

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 5

CX/PR 07/39/3-Add. 1  
April 2007

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON PESTICIDE RESIDUES

Thirty-ninth Session  
Beijing, China, 7 - 12 May 2007

#### **COMMENTS on the Draft and Proposed Draft Maximum Residue Limits for Pesticides in Foods and Feeds at Steps 7 and 4, submitted by Australia, Canada, EC, Guatemala, Kenya, Korea, Japan, United States of America,**

#### 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

### **GUATEMALA**

Dichas observaciones fueron consensuadas entre los miembros que integran el Comité Técnico del Codex de Plaguicidas de Guatemala.

1. Guatemala está consciente que todos los productos deben ser inocuos y siempre apoyaremos esta línea, pero el impacto económico que tendrá dentro de los pequeños y medianos agricultores guatemaltecos será evidente, ya que el cambio en los LMR de algunos plaguicidas de uso frecuente en los cultivos de nuestro país, donde se sugiere la W (se retira la recomendación previa o se recomienda suprimir el LMR recomendado) vendrá a afectar la economía informal nacional, ya que anteriormente los LMR eran más flexibles.

2. Guatemala es un país agropecuario por naturaleza y basa una parte muy importante de su economía en la producción hortícola para consumo nacional y de exportación, por lo que la introducción de nuevos productos como substitutos de los plaguicidas en mención, incrementará los costos de producción de los pequeños y medianos productores versus las ventajas del productor a gran escala, quien puede amortiguar mejor este incremento económico.

3. Además la realidad en una región como la de Guatemala, conlleva a que los pequeños agricultores subdosifiquen los plaguicidas, debido a su ya frágil condición económica. Esta acción de subdosificación hace que la IDA tenga un valor mayor al especificado en el Codex, por consiguiente el Margen de Exposición proporciona aún mayor seguridad al usuario que pueda ingerir alimentos tratados con plaguicidas.

4. De acuerdo con las definiciones de la FAO, emitidas en 1987, “El uso de plaguicidas esta regulado sobre la base de los Limites Máximos de Residuos (LMR) establecidos para residuos en varios cultivos. El establecimiento de un LMR debería, entre otras cosas, tomar en cuenta que la Ingesta Diaria Admisible (IDA) para los humanos de un plaguicida en particular no debe excederse cuando los alimentos son ingeridos por el consumidor. La IDA es definida como “una estimación de la cantidad total de residuos, expresado en base al peso corporal de un ser humano, que puede ser ingerida diariamente a lo largo de la vida de este ser sin poner en riesgo su salud”.

8. De acuerdo con los cálculos realizados con base en los nuevos LMR propuestos por la FAO, consideramos que los mismos fueron distribuidos en una forma poco equitativa y parece ser que con objetivos comerciales, más que por razones de seguridad hacia los consumidores.

9. Finalmente solicitamos de la manera más atenta puedan darnos por lo menos 6 meses más de tiempo, para poder evaluar bajo las condiciones nacionales y con otras autoridades la utilización de estos plaguicidas, ya que muchas de las hortalizas mencionadas se consumen crudas en Guatemala y debemos hacer un diagnóstico acorde a la realidad nacional.

**Captan (007)****AUSTRALIA**

Australia notes that the 2004 JMPR set an ARfD for captan and that THPI could not be excluded as the component of the residue responsible for the toxicological effect, in essence leading to a requirement to include THPI in the residue definition for risk assessment for dietary intake. The JMPR was unable to complete this task at the meeting. Australia recommends that MRLs for captan be returned to Step 6, awaiting further consideration by the 2007 JMPR in relation to inclusion of THPI in the dietary intake assessment.

**Carbaryl (008)****AUSTRALIA**

Existing registrations of carbaryl products are currently under review in Australia, including aspects relating to dietary exposure.

Australia supports the progress of the MRL for citrus fruit to Step 8.

Based on the dietary intake calculations of JMPR 2002, Australia continues to express reservations regarding the MRL recommendations for stone fruits and grapes.

Therefore Australia recommends the draft MRLs are returned to Step 6 pending evaluation of alternative GAP and additional MRLs by the 2007 JMPR

**UNITED STATES OF AMERICA**

The acute dietary intake is exceeded for cherries, grapes, and nectarines, based on the JMPR calculations of 2003, with a variability factor of 3. In response to the scheduled retrospective analysis by the 2007 JMPR, the US EPA searched its evaluations for alternative GAP and found none. The supervised field trial data reviewed by the JMPR for both cherries and grapes reveal one high value considerably beyond the remaining values. The US rejected the extremely high values (09/13/1996, D218865). It is suggested that the JMPR validate or invalidate these extreme values as part of their retrospective analysis (JMPR 2007). The US evaluation has been supplied to the JMPR FAO Secretary.

**Chlorpyrifos (017)****AUSTRALIA**

Australia supports advancement of the MRL for cranberry

**CANADA**

Chlorpyrifos is under re-evaluation in Canada, and interim mitigation measures have been implemented awaiting final decision of the active ingredient pending a refined environmental risk assessment in 2008.

Canada notes that the residue definition is the parent chlorpyrifos in apples, grapes and tomatoes. The residue definition in other commodities is chlorpyrifos and TCP. Canada is aware that this differs from

JMPR's definition. Canada also notes that the ADI and the ARfD are significantly different in Canada. In Canada, the ADI and the ARfD have the same values assigned.

<b>Canada: Toxicological Reference Doses and Endpoints for CHLORPYRIFOS</b>		
<b>ADI</b>	<b>General population</b>	<b>0.01 mg/kg bw/day</b> , based on a NOAEL of 1 mg/kg bw/day derived from numerous repeat dose studies in 3 species, and a standard uncertainty factor of 100.
	<b>Women of child-bearing age (13-50 yrs)</b>	<b>0.001 mg/kg bw/day</b> , based on a LOAEL of 0.3 mg/kg bw/d for pregnant rats in a developmental neurotoxicity study and a 300-fold uncertainty factor (the additional 3-fold factor is included for the fact that there was no NOAEL identified)
	<b>Infants and children (up to age 12)</b>	<b>0.00075 mg/kg bw/day</b> , based on a NOAEL of 0.75 mg/kg bw/d observed for neonatal rats in a 14-day repeat dose study and 1000-fold safety factor (an additional 10-fold factor is included due to increased sensitivity in the young).

### **Diazinon (022)**

#### **AUSTRALIA**

Australia supports advancement of the MRL for cranberry

#### **CANADA**

Canada supports advancement of the MRL for cranberry.

The label for products registered for use on cranberries have been revised to include a restriction against using water from irrigated or flooded cranberry bogs to irrigate other crops (except other crops with registered diazinon uses) or for drinking purposes.

Canada notes that its ADI (0.002 mg/kg bw/day) and ARfD (0.005 mg/kg bw/day) are different from the ones recommended by JMPR.

### **Dimethoate (027)**

#### **AUSTRALIA**

Existing registrations of dimethoate are currently under review in Australia, including aspects relating to dietary exposure.

Based on the IESTI calculations of JMPR 2003, Australia expresses reservations regarding the MRL proposals for head cabbage, head lettuce and sweet peppers, which should be returned to Step 6.

Australia notes that the 2006 JMPR identified some errors in the total residues (dimethoate plus omethoate) estimated by the 2003 JMPR and it is proposed to publish a corrigendum in 2007, following a review of the 2003 data.

It is also noted that a number of MRL revocations for dimethoate have occurred since the dietary intake was last considered by JMPR. These revocations (including tomato) may resolve the long-

term (chronic) intake concerns for the European diet. Australia proposes that CCPR request JMPR to conduct new IEDI calculations taking into account the recent decisions of the last three meetings of CCPR and using the 13 GEMS food cluster diets.

## UNITED STATES OF AMERICA

Acute dietary intake concerns exist for cabbage, lettuce, and peppers, and the US awaits the outcome of the alternative GAP consideration by the 2007 JMPR.

### Endosulfan (032)

## AUSTRALIA

Australia supports the progress of the endosulfan recommendations with the exceptions of those for broccoli, celery, cherries and tomato for which the 2006 JMPR has identified short-term intake concerns that could not be resolved by the consideration of alternative GAP.

