulfoxaflor (252)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs.	Canada

Tebuconazole (189)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRL for coffee beans.	Canada

Thiamethoxam (245)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs.	Canada

Trifloxystrobin (213)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs.	Canada
<u>Citrus fruit</u>	CropLife International
Bayer requests the CCPR 53 to maintain the current CXL of 0.5 mg/kg for trifloxystrobin on citrus fruits under the four-year rule. Bayer is currently running new residue trials on citrus fruits in the US which match the revised US GAP and label. Final studies are anticipated to be submitted for review by the JMPR in December 2023.	
In December 2019 Bayer submitted new residue data for trifloxystrobin on citrus to the JMPR. These residue data were in support of the revised labelled Good Agricultural Practice (GAP) in the USA with the objective to increase the existing CXL of 0.5 mg/kg to 0.6 mg/kg for trifloxystrobin on citrus fruits. The extraordinary JMPR in May/June 2021 considered the submitted data as insufficient to amend the existing CXL. As a consequence JMPR proposed in May/June 2021 to withdraw its previous recommendation for citrus fruit.	
Bayer Crop Science would like to point out that we brought up the issue to the US Delegation which recommended against addressing this issue through the concern form process since there were no technical errors in the JMPR recommendation; Instead, the US Delegation believes it to be a management issue for CCPR.	

Trinexapac-ethyl (271)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs.	Canada

REGULAR JMPR MEETING

Afidopyropen (312)

COMMENT	MEMBER / OBSERVER
Canada supports JMPR's recommendation to rephrase the residue definition for dietary risk assessment for plant commodities.	Canada

Fenpyroximate (193)

COMMENT	MEMBER / OBSERVER
Australia notes the JMPR identified an acute exposure risk associated with commodities in subgroups of Mandarins, Oranges, sweet, sour, Cane berries, Bush berries, Cucumbers and Summer squash, and Stems and Petioles strawberry. Australia does NOT support advancement of the MRLs for these commodities.	Australia
The JMPR reassessed the acute exposure risk for FP 0226 Apple, FP 0230 Pear, FS 0240 Apricot, VC 0046 Melons (except watermelon), VO 2045 Subgroup of Tomatoes, VO 2046 Subgroup of Eggplants, VP 2060 Subgroup of Beans with pods and identified an acute exposure risk for these commodities previously evaluated in 2017 and 2018. Australia requests the CCPR consider action for the established MRLs for these commodities.	
Australia supports the advancement to step 5/8 of MRLs for commodities for which no acute exposure concerns were raised, namely the subgroup of lemons and limes, the subgroup of Pummelo and grapefruits, the subgroup of plums, the MRLs for animal commodities, the MRLs for oils of citrus, MRL for the subgroup plums, dried (prunes) and MRLs for dried pulp of citrus.	
Canada acknowledges JMPR's conclusions that the estimated acute dietary exposure to residues of fenpyroximate for the consumption of various commodities may present a public health concern.	Canada

Fipronil (202)

COMMENT	MEMBER / OBSERVER
Australia notes estimation of long-term exposure using the IEDI results in conservative overestimates of likely consumer exposure. The JMPR conclusion that the estimated long-term dietary exposure to residues of fipronil may present a public health concern is however supported.	Australia
Australia recommends that MRLs for fipronil be held at this time to allow for members and the company time to assess which MRLs may need to be withdrawn, or have alternative GAPs assessed by JMPR, to resolve chronic dietary exposure concerns	
Canada has no objection to the JMPR recommended ADI, ARfD and MRLs. Fipronil is not registered for use in Canada, nor have any import MRLs been established.	Canada
BASF requests the CCPR 53 to maintain the current CXLs for fipronil under the four-year rule. BASF has agreed to eliminate some of the uses which are driving the risk assessment. Our internal calculations indicate that we can pass the chronic risk assessment with these changes. We will resubmit a dossier with supported uses which pose no chronic risk for consumers.	CropLife International

Fluensulfone (265)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended MRLs for pome fruits.	Canada

Flutianil (319)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada supports the JMPR recommended ADI and MRLs. Flutianil was recently regsitered in Canada. See PRD2021-09 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-registration-decisions/2021/flutianil-gatten.html) and RD2022-03 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/registration-decision/2022/flutianil-gatten.html) for details.	Canada

Isoprothiolane (299)

COMMENT	MEMBER / OBSERVER
Canada has no objection to the JMPR recommended ADI. Isoprothiolane is not registered for use in Canada, nor have any import MRLs been established.	Canada

Mefentrifluconazole (320)

