CODEX ALIMENTARIUS COMMISSION

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CODEX COMMITTEE ON PESTICIDE RESIDUES

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DISCUSSION PAPER ON THE GUIDANCE TO FACILITATE THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS FOR PESTICIDES FOR MINOR USE AND SPECIALTY CROPS

(Prepared by the Electronic Working Group[1] led by the United States of America and co-chaired by Australia and Kenya)

I. BACKGROUND

At its 42nd Session, the Codex Committee on Pesticide Residues (CCPR) agreed to re-establish the Electronic Working Group (EWG) on Minor Uses and Specialty Crops. The Committee determined that the EWG should continue to identify and address issues related to minor uses and specialty crops by 1) identifying priority minor uses and specialty crops for MRL setting, and to facilitate data submissions to JMPR, and 2) to prepare proposals for definitions of minor uses and specialty crops for use by the CCPR and JMPR.

The Committee agreed the re-established EWG will be co-chaired by the United States, Kenya and Australia working in English. The List of Participants is given in Annex III of this document. This report summarizes the activities of the group to date.

II. SUMMARY OF ISSUES FOR CCPR CONSIDERATION

EWG Nominations to the JMPR for Review of PIP Chemicals

- The EWG appreciates that the JMPR completed review of the two PIP chemicals bifenthrin (mango, okra and papaya) and difenconazole (papaya) and recommended MRLs for the CCPR to consider. The EWG requests that CCPR approve these MRLs since data were developed to support the setting of MRLs for commodities grown in tropical regions and the residue field trials reflect the use patterns for these chemicals/commodities in those regions.

- Efforts are being made to ensure the label or letter is available for the other PIP chemicals that are scheduled for review by the JMPR. However, the EWG recommends that the CCPR request JMPR to proceed with all future PIP chemicals as they have done for difenoconazole and bifenthrin and, when submissions for PIP chemicals are made, and a label or letter is missing, provided the data are acceptable, JMPR conduct the appropriate risk assessments and recommend a MRL level and defer a final decision regarding the MRL to the CCPR for consideration.

Definition of Minor Use for JMPR and CCPR

- The EWG recommends that work on the definition of minor uses be limited to focus on defining minor uses and specialty crops for use by the CCPR and JMPR to determine the minimum number of field trials needed for risk assessment to support the establishment of a Codex MRL. The EWG would like to determine if Members agree with this limited focus.

- Based on the responses received from the EWG Members there currently is no agreement on the definition. Two approaches were identified to define minor uses for use by the CCPR and JMPR to determine the minimum number of field trials needed to support the establishment of a Codex MRL. Both of these approaches are discussed in this paper. Members are asked to provide their comments/recommendations on these two approaches.

Facilitating the Establishment of Codex MRLs for Minor Uses and Specialty Crops

- The EWG continues to recommend that CCPR 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 progress steps for suitable implementation on the *Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs to Commodity Groups*.

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1 Argentina, Brazil, Chile, Costa Rica, Ecuador, Japan, Korea, New-Zealand, Philippines, Thailand, The Netherlands, CIAA, CropLife International, Eurofins (see Annex I for additional information).

- If the Committee determines it is appropriate to re-establish the EWG for work during 2011-2012, the EWG Members suggest the EWG focus on identifying data that can be used to support Codex MRLs for one particular commodity. A few commodities suggested for consideration included tea, coffee, papaya and okra. Members are asked to provide their comments/recommendations on the commodity to be considered during 2011-2010.

III. DISCUSSION

A. EWG Nominations to the JMPR for Review of PIP Chemicals

During the 42nd CCPR meeting the EWG requested that CCPR nominate several chemicals/commodities for review by the JMPR. Included in this request were chemicals/commodities in which residue field trial data to support the establishment of Codex MRLs were available as a result of the Pesticide Initiative Programme (PIP) (http://pip.coleacp.org/en/pip/11784-homepage).