Australia notes that the text of the JMPR report records the JMPR's consideration of alternative GAP for endosulfan on these commodities, but this is not clearly indicated in Annex I of the report. Australia recommends that CCPR request the JMPR to include different annotations to Annex I of their reports to clearly indicate when (i) the recommended MRL is based on alternative GAP, and (ii) consideration of alternative GAP failed to resolve intake concerns.

## CANADA

Canada has implemented certain measures in advance of completing a full re-evaluation in order to mitigate potential dietary risk.

In Canada, the registrant has withdrawn support for the use of endosulfan on the same commodities recommended for withdrawal by JMPR.

In Canada, registrants of endosulfan technical and primary data providers no longer support the wettable powder use on tomatoes.

Canada has no objections to the progress of the endosulfan MRL recommendations.

## GUATEMALA

5. La intención del cálculo de la Ingesta Diaria Admisible es cubrir a todos los grupos vulnerables (de cualquier edad) de la población humana. Siendo esto así, nos sorprende ver que el LMR recomendado para Endosulfan en el cultivo de Apio se incremento de 2 a 7 mg/kg. El Instituto de Nutrición de Centro América y Panamá (INCAP) en el reporte de Seguridad Alimentaria de 1999 (el más reciente en Guatemala) indica que el individuo promedio consume 25 gramos de hojas verdes, entre los cuales se incluye el apio. Siendo esto así con el nuevo límite para un guatemalteco de 60 kg de peso corporal podrá ingerir 175 mg de Endosulfan cada vez que consuma apio.

6. El caso del apio en particular es consumido por la alta sociedad en Guatemala en forma de aperitivos. Consideramos que la modificación que se ha hecho a los LMR de Endosulfan entre otros productos ha sido realizada sin un fundamento sólido con base en la dieta de los guatemaltecos, por lo cual se debe reconsiderar la distribución de los LMR por cultivo para el caso de Endosulfan.

### **Fenitrothion (037)**

#### **AUSTRALIA**

Australia notes that the JMPR (2003 and 2004) have identified dietary intake concerns (both acute and chronic) for this compound. Since last evaluated by JMPR for toxicology, there have been changes in methodology used to set both the ADI and ARfD. Further consideration of the ADI and ARfD by JMPR is currently scheduled for 2007. Australia supports retention of fenitrothion MRLs at Step 6 until outstanding dietary issues are resolved.

Fenitrothion is important in Australia for control of plague locust and also finds limited use as a stored grain insecticide.

It is apparent that the intake problems reported by the 2004 JMPR are due to the lack of processing data for sorghum, millet and maize, which leads to overly conservative intake estimates for the African diet.

Australia has approached the manufacturer/registrant of fenitrothion products to explore other options. Consequently Sumitomo International wrote to the CCPR Chairman on 12 April 2005 to advise of plans to modify product labels. Australia will submit new labels for fenitrothion products in 2007. Clarification is sought on the use pattern on stored grain, and whether international registrations can be modified to exclude maize, millet and sorghum and thereby resolve the dietary intake concerns raised by JMPR. The manufacturer is also being approached to determine if suitable data on the effect of cooking on residues can be located to establish a generic processing factor applicable to all cereal grains.

#### **UNITED STATES OF AMERICA**

Fenitrothion has limited use in the US (imported wheat gluten). There are acute dietary intake concerns for cereal grains, and the US awaits the evaluation of new data by the 2007 JMPR.

### **Malathion (049)**

#### **AUSTRALIA**

The 38th CCPR decided to retain MRLs for commodities that may be associated with animal feeding at Step 6, due to lack of an animal transfer study. Australia notes the JMPR has not yet evaluated animal transfer data for malathion.

### **Parathion-methyl (059)**

#### **AUSTRALIA**

Existing registrations of parathion-methyl products are currently under review in Australia.

Australia supports the withdrawal of the draft MRLs for animal feed commodities if there is no commitment to provide animal transfer data for JMPR evaluation.

Thiabendazole (065)**AUSTRALIA**

The 38<sup>th</sup> CCPR decided to return the citrus fruit MRL to step 6 pending submission of data from Morocco to the 2006 JMPR for evaluation. JMPR 2006 evaluated new data for citrus fruits and recommended a new MRL of 5 mg/kg Po. (Annex I JMPR 2006). Australia proposes that the new recommendation replace the existing recommendation of 3 mg/kg Po and be advance to Step 8.

Australia does not support the recommendation of the 2006 JMPR of 5 mg/kg Po for citrus. **Refer to attached Concern Form.**

Australia notes that the highest residue observed in trials according to GAP was 5.2 mg/kg for whole oranges. Australia requests that the meeting proceed with a more appropriate level of 7 mg/kg for citrus fruit or request the JMPR reconsider the 2006 evaluation of the data. A recommendation of 7 mg/kg Po for citrus fruit will not alter the dietary intake estimates provided by the 2006 JMPR as these were based on the high residue and supervised trial median residue values in the edible portion of the fruit from the same dataset.

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

<b>Submitted by: Australia</b>			
<b>Date: 16 March 2007</b>			
<b>Pesticide/ Pesticide Code Number</b>	<b>Commodity/ Commodity Code Number</b>	<b>MRL (mg/kg)</b>	<b>Present Step</b>
Thiabendazole /065	FC0001 Citrus fruits	5 Po	3
<i>Is this a Request for Clarification? no</i>			
<i>Is this a Concern? yes</i>			
<i>Is this a Continuing Concern? No</i>			
<b>Concern</b> ( <i>Specific</i> statement of reason for concern to the advancement of the proposed MRL).  Australia notes that the highest residue observed in trials according to GAP was 5.2 mg/kg for whole oranges and is greater than the proposed maximum residue level.  Australia does not support the recommendation of the 2006 JMPR of 5 mg/kg Po for citrus and requests that the meeting proceed with a more appropriate level of 7 mg/kg for citrus fruit <b>or</b> request the JMPR reconsider the 2006 evaluation of the data.  A recommendation of 7 mg/kg Po for citrus fruit will not alter the dietary intake estimates provided by the 2006 JMPR as these were based on the high residue and supervised trial median residue values in the edible portion from the same dataset.			
<b>Request for Clarification</b> ( <i>Specific</i> statement of clarification requested).			
<i>Do you wish this Concern to be Noted in the CCPR Report? Yes</i>			
<b>Data/Information</b> (Description of each separate piece of data/information which is attached or will be provided to the appropriate JMPR secretary within one month of the CCPR meeting.)			



**UNITED STATES OF AMERICA**

Trials on the post harvest treatment of various citrus were reviewed. There were 23 values, with residues ranging from 1.3 – 5.2 mg/kg. The proposed value of 5 mg/kg fails to account for the value above 5 mg/kg. The appropriate MRL should be 7 mg/kg if the scale system is utilized. Based upon the use of a log normal statistical calculation, the appropriate value is 7, using upward rounding to one significant figure. A concern form is attached.

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

<b>Submitted by: USA</b>			
<b>Date: 18 Apr 2007</b>			
<b>Pesticide/ Pesticide Code Number</b>	<b>Commodity/ Commodity Code Number</b>	<b>MRL (mg/kg)</b>	<b>Present Step</b>
Thiabendazole/065	Citrus/FC01	5	3
<i>Is this a Request for Clarification?</i>			
<i>Is this a Concern? Yes</i>			
<i>Is this a Continuing Concern? No</i>			
<p><b>Concern</b> (<i>Specific statement of reason for concern to the advancement of the proposed MRL.</i>)</p> <p>The trial data (post harvest) ranged from 1.3 to 5.2 mg/kg. The proposed value of 5 mg/kg fails to account for the value above 5 mg/kg. The MRL should be set so as to encompass all valid trial results. The appropriate MRL should be 7 mg/kg if the scale system is utilized and would be 7 mg/kg (rounded up) if the new statistical procedure is used.</p>			
<p><b>Request for Clarification</b> (<i>Specific statement of clarification requested.</i>)</p>			
<i>Do you wish this Concern to be Noted in the CCPR Report? Yes</i>			
<p><b>Data/Information</b> (<i>Description of each separate piece of data/information which is attached or will be provided to the appropriate JMPR secretary within one month of the CCPR meeting.</i>)</p> <p>No additional information/data, but a request for reconsideration.</p>			

## CANADA

Canada supports the recommendation of the 2006 JMPR of 5 mg/kg Po for citrus. However, Canada notes that higher residues of thiabendazole were observed in trials for oranges, and lemons provided to Canada compared to the recommended MRL of 5 ppm by JMPR for citrus fruit. Consequently Canada has established an import MRL of 10 ppm on citrus fruit.