COMMENT	MEMBER / OBSERVER
Canada has no objection to the JMPR recommended ADI and ARfD. Mefentrifluconazole was recently registered in Canada. See PRD2019-09 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-registration-decisions/2019/mefentrifluconazole.html) and RD2019-17 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/registration-decision/2019/mefentrifluconazole.html) for details.	Canada

Metalaxyl (138)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the recommended ADI and ARfD and ackowledges that several of the previous recommendations for MRLs had to be withdrawn due to the lack of sufficient trials conducted in accordance to the critical GAP. For those MRLs that had to be lowered, these are based on new critical GAPs and corresponding new crop field trials.	Canada
Since 2003 JMPR has been evaluating metalaxyl (138) and metalaxyl-m (212). At JMPR 2021 it has been proposed to withdraw all proposed MRLs for metalaxyl-m and have a single entry under metalaxyl which covers both metalaxyl and metalaxyl-m.	CropLife International
For the sake of clarity, Syngenta proposes that the same naming principle be applied for metalaxyl and metalaxyl-M as for the following:	

COMMENT	MEMBER / OBSERVER
118 Cypermethrins (including alpha- and zeta- cypermethrin),	
146 Cyhalothrin (includes lambda-cyhalothrin).	
Thus it is proposed that the compound be changed from 138 "Metalaxyl" to 138 "Metalaxyl (including metalaxyl-m)"	
The JMPR evaluation of metalaxyl-m and re-evaluation has been underway for over twenty years. It has been complicated and disjointed, however JMPR has done a wonderful job in finally bringing the work to an end. Due to the time delays many labels originally supporting the setting of MRLs are no longer approved or the data is no longer fit for purpose.	
Syngenta is committed to supporting CODEX MRLs to facilitate international trade for metalaxyl-m and as such requests the four-year rule be implemented for a number of commodities as indicated below.	
Broccoli	
Syngenta requests the existing MRL of 0.2 mg/kg for avocado be maintained and the four-year be implemented to allow data to be generated.	
<u>Cacao bean</u>	
Syngenta requests the existing MRL of 0.2 mg/kg for cocoa be maintained and the four-year be implemented to allow the label to be amended to match the residue data.	
Carrot	
Syngenta requests the existing MRL of 0.05* mg/kg for carrot be maintained and the four-year be implemented to allow data to be generated. The proposed MRL of 0.02* (MM) be held at step 7.	
Citrus fruits, Group of	
Syngenta requests the existing MRL of 5 mg/kg for "Citrus fruits, Group of" be maintained and the four-year be implemented to allow data to be generated.	
Cucumber	
Syngenta requests the existing MRL of 0.5 mg/kg for cucumber be maintained and the four-year be implemented to allow data to be generated.	
<u>Gherkin</u>	
Syngenta requests the existing MRL of 0.5 mg/kg for gherkin be maintained and the four-year be implemented to allow data to be generated.	
Melons, except Watermelon	
Syngenta requests the existing MRL of 0.2 mg/kg for "Melons, except Watermelon" be maintained and the four-year be implemented to allow data to be generated. The proposed MRL of 0.15 (MM) be held at step 7.	
Oranges, Sweet, Sour, Subgroup of	
Syngenta requests the proposed MRL of 0.7 mg/kg for "Oranges, Sweet, Sour, Subgroup of" be moved to step 7 whilst data is generated to support the Citrus fruits group as outlined above.	
Peppers	
Syngenta requests the existing MRL of 1 mg/kg for peppers be maintained and the four-year be implemented to allow data to be generated.	
Peppers Chili, dried	
Syngenta requests the existing MRL of 10 mg/kg for "Peppers Chili, dried" be maintained and the four-year be implemented to allow data to be generated.	

COMMENT	MEMBER / OBSERVER
Potato	
Syngenta requests the existing MRL of 0.05* mg/kg for potato be maintained and the four-year be implemented to allow data to be generated. The proposed MRL of 0.02 (M) be held at step 7.	
Squash, summer	
Syngenta requests the existing MRL of 0.2 mg/kg for summer squash be maintained and the four-year be implemented to allow data to be generated.	
Sugar beet	
Syngenta requests the existing MRL of 0.05* mg/kg for sugar beet be maintained and the four-year be implemented to allow data to be generated.	
Watermelon	
Syngenta requests the existing MRL of 0.2 mg/kg for watermelon be maintained and the four-year be implemented to allow data to be generated.	
Winter squash	
Syngenta requests the existing MRL of 0.2 mg/kg for winter squash be maintained and the four-year be implemented to allow data to be generated.	

