

codex alimentarius commission E



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 09/41/03-Add. 1
April 2009

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

Forty-first Session

Beijing, China, 20 - 25 April 2009

DRAFT AND PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES IN FOODS AND FEEDS AT STEPS 7 AND 4

Comments submitted by Australia, Brazil and the 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

UNITED STATES OF AMERICA

The U.S.A. continues to be very concerned by the lack of harmonization of MRL estimates from the JMPR and estimates from national authorities where the same data sets have been utilized. Despite repeated requests from the CCPR asking that the JMPR use a statistical calculator and when the results of the calculator are not used, explain in detail why, this is still not consistently happening. As examples, the US has submitted concern forms for three instances where undefined “experience” was cited as the reason for the deviation from the calculator results. While there are various efforts underway that will help to address this issue including the OECD work on statistical calculation methods, the underlying issue of ensuring transparency in all of our work needs to be addressed more immediately. This can be done by providing more thorough and complete explanations for the MRLs that are proposed. In this way CCPR can exercise its risk management role appropriately.

Transparency extends to all aspects of the JMPR evaluation process. An example of this that does not involve the statistical calculator is Prothioconazole, discussed below. The U.S. believes that it would have been preferable, rather than just discarding data and work that had already been done, to discuss the situation in the report and present alternatives to the CCPR.

The issuance of variable food standards resulting from consideration of the same data for particular pesticide/commodity combinations is a serious impediment to trade and has been addressed in U.S.A comments on the Agenda Item 4(a) (General Considerations from the 2008 JMPR) and in U.S.A contribution to Agenda Item 8 (Achieving Globally Harmonized MRLs Through Codex, CX/PR 09/41/6).

General comment on Annex 1: Beer

A consistent approach has not been employed in Annex 1 for the entry “beer,” and the result may be confusion and misapplication of the recommendations. In the case of spirotetramat, there is a listing for “beer hops.” This could be interpreted as dried hops used in the manufacture of beer. For tebuconazole, beer is listed twice, once under barley and again under hops, with two different STMR values.

The U.S.A. suggests that the preferable approach is to list the entry as “beer” at the end after all MRL recommendations are enumerated and where other commodities with only STMR entries are listed. An example of this approach is azoxystrobin. The source of the residue in the beer, e.g., barley or hops, should be done by means of a footnote. This avoids the possibility of confusing the residue in beer with the source of the residue, i.e., the commodity with an MRL. The STMR value(s) for beer are used in the dietary intake risk assessment.

BRAZIL

Brazil supports the JMPR recommendations and informs that some MRLs are different due the national GAPs and risk assessment performed by the Brazilian authorities according to the current legislation.

CARBARYL (8)

AUSTRALIA

Australia supports the progress of the MRL for citrus fruit and citrus pulp, dry to Step 8 as there are no dietary intake concerns for these MRLs.

Australia considers an MRL for citrus juice is unnecessary as residues do not concentrate in this commodity and therefore recommends that this MRL recommendation be deleted.

Based on the intake calculations of the 2002 JMPR, Australia does not support the advancement of the MRLs for stone fruits and grapes.

UNITED STATES OF AMERICA

The U.S.A. supports advancement of the MRL for citrus to Step 8, as the 2008 JMPR confirmed the lack of a dietary intake concern. No new GAPs/data were available for the remaining commodities, and therefore the acute dietary intake concerns originally expressed in the 2002 JMPR Report could not be resolved. The MRLs for cherries, grapes, dried grapes, and stone fruits should **not** be advanced and consideration should be given to their withdrawal.

It is noted that the U.S.A. has no dietary intake concerns for these commodities as related to its GAPs and risk assessment considerations (RED, 09/2007).

DIMETHOATE (27)

AUSTRALIA

Australia notes following consideration of alternative GAP for lettuce and peppers by the 2008 JMPR, new MRL recommendations have been made that resolve dietary intake concerns. Australia supports deletion of the MRLs at step 6 and advancement of the recommendations of the 2008 JMPR to step 5/8.

Australia supports advancement of all MRLs to step 5/8

BRAZIL

ADI: 0–0.002 mg/kg bw

ADI Brazil: 0.002 mg/kg bw

ARfD: 0.02 mg/kg bw

not established

MRL were not established for the proposed commodities: Lettuce, Head; Peppers, sweet; Peppers, chili (dried).

UNITED STATES OF AMERICA

The U.S.A. supports withdrawal of the MRLs at Step 6 for lettuce and peppers and advancement of the alternative GAP MRLs for lettuce (0.3 mg/kg) and peppers (0. mg/kg), as proposed by the 2008 JMPR, to Step 8.