*The highest exposed group in Canada's Dietary Risk Assessment is children 1-2 years old (47.1% of the ADI), with apple juice and orange juice as the major contributors to exposure.*

### Carbendazim (072)

## AUSTRALIA

At 38<sup>th</sup> CCPR, the Committee was advised that the JMPR had set different ARfDs for the general population and for women of child-bearing age while the EC policy was to set one ARfD for the general population only. Australia considers that use of an ARfD based on a toxicological end-point only relevant to woman of child-bearing age for other groups such as children leads to an overestimate of risk.

Australia therefore continues to support the progression of the draft MRLs to Step 8 based on a satisfactory risk assessment by JMPR.

### Disulfoton (074)

## AUSTRALIA

Australia notes the decision of the 38<sup>th</sup> CCPR to return the draft MRLs for broccoli; cabbages, head; cauliflower; lettuce, head and lettuce, leaf to Step 6 because of acute intake concerns. The outcomes of the 2006 JMPR were that the dietary estimates (chronic and acute) remained unchanged following an evaluation of alternative GAP. Australia proposes that the draft MRLs currently at Step 6 be withdrawn, as there is no further possibility of refining the dietary exposure.

Australia notes that in consideration of alternative GAP, re-evaluation of data for cauliflower resulted a ten fold increase in the recommended MRL with greater acute intake concerns.

## CANADA

Canada supports the advancement of the MRL in/on cauliflower.

Canada notes that its ADI and ARfD are different than the ones recommended by JMPR.

<b>Canada: Toxicological Reference Doses and Endpoints for DISULFOTON</b>	
<b>ADI (chronic) mg/kg bw/day:</b>	<b>0.00045 mg/kg bw/day</b> is assessed based on a NOAEL of 0.045 mg/kg bw/day in a 2-year rat feeding study and using a 100-fold safety factor.
<b>ARfD (mg/kg bw/day):</b>	<b>none</b>

## UNITED STATES OF AMERICA

The US notes that a retrospective alternative GAP analysis by the JMPR (2006) did not resolve dietary intake concerns for cabbage, cauliflower, and lettuce. The withdrawal of these MRLs is supported.

### Thiophanate-methyl (077)

## CANADA

Canada supports the recommendations of the 2006 JMPR. However, Canada notes that its ADI and ARfD are different than the ones proposed by JMPR.

<b>Canada: Toxicological Reference Doses and Endpoints for THIOPHANATE-METHYL (TPM)</b>	
<b>Criteria</b>	<b>Information</b>
<b>ADI</b>	0.008 mg/kg bw/day, based on a NOAEL of 8 mg/kg bw/day and a safety factor of 1000.
<b>ARfD</b>	0.13 mg/kg bw/day for the general population, including infants and children based on a NOAEL of 40 mg/kg bw/day and a safety factor of 300.  0.067 mg/kg bw/day for females 13 to 50 years of age, based on a NOAEL of 20 mg/kg bw/day and a safety factor of 300.
<b>Q*</b>	0.0132 (mg/kg bw/d) <sup>-1</sup>

### Fenamiphos (085)

## AUSTRALIA

Existing registrations of fenamiphos products are currently under review in Australia, including aspects relating to dietary exposure.

Australia notes that the 2006 JMPR evaluated alternative GAP for fenamiphos and determined that the acute dietary estimates remained unchanged. Australia proposes that the draft MRLs currently at Step 6 be withdrawn, as there is no further possibility of refining the dietary exposure.

## CANADA

Canada supports the recommendations for melons, except watermelon and watermelon.

Canada notes that all existing registrations in Canada have been voluntarily cancelled by the registrant.

## UNITED STATES OF AMERICA

The US notes that a retrospective alternative GAP analysis by the JMPR (2006) did not resolve dietary intake concerns for peppers, watermelon, and tomato. The US does not have tolerances for these commodities and supports the withdrawal of these MRLs..

### Pirimiphos-methyl (086)

## CANADA

Canada notes that the submission of data in support of the registration of pirimiphos-methyl was withdrawn in 1992.

### Chlorpyrifos-methyl (090)

## AUSTRALIA

Australia agrees with the decision taken at previous sessions of CCPR to hold all draft MRLs at step 6 pending review by JMPR in 2008.

## KOREA

Republic of Korea has no objection to the advancement of the MRL especially for rice. At 37<sup>th</sup> CCPR, Korea submitted a suggestion of chlorpyrifos-methyl MRLs for rice as a CRD 19. At that time, rice consumption in Korea was very high but nowadays its rates decreased. Dietary intake data of Korea has been updated in 4 years cycle and this data changed in 2006. Based on this dietary intake data, the risk assessment of chlorpyrifos-methyl has shown that there is no safety concern on a proposed MRL for rice. As a reference data for the proposal of Korea, NTMDI data for chlorpyrifos-methyl are suggested as follows;

### National Theoretical Maximum Daily Intake(NTMDI)

- Pesticide Code - 90
- Name - Chlorpyrifos-methyl
- ADI - 0.01 mg/kg Body weight or **550** /person(55 kg)

Commodity		Korea				
		MRL mg/kg	DIET(g/day)		INTAKE( $\mu$ g/day)	
			former data	2006(year)	former data	2006(year)
Code	Name					
FV	Pepper/fresh-Korean	0.1	7.1	24.27	0.71	2.427
GC0640	Barley	6.0	5	4.62	30	27.72
GC0645	Maize	6.0	32.1	9.53	192.6	57.18
GC0647	Oat	6.0	0.1	0.04	0.6	0.24
GC0651	Sorghum	6.0	0.2	0.45	1.2	2.7

GC0654	Wheat	6.0	54.6	52.48	327.6	314.88
<b>GC0649</b>	<b>Rice</b>	<b>0.1</b>	<b>286.7</b>	<b>236.61</b>	<b>28.67</b>	<b>23.661</b>
MM0812	Cattle meat	0.05	26.2	26.2	1.31	1.31
MF0812	Cattle fat	0.05	3	3	0.15	0.15
MO0812	Cattle Edible offal of	0.05	9.3	9.3	0.465	0.465
PM0840	Chicken	0.05	9	9	0.45	0.45
PF0840	Chicken fat	0.05	1	1	0.05	0.05
PO0840	Chicken Edible offal of	0.05	3.2	3.2	0.16	0.16
ML0106	Milkes	0.01	91.9	91.9	0.919	0.919
PE0112	Eggs	0.05	20.8	20.8	1.04	1.04
<b>Total</b>			585.924		<b>433.352</b>	
<b>% ADI</b>			106.5		<b>78.79</b>	

#### UNITED STATES OF AMERICA

The manufacturer has notified us that they are supporting the periodic reevaluation process to begin with the 2008 JMPR, for which revised GAP and new residue trials will be available. They believe that dietary intake concerns (barley, oats, rice) can be resolved through this reevaluation and that no action on the pending MRLs needs to be taken.

#### Methomyl (094)

#### AUSTRALIA

The 2001 JMPR recommended different MRLs for apples (2 mg/kg) and pears (0.3 mg/kg) based on different use-patterns. Australia notes that the JMPR did not raise dietary intake concerns for pears and considers the draft MRL for pears should be advanced to step 8.

Australia considers the other draft MRLs at Step 6 should be returned to Step 6 until the JMPR has considered alternative GAP and the replacement of the group MRL for cucurbits with MRLs for individual cucurbit commodities, as requested by the 38<sup>th</sup> CCPR.

#### UNITED STATES OF AMERICA

Acute dietary intake concerns exist for apple, brassica vegetables, grapes, and leafy vegetables, based on the revised dietary intake calculations performed by the 2003 JMPR (variability factor 3, as appropriate). The US notes that methomyl has been referred to a future JMPR (2008) for retrospective analysis.