Metalaxyl-M (212)

COMMENT	MEMBER / OBSERVER
Canada has no objection to the recommended ADI and ARfD and ackowledges that several of the previous recommendations for MRLs had to be withdrawn due to the lack of sufficient trials conducted in accordance to the critical GAP.	Canada

Metconazole (313)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the recommended MRLs for wheat, triticale and processed commodities.	Canada

Pendimethalin (292)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada acknowledges that the JMPR recommended MRLs for most commodities are lower than the Canadian MRLs based on different critical GAPs and crop field trials.	Canada

Pyrasulfotole (321)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada supports the JMPR recommended ADI and MRLs.	Canada
Rice, hay and/or straw # replace "rice" with "rye"	CropLife International

Pyraziflumid (322)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended ADI, ARfD and MRLs. Pyraziflumid was recently registered for use in Canada. See PRD2022- 04 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest- management/public/consultations/proposed-registration-decisions/2022/pyraziflumid-parade-fungicide.html) for additional details.	Canada

Spiropidion (323)

COMMENT	MEMBER / OBSERVER
Australia supports advancement of the MRLs to Step 5/8.	Australia
Canada has no objection to the JMPR recommended ADI, ARfD and MRLs. Spiropidion is in the process of being reviewed in Canada to support MRLs for imported commodities.	Canada
Canada has no objection to the JMPR recommended ADI. Tetraniliprole was recently registered in Canada. See PRD2019-14 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-registration-decisions/2019/tetraniliprole.html) and RD2020-04 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/registration-decision/2020/tetraniliprole.html) for additional details.	

Annex II

CONCERN FORMS

EUROPEAN UNION: Terbufos (167)

<u>Annex A</u>

FORM FOR EXPRESSING CONCERNS WITH ADVANCEMENT OF AN MRL OR REQUEST FOR CLARIFICATION OF CONCERNS

	ACCENTS WITH ADVANCEMENT OF F			
Submitted by: The Europed	in Union			
Date: May 2022				
Pesticide / Pesticide Code Number:	Food(s) / Food Code Number(s)	MRL (mg/kg)	Present Step	
Terbufos (167)	All commodities	All MRLs	CXL	
Is this a request for clarific	ation?			
no				
Request for clarification (S	pecific statement of clarification req	uested)		
Is this a concern?				
yes				
Is this a continuing concer	n?			
no				
Concern (Specific statemer	t of reason for concern to the advan	cement of the propose	ed MRI)	
The European Union is aware of a recent Canadian notification of the active substance terbufos to the Rotterdam Convention (PIC Procedure). The Canadian authorities derived an ADI of 0.00015 mg/kg bw/d (4 times lower than the JMPR ADI) and an ARfD of 0.00015 mg/kg bw, being more than 10 times lower than the JMPR derived ARfD. On this basis, the MRL for terbufos in bananas is no longer safe within the EU (ARfD more than 1200%).				
"JMPR (2004) [author: JMI	-			
Acute reference dose (AR				
miosis in the stuc Since only in this be possible to ref	blished an acute RfD of 0.002 mg/kg ly of neurotoxicity in rats given a sing study miosis was observed in the ab fine the acute RfD after better charac 2013: 0-0 0006 mg/kg bw	gle dose of terbufos, ar sence of inhibition of c	nd a 100-fold safety factor. holinesterase activity, it may	
Acceptable Daily Intake (ADI): 0-0.0006 mg/kg bw The Meeting established an ADI of 0-0.0006 mg/kg bw based on an overall NOAEL of 0.06 mg/kg bw per day and a safety factor of 100 for inhibition of brain cholinesterase activity in a 1-year toxicity study in rats, 13-week study of neurotoxicity and two-generation study of reproduction in rats, and 1-year study in dogs.				
Canadian risk evaluation [author: 2004]:				
Acute reference dose (AR				
In animal studies, the adverse effects noticeable at the lowest dose (i.e., the toxicity end point) were clinical signs observed in an acute rat neurotoxicity study (NOAEL = 0.15 mg/kg bw). The uncertainty factor was 100 (10x for interspecies extrapolation x 10x intraspecies variability). An additional safety factor of 10x was applied to account for the steepness of the dose response and the high degree of potency (based on lethality at very low doses). The acute reference dose (ARfD) was calculated to be 0.00015 mg/kg bw (0.15 mg/kg bw ÷ 1000). This value was considered to be protective of infants and children.				
Acceptable Daily Intake (ADI): 0.00015 mg/kg bw/d				
As the ARfD value was lower than any acceptable daily intake (ADI) derived from any of the repeat-dose toxicity studies (reflecting the high acute toxicity and use of the additional safety factor), the ADI was established at the same value as the ARfD. Thus, the ADI is 0.00015 mg/kg bw/d."				
It is noted that the last toxicological re-evalution by JMPR was 19 years ago.				
Do you wish this concern to be noted in the CCPR Report?				
yes				
	tion of each separate piece of data/i month of the CCPR meeting)	information which will	be provided to the appropriate	