

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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Agenda Item 11(i)

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON PESTICIDE RESIDUES

Forty first Session

Beijing, China, 20 - 25 April 2009

#### DISCUSSION PAPER ON THE GUIDANCE TO FACILITATE THE ESTABLISHMENT OF CODEX MRLs FOR MINOR USES AND SPECIALTY CROPS

### I. BACKGROUND

At its 40<sup>th</sup> Session, the Codex Committee on Pesticide Residues agreed to establish an electronic workgroup on minor uses and specialty crops. The purpose of the workgroup is to provide guidance to facilitate the establishment of Codex maximum residue levels (MRLs) for minor uses and specialty crops (ALINORM 08/31/24, para. 160).

The Committee agreed to establish an electronic working group co-chaired by the United States, Australia and Kenya working in English. Barbara Madden ([madden.barbara@epa.gov](mailto:madden.barbara@epa.gov)) from the United States Environmental Protection Agency (EPA) represents the United States on this group, Alan Norden ([Alan.Norden@apvma.gov.au](mailto:Alan.Norden@apvma.gov.au)) from the Australian Pesticides and Veterinary Medicines Authority (APVMA) represents Australia and Lucy Namu ([lnamu@kephis.org](mailto:lnamu@kephis.org)) from the Kenya Plant Health Inspectorate Service represents Kenya.

In September of 2008 an invitation was sent via the Codex Secretariat soliciting participation in the group to all Codex Members and Observers. The response to that e-mail was limited. Therefore, the first communication from the electronic working group, which included a brief questionnaire, was sent to all Codex Members and Observers in January, 2009. Though the response from members to this January message was greater than what occurred in September, the response was still less than expected based on the interest indicated during the meeting of the 40<sup>th</sup> Session. Members now participating in the working group include representatives from Australia, Canada, Columbia, Costa Rica, Iran, Japan, Kenya, Korea, South Africa, Thailand, United States and Crop Life International. A representative from the OECD Pesticides Programme is an observer. A list of members is provided at Appendix I.

This report summarizes the activities of the group to date, responses to the survey and proposes recommendations for future action.

### II. SUMMARY OF PROPOSED RECOMMENDATIONS

A.1. The EWG on Minor Uses and Specialty Crops proposes member countries and CCPR to;

A.1.1. actively participate in and continue progress for the inclusion of new commodities into the *Revision of the Codex Classification on Foods and Animal Feeds* and

A.1.2. progress steps for suitable implementation on the *Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs to Commodity Groups*.

A.2. The EWG on Minor Uses and Specialty Crops proposes member countries and CCPR consider the establishment of;

A.2.1. Training manual that provides practical examples and exercises and a series of training programs to provide members guidance in the generation and submission of data to JMPR, and

A.2.2. Specialty Crops & Minor Use Interest Group of member countries and observers to collaboratively work to identify and nominate to the *EWG on Priorities* and collate submissions (including data and product labels) to JMPR for reviews in;

A.2.2.a. selected priority specialty crop and minor use commodities, and

A.2.2.b. chemicals nominated for periodic re-evaluation.

B.2. The EWG on Minor Uses and Specialty Crops proposes that member countries and CCPR:

B.2.1. Define Minor Uses as those uses of crop protection products where a chemical registrant does not generally consider the registration of those uses would provide sufficient economic return to justify investment. Minor uses encompass both minor crops and limited or infrequent uses within major crops,

B.2.2. Define Specialty Crops as high value minor crops grown over small areas and that are considered by chemical registrants as minor uses, and

B.2.3. DO NOT define or classify individual crops or commodities as minor or major as these must be determined at the member country or regional level. Where determinations of minor and major crops will vary given differences at the country or regional level in matters including dietary intake and levels of production (areas/tonnage) for the individual crop/commodity.