**Acephate (095)****AUSTRALIA**

Australia supports advancement of the MRL for cranberry

**CANADA**

Canada supports advancement of the MRL for cranberry. Canada notes that the ADI and ARfD are different than the ones recommended by JMPR.

<b>Canada: Toxicological Reference Doses and Endpoints for ACEPHATE</b>		
<b>Exposure Scenario</b>	<b>Dose Used in Risk Assessment, UF</b>	<b>Study and Toxicological Effects</b>
<b>Acute Dietary</b> General US pop.	NOAEL = 0.5 mg/kg/day UF = 100 Acute RfD = 0.005 mg/kg/day	Rat acute neurotoxicity study (inhibition of brain cholinesterase)
<b>Chronic Dietary</b> all populations	LOAEL = 0.12 mg/kg/day UF = 100 Chronic RfD = 0.0012 mg/kg/day	13-week rat dietary toxicity study (inhibition of brain cholinesterase) LOAEL = 0.12 mg/kg/day (LOAEL was considered to represent a threshold NOAEL)
Cancer	None	

**UNITED STATES OF AMERICA**

There are numerous acute dietary intake concerns (flowerhead brassicas, mandarins, nectarine, peach, peppers, pome fruits), based on the ARfD set in 2005. The US notes that acephate has been referred to the JMPR secretariat for retrospective analysis and awaits the outcome of this yet-to-be scheduled consideration.

**Carbofuran (096)****AUSTRALIA**

Australia agrees with the decision of the 38<sup>th</sup> CCPR to return all draft MRLs to Step 6 pending the JMPR's review of the ARfD and evaluation of additional residue data.

**UNITED STATES OF AMERICA**

Numerous delegations previously expressed dietary intake concerns for carbofuran, although the JMPR (2004) found no concerns. The USA has supplied its review of a new toxicity study to the WHO secretary of JMPR, and will work with the WHO to gain release of that study to the JMPR (2008).

**Methamidophos (100)****AUSTRALIA**

Australia considers the draft MRLs for both acephate and methamidophos should be retained at Step 6 pending the JMPR's consideration of alternative GAP, as requested by the 38<sup>th</sup> CCPR.

**UNITED STATES OF AMERICA**

There are numerous acute dietary intake concerns (cabbage, flowerhead brassicas, mandarins, nectarine, peach, peppers, pome fruits, tomato). The US notes that methamidophos has been referred to the JMPR secretariat for retrospective analysis (jointly with acephate) and awaits the outcome of this yet-to-be scheduled consideration

**Pirimicarb (101)****AUSTRALIA**

Australia supports the recommendations of the 2006 JMPR.

**CANADA**

Canada supports the recommendations of the 2006 JMPR to withdraw uses. Note that the registrant no longer supports pirimicarb registrations in Canada and all uses have been discontinued.

Pirimicarb has outstanding toxicology issues. Only a provisional ADI (pADI) has been established, and a dietary risk assessment cannot be conducted.

MRLs have been previously established on apple (0.5 ppm), celery (0.2 ppm), and spinach (0.1 ppm). No other MRLs have been established; therefore residues of pirimicarb equivalents on imports will be covered by subsection B.15.002 (1) of Division 15 of the Food and Drugs Act and Regulations.

**Phosmet (103)****AUSTRALIA**

Australia suggests the draft MRLs should be retained at Step 6 pending the JMPR's consideration of alternative GAP, as requested by the 38<sup>th</sup> CCPR.

**UNITED STATES OF AMERICA**

There is an acute dietary intake concern with pome fruit and children, per the 2003 JMPR. The US awaits the retrospective analysis by the 2007 JMPR, although we found no relevant data in our files that would support an alternative GAP.



**Dithiocarbamates (105)****AUSTRALIA**

Acute dietary concerns with propineb and peppers have been highlighted by the 2004 JMPR, therefore Australia does not support advancement of the MRL for sweet peppers.

**UNITED STATES OF AMERICA**

An acute dietary intake concern exists for propineb on peppers (110% general population and 120% children), JMPR 2005. It is noted that this is based on a temporary and most likely conservative ARfD. The WHO JMPR stated that refinement was possible with an appropriate single dose study. Propineb is not registered in the USA, and therefore we have no suitable toxicology studies for this compound

**Phorate (112)****AUSTRALIA**

(at Step 6) Based on the acute intake concerns expressed by the 2005 JMPR, Australia does not support the advancement of the MRL for potato.

**UNITED STATES OF AMERICA**

The acute dietary intake for children of micro waved potato with peel is 120% of the ARfD. This represents the worst possible case for consumption of potato with peel, but is also a realistic scenario from the US standpoint. Examination of the data base submitted to the JMPR (2005) indicates no alternate field trial studies with alternative GAP.

**Propargite (113)****AUSTRALIA**

Australia supports the recommendations of the 2006 JMPR.

**CANADA**

Canada does not support the recommendations of the 2006 JMPR. In Canada, the ADI is 0.0012 mg/kg bw/day and the PDI is 1926% of the ADI.

The use of propargite is no longer supported in Canada, and all uses have been discontinued.

**Aldicarb (117)****AUSTRALIA**

Australia has concerns over the acute dietary intake of aldicarb from potatoes (JMPR 2001) and bananas (JMPR 2002). Following an evaluation of alternative GAP, the outcomes of the 2006 JMPR were that the acute dietary estimates remained unchanged. Australia proposes that the draft MRLs currently at Step 6 be withdrawn, as there is no further possibility of refining the dietary exposure.

**CANADA**

Canada has an MRL of 0.5 ppm for aldicarb in/on potato which is the same as that proposed by the JMPR. However, aldicarb is no longer supported by the registrant. All uses of aldicarb have been discontinued.

**UNITED STATES OF AMERICA**

The short term dietary intake is exceeded for children for bananas and for the general population and children for potatoes. This was based on refined deterministic assessments performed by the 2001 and 2002 JMRPs, using extensive banana data and actual single potato data. Thus, there seems little room for refinement. The US notes that it is reconsidering its acute reference dose in 2007.

**Cypermethrins (118)****CANADA**

Canada notes that the toxicological end-points are significantly different from the ones proposed by JMPR.

<b>Canada: Toxicological Reference Doses and Endpoints <span style="color: blue;">CYPERMETHRINS</span></b>		
<b>Exposure Scenario</b>	<b>Dose Used in Risk Assessment, UF</b>	<b>Study and Toxicological Effects</b>
<b>Acute Dietary</b>	LOAEL = 20 mg/kg/day UF = 300 <b>Acute RfD = 0.07 mg/kg/day</b>	Acute neurotoxicity study in rats. LOAEL of 20 mg/kg/day based on <i>decreased</i> motor activity and gait abnormalities, and an uncertainty factor of 300 (3x for the use of a LOAEL, 10x for intraspecies variation and 10x for interspecies variation).
<b>Chronic Dietary</b>	NOAEL = 5 mg/kg/day UF = 100 <b>Chronic RfD = 0.05 mg/kg/day</b>	1-year dog study (capsule), 2-year rat chronic study (dietary), and the rat reproductive toxicity study (dietary).  NOAEL of 5 mg/kg/day based on clinical signs associated with neurotoxicity and reduced body weight gains (dog); <i>lower</i> food intake and <i>lower</i> body weights (rat, chronic);

Canada: Toxicological Reference Doses and Endpoints <b>CYPERMETHRINS</b>		
Exposure Scenario	Dose Used in Risk Assessment, UF	Study and Toxicological Effects
		and <i>lower</i> food consumption, body weights, mean number of pups born alive, mean number of pups surviving at days 7 and 21, and mean litter weights at days 4, 14, 21 (rat, reproductive). An uncertainty factor of 100 (10x for intraspecies variation and 10x for interspecies variation) was used.
<b>Cancer</b>	No Q* value was established for cypermethrin.	

### Oxamyl (126)

#### AUSTRALIA

Australia does not support progression of the MRLs for citrus fruits, cucumber, melons except watermelons and peppers on the basis of the IESTI calculations of JMPR 2002. Australia considers the draft MRLs should be returned to Step 6 pending the JMPR's consideration of alternative GAP as requested by the 38<sup>th</sup> CCPR.