DIPHENYLAMINE (30)

AUSTRALIA

Australia supports advancement of all MRLs to step 5/8

BRAZIL

ADI: 0–0.08 mg/kg bw

ARfD: unnecessary

Compound not registered in Brazil.

ETHOXYQUIN (035)

AUSTRALIA

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

BRAZIL

ADI: 0–0.005 mg/kg bw

ARfD: 0.5 mg/kg bw

Compound not registered in Brazil.

MALATHION (49)

AUSTRALIA

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

CHLORPYRIFOS-METHYL (90)

AUSTRALIA

Australia agrees with the decision taken at previous sessions of CCPR to hold all draft MRLs at step 7 pending review by JMPR, tentatively scheduled for 2009.

METHOMYL (94)**AUSTRALIA**

As no new residue data or information was made available to the 2008 JMPR for brassica vegetables and celery and that alternative GAP was not identified for leafy vegetables, Australia supports the deletion of these MRLs.

The 2008 JMPR evaluated alternative GAP and/or recalculated intakes for apples, pears, fruiting vegetables cucurbits, tomatoes, grapes and lettuce. Australia notes that with the new MRL recommendations from the 2008 JMPR, dietary intake concerns are resolved and supports advancement of the recommendations of the 2008 JMPR to step 5/8.

Australia supports advancement of all MRLs to step 5/8

BRAZIL

ADI: 0–0.02 mg/kg bw

ADI Brazil: 0.02 mg/kg bw

ARfD: 0.02 mg/kg bw

not established

From the proposed MRLs, Brazil has established only for brassica (3 mg/kg) and tomato (1 mg/kg)

UNITED STATES OF AMERICA

The U.S.A. supports the recommendations of the 2008 JMPR. Thus, the MRLs for Brassica vegetables and celery should not be advanced and should be considered for withdrawal because of acute dietary intake concerns. (No new data were submitted to the JMPR 2008 for these crops.) The new recommendations for grapes (0.3 mg/kg) and lettuce (0.2 mg/kg) should be advanced to Step 8. The MRLs at Step 6 for grapes (7 mg/kg) and leafy vegetables (30 mg/kg) should be withdrawn, due to acute dietary intake concerns. The MRL for cucurbit fruiting vegetables (0.1 mg/kg) is supported for advancement to Step 8, as the 2008 JMPR confirmed a lack of acute dietary intake concern. The MRL proposals for apples (0.3 mg/kg) and pears (0.3 mg/kg) are supported for advancement to Step 8.

ACEPHATE (95)**AUSTRALIA**

Australia notes that the Committee decided to retain the draft MRLs for flowerhead brassicas, mandarins, nectarine, peach, peppers and pome fruits at Step 7 and to consider their revocation at the next meeting if no data were available to support alternative GAP. No additional data were reviewed by the 2008 JMPR. Australia supports deletion of the MRLs for flowerhead brassicas, mandarins, nectarine, peach, peppers and pome fruits.

CARBOFURAN (96)**AUSTRALIA**

The ARfD was re-evaluated by the 2008 JMPR. Using the new ARfD, the short term intake exceeds the ARfD for cucumber, cantaloupe, orange, potato, summer squash, sweet corn on the cob and mandarins. Australia supports the deletion of these MRLs.

UNITED STATES OF AMERICA

Consideration of additional toxicological data and subsequent dietary intake considerations by the 2008 JMPR led to an acute dietary intake concern for several commodities, including those listed at Step 6 in Appendix VII. Therefore, the U.S.A. supports retaining cantaloupe, cucumber, orange, potato, summer squash, and sweet corn at Step 6. Banana and milk also have dietary intake concerns as a result of the new lower ARfD.

METHAMIDOPHOS (100)**AUSTRALIA**

See acephate.

PHORATE (112)**AUSTRALIA**

Australia notes that the manufacturers have committed to provide additional data for processed potato in 2008 for evaluation by the 2009 JMPR and that the EC are to submit a "concern form" regarding the acute intake concern associated with the MRL for potato, which would be taken into account by the 2009 JMPR.

CYPERMETHRINS (118)**AUSTRALIA**

Australia supports advancement of all MRLs recommended by the 2008 JMPR to Step 5/8.

BRAZIL

ADI: 0–0.02 mg/kg bw

ADI Brazil = 0.05 mg/kg bw

ARfD: 0.04 mg/kg bw

not established

From the proposed commodities, in Brazil MRLs are established for the following: Peanuts, Rice, Potato, Coffee beans, Onions, Peas, Beans (pulses), Watermelon, Maize (cereal grain), Cucumber, Cabbage (brassica), Soybean (oilseed), Tomato.

OXAMYL (126)**AUSTRALIA**

Australia notes the 2008 JMPR concluded that there was insufficient data to support alternative GAP assessments for citrus, cucumber, melons (except watermelon), summer squash, peppers and tomatoes. Australia supports deletion of these MRLs.