### **III. DISCUSSION**

#### **A. Questionnaire sent to all Codex Members and Observers**

As a starting point, a brief questionnaire was sent to all Codex members and observers. The goal of this questionnaire was to collate information from member countries on issues associated with Codex MRLs for minor uses and specialty crops. The following questions were asked:

- *Please identify the top ten specialty crops or minor use commodities exported from the country you represent. Are you aware of any trade barriers for those compounds listed for periodic re-evaluation in the upcoming years, 2010, 2011 etc.?*
- *Please identify the ten most important MRL trade barriers growers are faced with when exporting specialty crops or minor use commodities from the country you represent. Please include the crop, pesticide and pest being controlled in your response.*
- *In your experience why don't more countries put forth nominations to the JMPR for review for new chemicals and new uses? What are the roadblocks that countries are faced with when making nominations to the JMPR?*
- *Do countries see the lack of knowledge of what to do regarding data generation/submission as an obstacle that prevents nominations to the JMPR for consideration? If yes, is there an interest in developing a training manual and a training program that will provide guidance in these areas?*

#### **1. Most Important Commodities and Trade Barriers**

In general countries response's to these questions indicate that some of the most important commodities for export do not have MRLs for any chemical. The biggest obstacle for most of the minor commodities identified is that there is either no or inadequate data to support the establishment of Codex MRLs. It is also understood that some countries may base local authorizations upon authorizations granted in other countries and where they do not have access to supporting data. These are largely attributable to the pesticide producer having no economic interest in registration of the crop due to a lack of return on investment and where no national grower or government program exists to generate (or access) the supporting data. Some countries noted that whilst some markets may apply a default MRL the value of 0.01 mg/kg the approach does not offer solutions for all commodities in trade when those commodities have residues above this limit.

The following table lists those responses received for the most important specialty crops or minor use commodities exported (and other comments provided).

**Table 1. Most Important Specialty Crops or Minor Use Commodities Exported \***

Country	Specialty crops or minor use commodities exported
Australia	Carrots, onions, grapes (dried), cherries, tomatoes, mangoes, plums, apples, pears, potatoes and avocado.
Canada	Soybeans, peas, lentils, tomatoes, peppers (of the genus <i>Capsicum</i> or <i>Pimenta</i> ), potatoes, cranberries, bilberries (and other fruits of the genus <i>Vaccinium</i> ), beans, mustard seed, cucumbers and gherkins. For those compounds listed for periodic re-evaluation in the upcoming years, 2010, 2011, etc. potential trade barriers for Canada would be those pesticide/crops that have Codex CXLs that are lower than Canadian MRLs. Appendix II contains a list of potential trade barriers for Canada for the chemicals that are scheduled for periodic re-evaluation by JMPR.
Columbia	uchuva ( <i>Physalis peruviana</i> ), granadilla ( <i>Passiflora ligularis</i> ), maracuyá ( <i>Passiflora edulis</i> ), tamarillo or tomate de árbol ( <i>Cyphomandra betacea</i> ), and pitahaya ( <i>Selenicereus megalanthus</i> ).
Costa Rica	chayote ( <i>Sechium edule</i> ), culantro coyote ( <i>Eryngium foetidum</i> ), yuca ( <i>Manihot esculentum</i> ), tiquisque ( <i>Xanthosoma violaceum</i> ), and <i>Dioscorea alata</i> .
Iran	Barbery ( <i>Berberis vulgaris</i> L.), Cornelian Cherry ( <i>Cornus mas</i> L.), Saffron ( <i>Crocus sativus</i> L.), Cumin seed, ( <i>Cuminum cyminum</i> L.), <i>Rosa damascena</i> Mill., Hops ( <i>Foeniculum vulgare</i> Miller.) <i>Ferula gumosa</i> Boiss., and <i>Valeoiana officinalis</i> L. For <i>Rosa damascena</i> Mill. Pest of concern is aphids. Chemicals of concern are Malathion, Primicarb, Dichlorvos
Kenya	Passion fruit ( <i>Passiflora edulis</i> ), green beans; immature/green pods, runner immature/green pods ( <i>Phaseolus vulgaris</i> ), Peas, both immature pods and whole green, mangetout (all <i>Pisum sativum</i> ), ravaya ( <i>Solanum melongena</i> ), okra ( <i>Abelmoschus esculentus</i> ), karella ( <i>Momordica charantia</i> ), and avocado ( <i>Persea americana</i> ).
Korea	Ginseng ( <i>Panax ginseng</i> C.A. Meyer) Pests of concern are Alternaria Blight ( <i>Alternaria Panax</i> ) and Damping-off ( <i>Rhizoctonia Solani</i> ). Chemicals of concern are Difenconazole and Tolclofos-methyl