EC

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

<b>Submitted by: European Community</b>			
<b>Date:</b>			
<b>Pesticide/ Pesticide Code Number</b>	<b>Commodity/ Commodity Code Number</b>	<b>MRL (mg/kg)</b>	<b>Present Step</b>
Oxamyl (126)	Citrus FC 0001	3	6
	Cucumber VC 0424	1	6
	Melon VC 0046	1	6
	Pepper VO 0051	5	6
<i>Is this a Request for Clarification?</i>			
<i>Is this a Concern? Yes</i>			
<i>Is this a Continuing Concern? Yes</i>			
<b>Concern</b> ( <i>Specific statement of reason for concern to the advancement of the proposed MRL.</i> )  Acute intake concern for the above commodities with exceedence of the ARfD			
<b>Request for Clarification</b> ( <i>Specific statement of clarification requested.</i> )			
<i>Do you wish this Concern to be Noted in the CCPR Report? YES</i>			
<b>Data/Information</b> (Description of each separate piece of data/information which is attached or will be provided to the appropriate JMPR secretary within one month of the CCPR meeting.)			

**UNITED STATES OF AMERICA**

There are short term dietary intake concerns for citrus, apple, cucumber, melons, peppers, and tomato, and the compound has been referred to the Joint Secretariat of JMPR for retrospective analysis (2008). We note that the NOAELs derived in the US and JMPR are similar, but the Codex ARfD is about 10X greater due to the use of human data.

**Prochloraz (142)****AUSTRALIA**

Australia does not support the progression of the MRL for mushrooms on the basis of IESTI calculations of the 2004 JMPR which identified acute intake concerns. Australia is of the understanding that UK GAP leads to the high residue, whereas GAP in other European countries leads to lower residues. Australia suggests that CCPR request the JMPR to consider alternative GAP for this use.

**EC**

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

<b>Submitted by: European Community</b>			
<b>Date:</b>			
<b>Pesticide/ Pesticide Code Number</b>	<b>Commodity/ Commodity Code Number</b>	<b>MRL (mg/kg)</b>	<b>Present Step</b>
Prochloraz (142)	Mushrooms VO 0450	40	6
<b><i>Is this a Request for Clarification?</i></b>			
<b><i>Is this a Concern? Yes</i></b>			
<b><i>Is this a Continuing Concern? Yes</i></b>			
<b><i>Concern</i></b> (Specific statement of reason for concern to the advancement of the proposed MRL). Acute intake concern for the above commodities with exceedence of the ARfD			
<b><i>Request for Clarification</i></b> (Specific statement of clarification requested).			
<b><i>Do you wish this Concern to be Noted in the CCPR Report? YES</i></b>			
<b><i>Data/Information</i></b> (Description of each separate piece of data/information which is attached or will be provided to the appropriate JMPR secretary within one month of the CCPR meeting.)			

**UNITED STATES OF AMERICA**

Prochloraz is not registered in the USA, and any study evaluations in our possession that might help resolve short term dietary intake concerns for mushroom are outdated (1980's).

**Carbosulfan (145)****AUSTRALIA**

Australia notes the 38<sup>th</sup> CCPR decided to return the draft MRLs for mandarin; oranges, sweet, sour; and potato to Step 6 in line with the decisions on these commodities for carbofuran, as they were based on the use of carbofuran.

**Propamocarb (148)****AUSTRALIA**

Australia supports the recommendations of the 2006 JMPR.

**CANADA**

Canada supports the MRL recommendations of the 2006 JMPR.

Canada notes that it has not established an acute reference dose. Also, the Canadian residue definition for monitoring, MRL and risk assessment in livestock commodities is propamocarb, AE B132675, AE F155306, AE B132679, and propamocarb glucuronide.

**EC**

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

<b>Submitted by: European Community</b>			
<b>Date:</b>			
<b>Pesticide/ Pesticide Code Number</b>	<b>Commodity/ Commodity Code Number</b>	<b>MRL (mg/kg)</b>	<b>Present Step</b>
Propamocarb (148)	Cauliflower VB 0404	0.2	3/6
	Spinach VL0504	40	3/6
<b><i>Is this a Request for Clarification?</i></b>			
<b><i>Is this a Concern? No</i></b>			
<b><i>Is this a Continuing Concern? No</i></b>			
<b><i>Concern</i></b> (Specific statement of reason for concern to the advancement of the proposed MRL).			
<b><i>Request for Clarification</i></b> (Specific statement of clarification requested).			
For cauliflower the draft MRL was based on 4 trials with PHI of 14 or 21 days. (Source JMPR summary report 2006). Are there additional trials available to support the MRL?			
For spinach, a draft MRL of 40 mg/Kg was based on 4 trials. Clarification required on GAP used and if other trials can be used to support the MRL.			
<b><i>Do you wish this Concern to be Noted in the CCPR Report? No</i></b>			
<b><i>Data/Information</i></b> (Description of each separate piece of data/information which is attached or will be provided to the appropriate JMPR secretary within one month of the CCPR meeting.)			



## GUATEMALA

7. Otro caso crítico es el incremento del LMR de Propamocarb en lechuga que se incrementa de 10 a 100 mg/kg. De acuerdo con el mismo informe de INCAP mencionado en el numeral dos, un individuo consume 25 gamos de hojas verdes, entre estos está también la lechuga. Nuevamente siendo esto para un guatemalteco de 60 kg de peso corporal podrá ingerir 2,500 mg. de Propamocarb.

### Cyfluthrin/beta-cyfluthrin (157)

## CANADA

Canada notes that its reference doses for cyfluthrin are significantly different from the ones proposed by JMPR.

<b>Canada: Toxicological Reference Doses and Endpoints <span style="color: blue;">CYFLUTHRIN (β-CYFLUTRHIN – not registered)</span></b>	
<b>ADI (chronic) mg/kg bw/day:</b>	<b>0.02 mg/kg bw</b> based on the NOEL of 2.0 mg/kg bw/day that was established for chronic toxicity/carcinogenicity in the rat and a 100-fold safety factor.
<b>ARfD (mg/kg bw/day):</b>	<b>None established in Canada</b>

### Propiconazole (160)

## CANADA

Canada supports advancement of the MRL for cranberry.

Canada notes that there is no Canadian residue data at GAP for cranberries.

Canada also notes that the residue definition is different than the one proposed by JMPR. In Canada, the residue definition in plant and animal matrices is propiconazole and the metabolites containing the 2,4-dichlorophenyl moiety. The toxicological end-points in Canada differ from the ones reported by JMPR.

<b>Canada: Toxicological Reference Doses and Endpoints for <span style="color: blue;">PROPICONAZOLE</span></b>		
<b>Exposure Scenario</b>	<b>Dose Used in Risk Assessment, UF</b>	<b>Study and Toxicological Effects</b>
<b>Acute Dietary</b>	NOEL = 90 mg/kg bw/day UF = 100 <b>ARfD = 0.9 mg/kg bw/day</b>	Acute toxicity was observed in the rabbit teratology study. A clinical sign of sedation was observed in the high-dose (180 mg/kg bw/day) obtained in the chronic toxicity and oncogenicity study in the rat and a 100-fold safety factor. In addition this NOEL provides an approximately 10-fold additional margin of exposure for the fetotoxicity NOEL of 30

Canada: Toxicological Reference Doses and Endpoints for <b>PROPICONAZOLE</b>		
Exposure Scenario	Dose Used in Risk Assessment, UF	Study and Toxicological Effects
		mg/kg bw/day established in the rat teratology study.
<b>Acute Dietary</b>		No toxicological acute endpoint was established for any population subgroups
<b>Chronic Dietary all populations</b>	NOEL= 3.6 mg/kg/day UF = 100 <b>Chronic RfD = 0.04 mg/kg/day</b>	Based on the chronic toxicity and oncogenicity study in the rat. The NOEL provides an approximately 10-fold additional margin of exposure for the fetotoxicity NOEL of 30 mg/kg bw/day established in the rat teratology study.