During the September, 2010 JMPR meeting two of these PIP chemicals were reviewed for bifenthrin (mango, okra and papaya) and difenconazole (papaya) (JMPR 2010 Report, ISSN0259-2517). The data reviewed were found acceptable and the JMPR recommended MRL levels. However, the JMPR deferred to the CCPR as to whether these MRLs should be established since no label or letter from a government body confirming that the use pattern in these trials actually reflects the national use pattern was submitted along with these data. In the 42nd CCPR meeting it was reported that the JMPR agreed to accept residue field trial data on a minor crop when there is no formal label available, but will instead accept an official letter from a government agency that states the chemical is being used on the crop in that country and the letter outlines the use pattern (GAP) being used by growers in that country. In the case of the two PIP submissions sent to JMPR no such letter or label accompanied the data submitted to the JMPR. However the residue field trials reflect the use patterns for these chemicals on the crops in the regions.

The EWG appreciates that the JMPR completed review of these actions and recommended MRLs for the CCPR to consider. The EWG requests that CCPR approve these MRLs since they were conducted to support the setting of MRLs for commodities grown in tropical regions and the residue field trials reflect the use patterns for these chemicals/commodities in those regions. Efforts are ongoing to submit specific labels to JMPR that are available for these chemicals/commodities to support these MRLs.

Additionally, efforts are also being made to ensure the label or letter is available for the other PIP chemicals that are scheduled for review by the JMPR. However, the EWG recommends that the CCPR request JMPR to proceed with all future PIP chemicals as they have done for difenoconazole and bifenthrin and, when submissions for PIP chemicals are made, and a label or letter is missing, provided the data are acceptable, JMPR conduct the appropriate risk assessments and recommend a MRL level and defer a final decision regarding the MRL to the CCPR for consideration.

B. Definition of Minor Use for JMPR and CCPR

In October of 2009 the Organization for Economic Co-operation and Development (OECD) through its Expert Group on Minor Uses finalized a guidance document on mechanisms used amongst member countries and issues countries should be conscious of when developing a definition (or criteria) for minor uses and specialty crops. In December of 2009 the EWG circulated to Codex Members and Observers the published document by OECD titled: *Publication OECD Guidance Document on Defining Minor Uses of Pesticides* {ENV/JM/MONO(2009)39}. A copy of this document may be obtained from the OECD at (http://www.oecd.org/department/0,3355,en_2649_34383_1_1_1_1_1,00.html).

In the 2010 discussion paper prepared by the EWG, Members and Observers were asked to consider and comment on the OECD guidance document for the purpose of elaborating on the definitions of minor use and specialty crops for use by the CCPR and JMPR. In particular comments were requested on the suitability of aspects of the OECD guidance document in providing a basis for definitions, or if additional areas need to be considered in elaborating on such definitions for use by CCPR and JMPR. It was determined at the 42nd CCPR meeting that the EWG should continue to prepare proposals for definitions of minor use and specialty crops for use by the CCPR and JMPR.

Additionally, in the previous discussion paper prepared by the EWG for the 42nd CCPR meeting, several recommendations were made to help facilitate the establishment of Codex MRLs for minor uses. The Committee endorsed most of the recommendations made by the EWG except for the request that the JMPR provide guidance that identifies what minor crops grown on limited world-wide acreage or that have limited dietary intake in which 3 residue field trials to establish a Codex MRL would be acceptable. This recommendation was not endorsed noting the FAO JMPR Secretariat's observation that there was not yet an agreed international definition of minor uses nor any agreed upon data requirements for minor uses.

In the OECD report discussed above two approaches were identified used by countries to define minor uses, the "risk assessment approach" and the "economic return approach".

This OECD report makes it clear that there are many different areas to consider when defining minor uses. Since the EWG is charged with helping to facilitate data submissions to JMPR for the establishment of Codex MRLs on minor crops, the EWG decided to focus the work of defining minor uses and specialty crops for use by the CCPR and JMPR. The definition would be used to determine the minimum number of field trials needed to support a MRL for a minor use to address the issue raised by the FAO JMPR Secretariat. Once there is agreement, the request for JMPR to provide guidance on the number of residue data trials required for minor uses could again be raised to the CCPR and JMPR.