\* Please note the Chair of the Codex Electronic Working Group on Minor Uses and Specialty Crops has forwarded information on new commodities identified by member countries in response to the survey on to the International Crop Grouping Consulting Committee (ICGCC) for consideration and subsequent submission to the *Revision of the Codex Classification on Foods and Animal Feeds*.

#### **Approaches in the Absence of Commodity Specific Data**

A common approach utilized and accepted by regulators to support the registration of minor uses is to allow the scientific extrapolation of data between related commodities of the same crop group. This enables MRLs to be established for either individual commodities or for an entire crop group should data from identified representative commodities of that group be available.

Current work by the CCPR Electronic Working Group on the *Revision of the Codex Classification on Foods and Animal Feeds* is proposing the inclusion of many new commodities. The inclusion of new commodities will further serve to address some of the barriers for Codex MRLs on those commodities being considered for inclusion. Agenda Item 6 of the 41<sup>st</sup> session of the CCPR on the “*Proposed Draft Revision of the Codex Classification of Foods and Animal Feeds*” provides an update on the progress of that work.

However the benefits for the addition of new commodities into the *Codex Classification on Foods and Animal Feeds* (noted above) may only be fully realized where more Codex MRLs can be established for entire crop groups. In addition to Agenda Item 6 of the 41<sup>st</sup> session of the CCPR a document titled “*ADDENDUM I to: Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs to Commodity Groups*” will also be discussed.

## **Recommendations**

A.1.1. actively participate in and continue progress for the inclusion of new commodities into the *Revision of the Codex Classification on Foods and Animal Feeds* and

A.1.2. progress steps for suitable implementation on the *Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs to Commodity Groups*.

## **2. Nominations to JMPR**

The *Electronic Working Group on Priorities* has greatly assisted the submission of more nominations to JMPR. Priorities are regularly circulated to all member countries including information on what commodities will be submitted for review and by whom.

Member countries and observers were asked why more countries do not put forth nominations to the JMPR for review for new chemicals and new uses and what are the roadblocks that countries are faced with when making nominations to the JMPR.

In the case of new chemicals most if not all of the data available will be from the manufacturers (pesticide producer /registrant). Since much of the earliest data development occurs in the European Union (EU) and the U.S., the EU member states or the U.S. tend to be the delegations with which industry works to secure new chemical nominations. In these regions minor crops are often supported by data for representative commodities and crop groups so there are no data available on the minor crop. Whilst the concept of representative commodities is applied by JMPR there is no agreement between national regulators as to representative crops and the minimum number of trials required.

As discussed above a lack of available residue data is cited as the primary reason why nominations are not made to JMPR. Additionally, many countries do not always know how to appropriately generate data and present that data as required by the JMPR for its evaluations.

In 2007, a two day pilot training exercise was held for some member countries in the Pacific region. After that training one member country that participated in the pilot training successfully submitted field trial studies to the 2008 JMPR that resulted in an MRL. In the survey several member countries and observers responded positively for the support of developing a training manual and a training program to provide guidance in the areas of data generation and its submission to JMPR. One respondent recommended this training could be offered as a workshop at one of the CCPR meetings.

One successful approach to establishing Codex MRLs for minor uses has been in spices. JMPR 2004 considered an industry-based submission that resulted in the setting of Codex CXLs for a number of compounds. The spices group will again be reviewed by JMPR in 2009. The approaches used by this group could serve as a model whereby grower industries through their country delegation could be joined to focus on particular commodities or groups of commodities and make collective submissions to JMPR. In addition to this, member countries could establish interested minor use representatives to develop and submit priorities to the EWG on Priorities for those chemicals listed for periodic re-evaluation.