### Oxydemeton-methyl (166)

#### AUSTRALIA

Australia proposes that the MRLs for apple, head cabbage, grapes and oranges should be returned to Step 6 due to acute dietary concerns raised by JMPR 2004.

#### UNITED STATES OF AMERICA

There are short-term dietary intake concerns for apple, cabbages, grapes, and oranges, and the compound has been referred to the JMPR Secretariat for retrospective analysis at a future date.

### Cyromazine (169)

#### CANADA

Canada notes that its ADI, ARfD are different from the ones proposed by JMPR.

Canada: Toxicological Reference Doses and Endpoints for <b>CYROMAZINE</b>		
Exposure Scenario	Dose Used in Risk Assessment, UF	Study and Toxicological Effects
<b>Acute Dietary</b>	<b>Not applicable</b>	No acute hazards identified at the time of the most recent review.
<b>Chronic Dietary</b>	NOAEL= 1.6 mg/kg/day UF = 100 <b>Chronic RfD = 0.016 mg/kg/day</b>	2-generation rat reproductive study NOAEL = 1.6 mg/kg/day based on reproductive toxicity.  (This ADI provides an acceptable margin of safety (625-fold) to the NOEL for maternal

<b>Canada: Toxicological Reference Doses and Endpoints for <b>CYROMAZINE</b></b>		
<b>Exposure Scenario</b>	<b>Dose Used in Risk Assessment, UF</b>	<b>Study and Toxicological Effects</b>
		and developmental effects seen in the rabbit as well.)
<b>Cancer</b>	Q* = none	No evidence of carcinogenic potential.

### **Fenproparthrin (185)**

#### **AUSTRALIA**

Australia supports the recommendation for tea.

#### **CANADA**

Canada has no objection to the MRL recommendation for tea.

Canada notes that fenproparthrin is not registered for use in Canada.

### **Fenpyroximate (193)**

#### **AUSTRALIA**

Based on the IESTI calculations of the 2004 JMPR, Australia has reservations about the MRLs for apples and grapes that should be returned to Step 6.

#### **UNITED STATES OF AMERICA**

There is a short term dietary intake concern for apples (children 130%) and grapes (120% general population, 310% children). It is noted that the 2007 WHO JMPR will be reconsidering the acute reference dose. The JMPR previously decided that a study used by the US used to establish its ARfD is not relevant to short term effects. The US ARfD is a factor of 5X above that recommended by the JMPR.

### **Haloxypop (194)**

#### **AUSTRALIA**

Australia notes that the 2006 JMPR established an ADI and acute RfD for haloxypop (including the racemic haloxypop, haloxypop-R and their esters).

As noted at the 38<sup>th</sup> CCPR, Australia considers that the MRL for cattle meat should be set in the fat. The most recent review of haloxypop by JMPR was not a periodic evaluation and the meeting was not in a position to redefine the residue as being 'fat-soluble', hence JMPR recommended an MRL for cattle meat at 0.05 mg/kg. This was based on residues in the feeding study of: 0.03 mg/kg for meat and 0.53 mg/kg for fat.

In the 2005 JMPR general considerations item *Fat-Soluble pesticides in Meat and Fat* it is clearly shown that haloxyfop residues should be classified as ‘fat soluble’ and MRLs should be set for meat (fat) and if possible milk fat.

Australia therefore proposes that all draft MRLs are held at Step 6 and the compound is scheduled for a **periodic re-evaluation** on the basis that national GAPs for the compound may have changed and the need to review the MRLs for animal commodities with regard to residue definition and fat solubility. This will also provide JMPR with the opportunity to extrapolate the cattle MRLs to other livestock species.

### **CANADA**

Canada notes that haloxyfop is not registered for use in Canada.

### **JAPAN**

Japan does not support advancing the proposed draft MRLs of haloxyfop (for cattle kidney; cattle liver; cattle meat and cattle milk) beyond Step 4 because of dietary intake concern. The 2006 JMPR did not conduct either long-term or short-term intake assessment for haloxyfop as the residue data available were inappropriate: they were mostly outdated and did not seem to reflect the current GAP. Therefore, the proposed draft MRLs for haloxyfop should be returned to Step 3 and remain at this step until JMPR conducts re-evaluation of residue data and intake assessment. Furthermore, the IEDIs from cattle milk (0.0051-0.063 mg/day) calculated by the 2001 JMPR using the STMR (0.22 mg/kg) exceed the ADI (0.012 mg for a 60 kg person) in three of the five regional diets. Even with a newer ADI of 0.0007 mg/kg body weight (0.04 mg for a 60 kg person) and the 13 Cluster Diets, the IEDIs calculated for cattle milk (0.0076-0.0628 mg/day) exceed the ADI in four of the 13 diets (six of the 13 if the body weight of 55 kg is used). Therefore, the current proposed draft MRL for cattle milk (0.3 mg/kg) is not appropriate for protecting the health of consumers and should not be advanced beyond Step 4.

## **Esfenvalerate (204)**

### **AUSTRALIA**

Australia supports the retention of these MRLs at step 6 until fenvalerate MRLs are phased out.

## **Imidacloprid (206)**

### **AUSTRALIA**

Australia supports advancement of the MRL for cranberry.

### **CANADA**

Canada supports advancement of the MRL for cranberry.

**Methoxyfenozide (209)****AUSTRALIA**

Australia proposes that the MRL for spinach should not advance beyond Step 6 due to acute dietary concerns identified by the JMPR.

Australia supports advancement of the MRL for cranberry.

**CANADA**

Canada supports advancement of the MRL for cranberry.

**UNITED STATES OF AMERICA**

There is a short term dietary intake concern for spinach (children 310%). Most countries, the US included, did not find a significant effect related to acute dietary exposure. However, the JMPR interpretation is scientifically valid. Any refinement would most likely be with the residue level and would necessitate a *substantial* decrease in application rate or increase in PHI (current US label: 0.28 kg ai/ha, 1 d PHI).

**Pyraclostrobin (210)****AUSTRALIA**

Australia supports the recommendations of the 2006 JMPR.

Australia notes the commodity description for VP0064 is Peas, shelled (succulent seeds) and not Peas (immature succulent seeds) as listed in Annex I of the JMPR report. Australia seeks clarification of the actual commodity to which the MRL is meant to apply.

Australia notes that when the GAP leading to highest residues on head lettuce was found to lead to a potential exceedence of the ARfD, the 2006 JMPR considered the next alternative GAP available (Belgium and UK) and estimated a highest residue of 0.81 mg/kg enabling a maximum residue level recommendation to be made that does not lead to short-term intake concerns. Australia supports the continued application of alternative GAP by the JMPR in situations where there are short-term intake concerns.

**CANADA**

Canada supports the recommendations of the 2006 JMPR.

Canada notes that its residue definition for compliance with MRL and for dietary intake estimation is different than the one defined by JMPR.

<b>Canada: Residue Definition for PYRACLOSTROBIN</b>	
<b>PLANT STUDIES</b>	
<b>RD FOR MONITORING, MAXIMUM RESIDUE LIMIT AND RISK ASSESSMENT Enforcement method #D9808</b>	pyraclostrobin and the desmethoxy metabolite BF 500-3 ([2-[[[1-(4-chlorophenyl)-1 <i>H</i> -pyrazol-3-yl]oxy]methyl]phenyl]carbamate)

<b>(LC-MS/MS) and #D9904 (HPLC-UV)</b>	
<b>ANIMAL STUDIES</b>	
<b>RD FOR MONITORING, MAXIMUM RESIDUE LIMIT AND RISK ASSESSMENT Enforcement method#439/0 for livestock (HPLC-UV), #446/1 for ruminant (LC-MS/MS)<sup>2</sup> and #D9902 for poultry matrices (LC-MS/MS)</b>	<b>RD in ruminant matrices:</b> pyraclostrobin and the metabolites hydrolyzable to BF 500-5 (1-(4-chlorophenyl)-1 <i>H</i> -pyrazol-3-ol) and BF 500-8 (1-(4-chloro-2-hydroxyphenyl)-1 <i>H</i> -pyrazol-3-ol); <b>RD in poultry matrices:</b> pyraclostrobin and the metabolites hydrolyzable to BF 500-5 (1-(4-chlorophenyl)-1 <i>H</i> -pyrazol-3-ol) and BF 500-9 (1-(3-chloro-4-hydroxyphenyl)-1 <i>H</i> -pyrazol-3-ol)

Also, Canada notes that its toxicological end-points are different than those proposed by JMPR.