As discussed in the 2009 FAO Manual regarding requirements on the number of supervised field trials needed to support the establishment of an MRL, generally a minimum of 6 to 10 trials are needed to recommend for a MRL. However, there have been some instances when the JMPR has been willing to accept a fewer number of field trials for minor crops. A minor crop has been defined vaguely as something produced in relatively small quantities (acres or tons) and consumed overall as a very small part of the diet (although it could be major in limited geographic areas). Members of the EWG were asked to identify what factors, including total numbers of acres of a crop grown world wide, total production (tonnage), or dietary intake, are appropriate to consider when defining minor uses for risk assessment purposes by the JMPR. Based on the responses received from the EWG, the following two approaches were identified for defining minor uses for consideration by the CCPR.

- Dietary intake contribution as the most important factor with consideration to total cultivation area. Some Members of the EWG indicated that both daily dietary intake contribution and cultivation area can be used as a cut-of point for minor crops but felt dietary intake contribution is the most important consideration. Since Codex MRLs are intended to facilitate trade, even if the total cultivation area is very low and restricted to a certain area there will be the probability of a high consumer encountering a high residue somewhere in the world. It is recommended that the European Union's (SANCO document 7525/VI/95 rev.7) definition for minor use be used to define minor uses for use by CCPR and JMPR for the purposes of setting Codex MRLs:

    a. daily dietary intake contribution <7.5 g (i.e. 7.5 g mean daily consumption over the population for a 60 kg person) and/or

    b. cultivation area < 10000 ha

    However, one Member suggested that the European Union's (SANCO document 7525/VI/95 rev.7) definition for a very minor use be used to define minor uses for use by CCPR and JMPR for the purposes of setting Codex MRLs:

    a. daily dietary intake contribution <1.5 g (i.e. 1.5 g mean daily consumption over the population for a 60 kg person) and/or

    b. cultivation area < 600 ha

    As discussed above the criteria used for classifying a crop or a product as minor or in the European Community (http://ec.europa.eu/food/plant/protection/resources/app-d.pdf) are:

    - daily dietary intake contribution < 7.5 g (i.e. 7.5 g mean daily consumption over the population for a 60 kg person) and/or
    - cultivation area < 10000 ha and
    - production < 200000 tonnes per year.

    Presumably, the EU 7.5 g daily dietary intake criterium is based on the old GEMS/Food Regional diets, in which 7.5 g is 0.4-0.7% (mean 0.6%) of the five total diets in grams per person per day. Please note that 7.5 g is 0.3-0.5 % (mean 0.4%) of the total intake in the current thirteen GEMS/Food Cluster diets.

    To give an indication of which crops could be classified as 'minor crops' when applying a dietary intake criterium only, an inventory is listed in Annex 1 of crops that comply with the EU dietary intake criterium of a daily dietary intake contribution <7.5 g in all 13 GEMS/Food Cluster diets.

    CCPR would need to consider if the 7.5 g daily dietary intake is an acceptable cut-off value and if the dietary intake be <7.5 g in all 13 Cluster diets, or are slight exceptions acceptable. For example, okra has a daily dietary intake < 7.5 g in 12 of the 13 Cluster diets, but the intake is 15.9 g in the remaining diet.

- Total production as the most important factor with consumption addressed by risk assessment. Other Members of the EWG also agreed that for purposes of establishing international trade standards for food/feed commodities, both consumption (safety aspect) and production (trade aspect) should be considered but believe that total production is the most important consideration. If designating a commodity as minor is for purposes of setting the minimum number of field trials to support an MRL, then the argument can be made to look only at production. The safety aspect will be covered by the risk assessment, with the understanding that the MRL is conservative based on a limited data set. A set production amount could be defined below which the commodity is called minor. Based on the definition of the production amount, minor crops would need a minimum number of trials, somewhere between 3 and 6. This number would need to be determined.