In the Canadian response to the survey a listing of potential trade barriers by identification of commodities with a Codex CXL lower than that established in Canada (refer to Appendix II) was provided for those chemicals nominated for periodic re-evaluation for the period to 2016.

In examining the commodities listed in Table 1 above provided by survey respondents, there are some commonalities in commodities such as beans, peas, avocado, tomatoes, potatoes, granadilla/passionfruit. There may be merit in member countries working collaboratively to identify commonalities in commodities affected by trade barriers with a specific aim of collating available supporting information relevant for JMPR. This may serve to enhance the quality of submissions to JMPR in terms of the amount of supporting data and breadth of product labels available. This could enhance outcomes possible for (i) chemicals currently identified for periodic re-evaluation and/or (ii) via the identification and nomination to JMPR for commodity based reviews (similar to that which has occurred previously with spices).

## **Recommendations**

A.2. The EWG on Minor Uses and Specialty Crops proposes member countries and CCPR consider the establishment of a;

A.2.1. training manual that provides practical examples and exercises and a series of training programs to provide members guidance in the generation and submission of data to JMPR, and

A.2.2. Specialty Crops & Minor Use Interest Group of member countries and observers to collaboratively work to identify and nominate to the *EWG on Priorities* and collate submissions (comprising of data and product labels across member countries) to JMPR for reviews in;

A.2.2.a. selected priority specialty crop and minor use commodities, and

A.2.2.b. chemicals nominated for periodic re-evaluation.

## **B. Additional Issues Raised by Codex Members and Observers**

### **1. Global Joint Review Projects and JMPR Review**

The working group was not able to reach consensus on the recommendations concerning Global Joint Review Projects and JMPR Review, although the following comments are provided as background to issues raised by some members.

Some member countries have been involved in efforts outside of Codex to simultaneously review data for new chemicals as a joint review project between several nations. These are typically referred to as global joint reviews. These projects divide the work of reviewing data between countries: participating countries complete reviews and peer review each others work; and finally share risk assessments with the goal of harmonizing endpoints and MRLs where possible. These efforts have the potential to reduce workloads with multiple benefits for the chemical manufacturers, the regulatory agencies, growers of export commodities to other nations and the consumers who have access to more products. A concern was raised regarding the global joint review efforts and recommendations made for some of these chemicals at the JMPR 2008 meeting. For example, chlorantraniliprole was a global joint review between Australia, Canada, the European Union, New Zealand and the United States. When this chemical was considered by the JMPR in 2008, the recommendations for MRLs for some commodities differed than those established by the countries that participated in the global joint review.

It is noted that a discussion paper will also be presented at the 41<sup>st</sup> session of the CCPR titled “*Pilot Project on JMPR Recommending MRLs before National Authorities*”.

#### **Recommendations**

B.1. The EWG on Minor Uses and Specialty Crops proposes that member countries and CCPR;

B.1.1. progress steps for the suitable implementation of the “*Pilot Project on JMPR Recommending MRLs before National Authorities*”, and

B.1.2. based on the pilot project CCPR consider the possible development of a global MRL calculator.

### **2. Definition of Terms**

Some member countries recalled the discussion at the last CCPR Session (para. 158, ALINORM 08/31/24) in which some delegations emphasized the importance of defining the term “minor use” and “specialty crop” and wanted the first action of this group to be to define these terms. However, others expressed concern that since the crops will differ from country to country it may not be possible for this group to reach an agreement on this issue.

It is acknowledged that the definition of what crops may be “minor uses” or “specialty crops” may be different from country to country. OECD through its Expert Group on Minor Uses is currently developing a guidance document on mechanisms used amongst member countries and issues countries should be conscious of when developing a definition (or criteria). The OECD guidance document when published might be something that CCPR can use as a basis for discussion and possible adoption.