<b>Canada: Toxicological Reference Doses and Endpoints for PYRACLOSTROBIN</b>		
<b>Exposure Scenario</b>	<b>Dose Used in Risk Assessment, UF</b>	<b>Study and Toxicological Effects</b>
Acute Dietary females 13+	NOAEL = 5 mg/kg/bw/day UF = 300 <b>Acute RfD = 0.017 mg/kg bw/day</b>	For females 13+ years, the study considered most appropriate in the submitted toxicological data base is the rabbit teratology study. The dose and endpoint selected for acute risk assessment is 5 mg/kg bw/d (increased resorptions/litter and increased total resorptions, i.e., dams with complete litter loss, at 10 mg/kg bw/d). For the calculation of the ARfD, an uncertainty factor (UF) of 300 is proposed
Chronic Dietary	NOAEL= 9 mg/kg bw/day MOE = 3000 <b>interim Chronic RfD = 0.003 mg/kg bw/day</b>	As a maximum tolerated dose was not attained in the mouse oncogenicity study, rat oncogenicity study, rat chronic study, rat reproduction study and 28-day dermal study, <b>a definitive ADI could not be determined.</b>  The most appropriate toxicological endpoint is duodenal hyperplasia, which may progress to neoplasia following long-term exposure. The lowest NOAEL for duodenal hyperplasia was 9.0/9.6 mg/kg bw/d, which was seen in the 28-day rat dietary study. The PMRA therefore considered that for an interim period of 5 years, an MOE of 3000x (i.e., 10x for interspecies differences, 10x for intraspecies differences, 10x for data deficiencies and 3x for the increase in the qualitative susceptibility of the rabbit fetuses) would provide an adequate margin of safety for this endpoint.
<b>Cancer</b>	No Q* value was established for pyraclostrobin.	

### **Fludioxonil (211)**

#### **AUSTRALIA**

Australia supports the recommendations of the 2006 JMPR.

#### **CANADA**

Canada supports the MRL recommendations of the 2006 JMPR.

Canada notes that the residue definition for livestock matrices is fludioxonil *per se*. This differs from the JMPR's definition which also includes metabolites.

### **Metalaxyl-M (212)**

#### **AUSTRALIA**

Australia considers CXLs are not currently necessary for metalaxyl-M as they are covered by existing MRLs for metalaxyl. The draft MRLs for metalaxyl-M should remain at Step 6 until such time as CXLs for metalaxyl are withdrawn.

#### **UNITED STATES OF AMERICA**

The USA requests retention of the MRLs for metalaxyl where there is no corresponding metalaxyl-M commodity MRL until such time as supervised field trials can be submitted for either metalaxyl or metalaxyl-M. Commodities of interest to the USA include: asparagus, avocado, broccoli, sugar beet, broccoli, Brussels sprouts, cabbage, cauliflower, citrus, cotton seed, cereal grains, hops, peanut, raspberry, soya bean (dry), cucumber, melon, watermelon, and squash.

### **Indoxacarb (216)**

#### **AUSTRALIA**

(at Step 6) Based on acute intake concerns expressed by the 2005 JMPR, Australia does not support the advancement of the MRL for cabbage head.

Australia supports advancement of the draft MRLs for lettuce leaf, milks and milk fats to Step 8.

#### **UNITED STATES OF AMERICA**

The acute dietary intake for children of cabbage is about 130% of the ARfD. This evaluation is based upon 8 field trials from SA and USA, with residues as high as 2.7 mg/kg. We note that the JMPR Evaluation (2005) contains alternate field trial data from Europe, 22 trials with a maximum residue of 0.09 mg/kg. It appears that an alternative GAP analysis would resolve the dietary intake issue for indoxacarb on cabbage. It is noted that indoxacarb is on the 2007 FAO JMPR schedule.

**Bifenazate (219)****AUSTRALIA**

Australia supports the progress of the 2006 JMPR recommendations for bifenazate.

**CANADA**

Canada supports the progress of the 2006 JMPR MRL recommendations for bifenazate. Canada notes that the residue definition for monitoring, MRL and risk assessment in plant matrices and animal fat is bifenazate and the metabolite D3598 (diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester. In milk and tissues, except fat, the residue definition is bifenazate and D3598 (diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester), A1530 (1,1'-biphenyl,4-ol) and A1530-sulfate (1,1'-biphenyl,4-ol sulfate).

**KENYA**

MO 0105 Edible offal (mammalian)-----0.01\*(mg/kg)

PE0112 Eggs -----0.01\* (mg/kg)

ML0106 milk -----0.01\*(mg/kg)

PM0110 poultry meat. -----0.01\*(mg/kg)

PO0 0111 poultry ,edible offal of ----0.01\* (mg/kg)

Kenya noted that the limit of quantification is the same as MRL in some cases, the sensitivity of method currently used for this analysis needs to be reviewed. More data is needed from JMPR considering that it is a new compound and it is widely used.

**UNITED STATES OF AMERICA**

The JMPR recommendation of 0.05 mg/kg for meat (fat) is questioned. The diet calculation for beef cattle (page 66 of the Report) utilized a high residue value of 18 mg/kg for cotton fodder, presumably cotton gin byproducts, and the main contributor (90%) to the residue in the cattle diet. The storage stability section of the same Report notes stability issues with bifenazate in cotton commodities (page 59). The US believes that up to 50% of the bifenazate residue may be lost due to storage instability in cotton gin trash. It appears that the cotton gin byproduct samples from the supervised field trials were stored for a substantial interval prior to analysis. Actual crops fed to cattle might not be stored for long intervals. Thus, it might be appropriate to upwardly adjust the cotton "forage" value from 18 to approximately 30 mg/kg. This would significantly increase the cattle exposure. This in turn would lead to a higher estimate of the meat (fat) MRL. A concern form is attached.



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

<b>Submitted by: USA</b>			
<b>Date: 18 Apr 2007</b>			
<b>Pesticide/ Pesticide Code Number</b>	<b>Commodity/ Commodity Code Number</b>	<b>MRL (mg/kg)</b>	<b>Present Step</b>
Bifenazate/219	Meat (fat)/MM095	0.05	3
<b><i>Is this a Request for Clarification? Yes</i></b>			
<b><i>Is this a Concern? Yes</i></b>			
<b><i>Is this a Continuing Concern? No</i></b>			
<p><b><i>Concern</i></b> (<i>Specific statement of reason for concern to the advancement of the proposed MRL.</i>)</p> <p>The JMPR recommendation of 0.05 mg/kg for meat (fat) is questioned. The diet calculation for beef cattle (page 66 of the Report) utilized a high residue value of 18 mg/kg for cotton fodder, presumably cotton gin byproducts, and the main contributor to the residue in the cattle diet. The storage stability section of the same Report notes stability issues with bifenazate in cotton commodities (page 59). The US believes that a substantial portion of the bifenazate residue may be lost due to storage instability in cotton gin trash. It appears that the cotton gin byproduct samples from the supervised field trials were stored for a long interval prior to analysis. Actual crops fed to cattle might not be stored for long intervals. Thus, it might be appropriate to upwardly adjust the cotton "forage" value from 18 mg/kg. This would increase the cattle exposure from 4.40 ppm. This in turn would lead to a higher estimate of the meat (fat) MRL, possibly 0.1 mg/kg. We request JMPR to reconsider the livestock diet as related to the stability of some feed commodities and to ascertain the impact on the MRL recommendation.</p>			
<p><b><i>Request for Clarification</i></b> (<i>Specific statement of clarification requested.</i>) The Report refers to cotton fodder in the calculation of the livestock diet. Does this mean cotton gin byproducts? If not, where is the field trial data on cotton fodder in the Report and why was cotton gin by-products not considered in the livestock diet?</p>			
<b><i>Do you wish this Concern to be Noted in the CCPR Report? Yes</i></b>			
<p><b><i>Data/Information</i></b> (Description of each separate piece of data/information which is attached or will be provided to the appropriate JMPR secretary within one month of the CCPR meeting.)</p> <p>No additional information/data, but a request for reconsideration.</p>			

### **Aminopyralid (220)**

#### **CANADA**

We note that the JMPR indicated that its evaluation could not be finalized

Canada has MRLs in place for wheat grain, wheat bran, meat and meat by products, kidney for swine, poultry, cattle, goat, sheep and horse.