    In order to determine the proper cut-off of production for a minor use, one suggestion is to rely on the FAOStat data base for crop production around the world. This data base provides data for a large number of crops. Total production (tonnnes) of all crops can be identified. A production value number (so many tonnes) for distinguishing major from minor would need to be identified. Attached at the end of this document (Annex II) are examples of total production for two crops which JMPR has been willing to accept a reduced residue field trial data set because these crops were considered minor. It would be necessary to look at every crop which could conceivably be called minor. If the crop is not listed in FAOStat, then it is minor by definition.

Another suggestion is to define a percentage cut off point of the global measure. For example, if the percentage threshold is 5% or less then if the world total production of crops on a hectare basis was X, then if the world total production for a single crop on a hectare basis was 5% or less of X then it would be considered a minor crop. A decision would be needed on what the percentage point and measurement parameter to use but in determining the measurement parameter it was recommended it should be a simple parameter that can easily be determined and kept up to date.

C. Facilitating the Establishment of Codex MRLs for Minor Uses and Specialty Crops

Crop Grouping:

The EWG continues to recommend that CCPR 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 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 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 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. However the benefits for the addition of new commodities into the *Codex Classification on Foods and Animal Feeds* may only be fully realized where Codex MRLs can be established for entire crop groups or proposed subgroups. This can only be accomplished after representative commodities are identified and accepted by the CCPR as discussed in the *Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs to Commodity Groups*.

Possible Future Work of the EWG:

If the Committee determines it is appropriate to re-establish the EWG for work during 2011-2012, the EWG Members suggest that future work focus on one particular commodity and go out with a call to Member Countries and companies for any available data/GAPs that can be used to support the establishment of Codex MRLs for that commodity.

As agreed to in the April, 2010 Committee meeting, JMPR will accept data from multiple countries for a specific chemical/commodity which would allow the EWG to facilitate the collection of available data to support the establishment of MRLs on a specific commodity. Two commodities that EWG Members were asked to consider were tea and coffee. These commodities were selected because they are somewhat unique and not necessarily part of a broader crop group. For the most part EWG members agreed with the proposal to concentrate on a single commodity however, some commented that coffee would not be good project since they were considered to be major crop. Papaya and okra were suggested as other possible commodities that should be considered first.

ANNEX I: Example of a minor crops selection based on the EU dietary intake criterium of a daily dietary intake contribution <7.5 g in all 13 GEMS/Food Cluster diets.

001	CITRUS FRUIT
FC 0205	Lime (incl juice)
022	TREE NUTS
TN 0295	Cashew nut
TN 0660	Almond
TN 0662	Brazil nut
TN 0664	Chestnut
TN 0666	Hazelnut
TN 0669	Macadamia nut
TN 0672	Pecan
TN 0673	Pine nut
TN 0675	Pistachio nut
TN 0678	Walnut
002	POME FRUIT
FP 0228	Loquat
FP 0231	Quince
003	STONE FRUIT
FS 0013	Cherries
FS 0014	Plum (incl dried)
FS 0240	Apricot (incl dried)
FS 0245	Nectarine
004	BERRIES AND OTHER SMALL FRUITS
FB 0019	Vaccinium berries (incl. bearberry)
FB 0020	Blueberries
FB 0265	Cranberries
FB 0021	Currants, red, black, white
FB 0264	Blackberries
FB 0266	Dewberries, incl boysen- & loganberry
FB 0267	Elderberries
FB 0272	Raspberries, red, black
FB 0273	Rose hips
FB 0275	Strawberry
005	ASSORTED (SUB)TROPICAL FRUITS - EDIBLE PEEL
FT 0289	Carambola
FT 0291	Carob
FT 0297	Fig (incl dried)
FT 0303	Kumquats
FT 0307	Persimmon, Japanese
FT 0312	Tree tomato