#### **Recommendations**

B.2. The EWG on Minor Uses and Specialty Crops proposes that member countries and CCPR:

B.2.1. Define Minor Uses as those uses of crop protection products where a chemical registrant does not generally consider the registration of those uses would provide sufficient economic return to justify investment. Minor uses encompass both minor crops and limited or infrequent uses within major crops,

B.2.2. Define Specialty Crops as high value minor crops grown over small areas and that are considered by chemical registrants as minor uses, and

B.2.3. DO NOT define or classify individual crops or commodities as minor or major as these must be determined at the member country or regional level. Where determinations of minor and major crops will vary given differences at the country or regional level in matters including dietary intake and levels of production (areas/tonnage) for the individual crop/commodity.

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**APPENDIX II****Potential Trade Barriers for Canada for Chemicals Scheduled for Periodic Re-evaluation by JMPR**

Note: Canadian MRLs current as of November 2008

Year	AI	Commodity	CAN MRL	Codex CXL
2010	Amitraz	Pears	1	0.5
	Azinphos-methyl	Apricots	2	1
		Blackberries	2	1
		Cranberry	1	0.1
		Grapes	5	1
		Raspberries	2	1
	Chlorothalonil	Cabbages, Head	5	1
		Cauliflower	5	1
		Celery	15	10
		Peach	0.5	0.2
Sweet corn (corn-on-the-cob)		0.1 (default)	0.01	
2011	Dicofol	Common bean (pods and/or immature seeds)	3	2
		Cucumber	3	0.5
		Peppers	3	1
		Plums (including prunes)	3	1
		Tomato	3	1
	Diquat	Potato	0.1	0.05
2012	Bentazone	Beans (dry)	0.1 (default)	0.05
		Broad bean (dry)	0.1 (default)	0.05
		Field pea (dry)	3	1
		Garden pea (youngpods)	3	0.2
		Lima bean (young pods and / or immature beans)	0.1 (default)	0.05
	Glufosinate-ammonium	Rape seed oil, Crude	0.1 (default)	0.05
2013	Metalaxyl	Asparagus	7	0.05
		Carrot	0.5	0.05
		Cereal grains	0.1 (default)	0.05
		Citron melons	1	0.2
		Cucumber	1	0.5
		Lettuce, Leaf	5	2
		Peas, Shelled (succulent seeds)	0.2	0.05
		Potato	0.5	0.05
		Soyabean(dry)	1	0.05
		Spinach	10	2
		Squash, Summer	1	0.2
		Sugarbeet	1	0.05
		Sunflower seed	0.1	0.05

Year	AI	Commodity	CAN MRL	Codex CXL
2014	Diazinon	Apple	0.75	0.3
		Broccoli	0.75	0.5
		Cabbages,Head	0.75	0.5
		Cantaloupe	0.25	0.2
		Common bean (pods and/or immature seeds)	0.5	0.2
		Cranberry	0.25	0.2
		Cucumber	0.5	0.1
		Kale	0.75	0.05
		Kohlrabi	0.75	0.2
		Lettuce, Head	0.75	0.5
		Lettuce, Leaf	0.75	0.5
		Onion, Bulb	0.75	0.05
		Peach	0.7	0.2
		Pears	0.75	0.3
		Peppers, Sweet	0.75	0.05
		Peppers,Chili (dry)	0.75	0.5
		Potato	0.1 (default)	0.01
		Radish	0.25	0.1
		Spinach	0.75	0.5
		Squash,Summer	0.1 (default)	0.05
	Strawberry	0.75	0.1	
	Tomato	0.75	0.5	
	Phosalone	Apple	5	2
Peaches/nectarines		4	2	
Plums		5	2	
2015	Abamectin	Potato	0.1 (default)	0.01
2016	Iprodione	Lettuce, Leaf	15	10
		Rape seed	1	0.5
	Permethrin	Potato	0.1 (default)	0.05
		Rape seed	0.1 (default)	0.05
		Sugarbeet	0.1 (default)	0.05