### **Boscalid (221)**

#### **AUSTRALIA**

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

Australia notes that because residues of boscalid persist in soil and can be detected in succeeding crops, the 2006 JMPR decided to make recommendations for permanent and semi-permanent crops but not for other crops. Australia supports this decision of the JMPR and agrees that the JMPR needs to review more residue data from follow-up and rotational crops studies before considering MRLs for any treated crops with the potential to have residue levels affected by the presence of persistent residues in the soil. The potential impact of persistent soil residues on residue levels in non-treated follow-up and rotational crops also needs consideration.

Noting the JMPR request for information regarding residues in follow-up crops, with specific attention to boscalid (reference 2006 JMPR Report, General Consideration 2.9), Australia recommends that CCPR request this information from member countries via a Circular Letter.

In addition, Australia notes the residue definition for compliance for plant and animal products and for dietary intake estimation for plant products is recommended to be boscalid and that a different residue definition has been recommended for the dietary intake estimation for animal products. The complex residue definition for animal products is at odds with the toxicological evaluation that suggests only the parent compound is of toxicological concern.

Australia recommends that CCPR requests the JMPR revisit the boscalid residue definition currently recommended for estimating the dietary intake of animal products.

#### **CANADA**

Canada supports advancement of the recommended MRLs to Step 5/8.

Canada has a temporary registration for boscalid pending submission of more supplemental residue trials to support the residue levels resulting in rotated crops from the use of boscalid in any crop: radish, leaves of root and tuber vegetables (crop group 2), bulb vegetables (crop group 3), leafy vegetables (crop group 4) – excluding lettuce, leafy Brassica greens (crop subgroup 5B), fruiting vegetables (crop group 8), cucurbit vegetables (crop group 9), berries (crop group 13) and mint. Canada supports the decision that the JMPR needs to review more residue data from follow-up and rotational crops studies in order to elucidate the impact of persistent soil residues.

In addition, Canada notes the residue definition in animal matrices for monitoring, MRL and risk assessment purposes is boscalid and the hydroxy metabolite (M510F01), (2-chloro-N-(4'-chloro-5-

hydroxy-biphenyl-2-yl)nicotinamide), free (M510F01) and bound (M510F02), expressed as parent equivalents.

Canada notes that its ADI is different than the one proposed by JMPR. The ADI is 0.14 mg/kg bw/day based on a NOAEL of 14 and an uncertainty factor of 100. The PDI is 51% of the ADI for children 1 to 2.

### **Quinoxifen (222)**

#### **AUSTRALIA**

Australia supports the recommendations of the 2006 JMPR for crops and animal commodities with the exception of for meat (from mammals other than marine mammals). **Refer to attached Concern Form.**

The dietary burdens for MRL setting purposes for dairy cattle and beef cattle were determined to be 2.1 and 0.66 ppm respectively. As the dairy cattle dietary burden is larger than that for beef cattle it should be used for estimation of highest residues for both milk and tissues in line with normal JMPR practice (see FAO Manual, page 80. For an example of normal JMPR practice see thiacloprid evaluation of 2006 JMPR). Cull dairy cows are a significant source of beef commodities. Using the higher dietary burden to recommend a meat MRL would give rise to a high residue in fat of 0.1 mg/kg and an MRL recommendation of about 0.2 (fat) mg/kg for meat (from mammals other than marine mammals) instead of the current recommendation of 0.02 mg/kg (fat). The other animal commodity recommendations would not be affected as residues were not detected in the other tissues at the 2 ppm feed level.

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

<b>Submitted by: Australia</b>			
<b>Date: 16 March 2007</b>			
<b>Pesticide/ Pesticide Code Number</b>	<b>Commodity/ Commodity Code Number</b>	<b>MRL (mg/kg)</b>	<b>Present Step</b>
Quinoxifen /222	MM278 Meat (from mammals other than marine mammals)	0.02 fat	3
<b><i>Is this a Request for Clarification?</i></b>			
<b><i>Is this a Concern? Yes</i></b>			
<b><i>Is this a Continuing Concern? No</i></b>			
<p><b><i>Concern</i></b> (<i>Specific statement of reason for concern to the advancement of the proposed MRL.</i>)</p> <p>Australia supports the recommendations of the 2006 JMPR for crops and animal commodities with the exception of meat (from mammals other than marine mammals). Note below the justification for re-consideration of the meat (fat) MRL. Australia requests that the meat (fat) MRL be reviewed as the incorrect dietary burden was used in the estimation of the MRL.</p> <p>The dietary burdens for MRL setting purposes for dairy cattle and beef cattle were determined to be 2.1 and 0.66 ppm, respectively. As the dairy cattle dietary burden is larger than that for beef cattle it should be used for estimation of highest residues for both milk and tissues in line with normal JMPR practice (see FAO Manual, page 80. For an example of normal JMPR practice see thiacloprid evaluation of 2006 JMPR).</p> <p>Cull dairy cows are a significant source of beef commodities. Using the higher dietary burden to recommend a meat MRL would give rise to an estimated high residue in fat of 0.1 mg/kg and an MRL recommendation of 0.2 (fat) mg/kg for meat (from mammals other than marine mammals). The other animal commodity recommendations would not be affected as residues were not detected in the other tissues at the 2 ppm feed level.</p>			
<b><i>Request for Clarification</i></b> ( <i>Specific statement of clarification requested.</i> )			
<b><i>Do you wish this Concern to be Noted in the CCPR Report? Yes</i></b>			
<p><b><i>Data/Information</i></b> (Description of each separate piece of data/information which is attached or will be provided to the appropriate JMPR secretary within one month of the CCPR meeting.)</p>			

**CANADA**

Canada supports the MRL recommendations of the 2006 JMPR for crops and animal commodities.

Note based on Canadian GAP at the time of registration, no MRLs for animal commodities were established.

**Thiacloprid (223)****AUSTRALIA**

Australia supports the recommendations of the 2006 JMPR

**CANADA**

Canada supports the MRL recommendations of the 2006 JMPR. However, Canada notes that its ADI and ARfD are different than the ones proposed by JMPR.

Canada only has the following MRLs in place: pome fruit (0.3 ppm), meat (0.03 ppm), milk (0.03 ppm), liver (0.15 ppm), kidney (0.05 ppm), fat (0.02 ppm) and meat byproducts (0.05 ppm).

<b>Canada: Toxicological Reference Doses and Endpoints for THIACTOPRID.</b>		
<b>Exposure Scenario</b>	<b>Dose Used in Risk Assessment, UF</b>	<b>Study and Toxicological Effects</b>
<b>Acute Dietary</b>	NOAEL = [3.1 ] mg/kg/day UF = [ 300] ARfD = [ 0.01] mg/kg/day	Acute neurotoxicity study in rats (Decrease motor and locomotor activity)
<b>Chronic Dietary</b>	NOAEL= [ 1.2] mg/kg/day UF = [300] ADI = [ 0.004] mg/kg/day	2-year dietary study in rats (Liver enzyme induction, liver and thyroid pathology, retinal atrophy)
<b>Cancer</b>	$Q_1^* = 3.79 \times 10^{-2}$ (mg/kg bw/day) <sup>-1</sup>	2-year dietary study in rats (Uterine adenoma, adenocarcinoma, and adenosquamous carcinoma)

**Dried chilli peppers (dimethoate, methamidophos, oxamyl)****AUSTRALIA**

Australia supports advancement of the draft MRLs for methamidophos and oxamyl in dried chilli peppers to Step 8.

The draft MRL for dimethoate should be returned to Step 6 until the JMPR has the opportunity to re-evaluate the IEDIs for this compound based on the thirteen cluster diets and existing CXLs.