006	ASSORTED (SUB)TROPICAL FRUITS-INEDIBLE PEEL
FI 0332	Custard apple
FI 0335	Feijoa
FI 0336	Guava
FI 0338	Jackfruit
FI 0341	Kiwi fruit
FI 0351	Passion fruit
FI 0352	Persimmon, American
FI 0358	Rambutan
016	ROOT AND TUBER VEGETABLES
VR 0469	Chicory, roots
VR 0494	Radish
VR 0498	Salsify
VR 0578	Celeriac
VR 0583	Horseradish
VR 0585	Jerusalem artichoke
VR 0588	Parsnip
VR 0590	Radish, black
VR 0591	Radish, Japanese
009	BULB VEGETABLES
VA 0380	Fennel, bulb
VA 0381	Garlic
VA 0384	Leek
VA 0387	Onion, Welsh
VA 0388	Shallot
VA 0389	Spring onion
011	FRUITING VEGETABLES, CUCURBITS
VC 0423	Chayote
VC 0433	Winter squash (= pumpkin)
012	FRUITING VEGETABLES OTHER THAN CUCURBITS
VO 0450	Mushrooms
010	BRASSICA
VB 0401	Broccoli, Chinese
VB 0404	Cauliflower
013	LEAFY VEGETABLES
VL 0464	Chard
VL 0470	Corn salad
VL 0472	Cress, garden
VL 0473	Watercress
VL 0480	Kale
VL 0476	Endive
VL 0469	Chicory leaves (green and red)
VL 0492	Purslane
VL 0506	Turnip greens

027	HERBS
HH 0624	Celery leaves
HH 0738	Mints
HH 0740	Parsley
014	LEGUME VEGETABLES
VP 0534	Lima bean (green pods and/or immature seeds)
017	STALK AND STEM VEGETABLES
VS 0469	Witloof chicory (sprouts)
VS 0621	Asparagus
VS 0622	Bamboo shoots
VS 0624	Celery
VS 0627	Rhubarb
-	Bean sprouts
015	PULSES
VD 0534	Lima bean (dry)
VD 0520	Bambara groundnut (dry seed)
VD 0523	Broad bean (dry)
VD 0524	Chick-pea (dry)
VD 0533	Lentil (dry)
VD 0536	Mung bean (dry)
VD 0545	Lupin (dry)
VD 0537	Pigeon pea (dry)
VD 0561	Field pea (dry)
023	OILSEED
SO 0090	Mustard seed (incl flour)
SO 0698	Poppy seed (incl oil)
SO 0699	Safflower seed (incl oil)
SO 0700	Sesame seed (incl oil)
SO 0701	Shea nut
066	TEAS
DT 1114	Tea, green, black (black, fermented and dried)
057	DRIED HERBS
DH 1100	Hops, dry
028	SPICES
HS 0692	Pimento, fruit
HS 0780	Cumin seed
HS 0784	Ginger, root
-d	Anise, badian & fennel
-d	Nutmeg, mace & cardamom
HS 0790	Pepper (black, white)

020	CEREAL GRAINS
GC 0641	Buckwheat (incl flour, incl bran)
GC 0655	Wild rice
024	SEED FOR BEVERAGES AND SWEETS
SB 0715	Cocoa beans (incl mass)
SB 0717	Cola nuts

ANNEX II

Production in Tonnes (2009) from the FAOSTAT data base for Blueberry (JMPR has been willing to accept a reduced residue field trial data set for this crop)	
COUNTRY	PRODUCTION
Blueberry	
Canada	103,070
France	1,000
Germany	4,500
Italy	1,500
Lithuania	1,794
Norway	25
Poland	11,023
Russia	1,700
Sweden	2,500
USA	165,198 (56%)
Uzbekistan	700
TOTAL	293,010

Production in Tonnes (2009) from the FAOSTAT data base for Asparagus (JMPR has been willing to accept a reduced residue field trial data set for this crop)	
Asparagus	
Argentina	7,200
Australia	6,981
Austria	2,479
Canada	7.856
Chile	18,849
China	6,502,667 (90%)
Columbia	82
Denmark	60
France	20,000
Germany	98,200
Hungary	4,649
Israel	83
Italy	33,600
Japan	28,000
New Zealand	2,200
Peru	313,880
Philippines	7,121
Poland	2,000
Slovakia	1,296
South Africa	773
Spain	48,800
Switzerland	388
Macedonia	600
Turkey	18
USA	49,670
TOTAL	7,157,452

ANNEX III

LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

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