UNITED STATES OF AMERICA

The U.S.A. supports withdrawal of the oxamyl MRLs at Step 6 for citrus fruits, cucumber, melons, and peppers. The 2008 JMPR found the data submitted in support of alternative GAP for these commodities to be insufficient.

The U.S.A. notes that it has tolerances for cucumber (2ppm), melons (2 ppm), and peppers (2 ppm) and that there is are no intake concerns for the particular GAPs based on the U.S.A. risk assessment methodology.

TRIADEMEFON(133)**UNITED STATES OF AMERICA**

The 2007 JMPR noted an acute dietary intake concern for grapes, and therefore this MRL should remain at Step 6, as triademefon/triadimenol were not considered at the 2008 JMPR.

It is noted that the acute dietary intake concern expressed for the commodities banana, cucurbits, and fruiting vegetables is that of the EC and not JMPR. The U.S.A. has only limited uses for triademefon: apple, pear, grape, pineapple.

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. Prochloraz has been scheduled for consideration of alternative GAP by the 2009 JMPR. Australia supports retention of the MRL at Step 7 pending the JMPR evaluation.

CARBOSULFAN (145)**AUSTRALIA**

See carbofuran. Australia supports deletion of these MRLs.

UNITED STATES OF AMERICA

See Carbofuran(96)

CYHALOTHRIN (146) (INCLUDES LAMBDA-CYHALOTHRIN)**AUSTRALIA**

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

BRAZIL

Group ADI: 0–0.02 mg/kg bw

ADI Brazil lambdacyhalothrin: 0.05 mg/kg bw

Group ARfD: 0.02 mg/kg bw

Lambdacyhalothrin is registered in Brazil

MRL for rice (0.05 mg/kg) is more restrict than the recommended by JMPR

Some MRLs are not established.

MRL for wheat is the same as the recommended one.

CYFLUTHRIN (157) / BETA-CYFLUTHRIN(228)**UNITED STATES OF AMERICA**

The U.S.A. supports maintaining the MRLs for broccoli and head cabbages at Step 6 pending possible resolution of acute dietary intake concerns (expressed by the 2007 JMPR).

FLUSILAZOLE(165)**UNITED STATES OF AMERICA**

The U.S.A. notes that the acute dietary intake concerns are those of the EC and not the JMPR, for edible offal, nectarine, peach, and pome fruits. The U.S.A. has only limited use for flusilazole: soybean.

TRIADIMENOL(168)**UNITED STATES OF AMERICA**

See Triademefon(133)

PROFENOFOS (171)**AUSTRALIA**

Australia supports advancement of all MRLs to step 5/8

BRAZIL

ADI: 0–0.03 mg/kg bw

ADI Brazil: 0.01 mg/kg bw

ARfD: 1 mg/kg bw

not established

From the proposed MRLs, Brazil has established only for Cabbages, Head 0,05 mg/kg); Cotton seed (0,02 mg/kg); potato (0,05 mg/kg) and tomato (1 mg/kg)

BUPROFEZIN (173)**AUSTRALIA**

Australia supports the advancement of all MRL recommendations to Step 5/8.

BRAZIL

ADI: 0 - 0,009 mg/kg bw

ADI Brazil: 0.01 mg/kg bw

ARfD: 0.5 mg/kg

not established

From the proposed MRLs, Brazil has established the following: citrus fruit (0,3 mg/kg), cucumber (0,3 mg/kg), tomato (0,5 mg/kg).

HEXYTHIAZOX(176)**BRAZIL**

ADI: 0–0.03 mg/kg bw
ARfD: Unnecessary

ADI Brazil: 0.03 mg/kg bw
not established

TEBUCONAZOLE (189)**AUSTRALIA**

Australia supports advancement of all MRLs to step 5/8

BRAZIL

ADI: 0–0.03 mg/kg bw

ADI Brazil: 0.03 mg/kg bw

Tebuconazole is registered in Brazil for many commodities, including MRLs established for the majority mentioned in the document

FENPYROXIMATE (193)**AUSTRALIA**

Australia supports retention of the MRL for grapes at step 7 pending re-evaluation of data for grapes scheduled for 2010. This follows the new ARfD recommended by the 2007 JMPR.

HALOXYFOP (194)**AUSTRALIA**

Australia supports retaining the MRLs at step 4 and 7 pending a review by JMPR scheduled for 2009.

CHLORPROPHAM (201)**AUSTRALIA**

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

BRAZIL

ADI: 0–0.05 mg/kg bw
ARfD: 0.5 mg/kg bw

Compound not registered in Brazil.

ESFENVALERATE (204)**AUSTRALIA**

Australia notes the Committee decided to retain the draft MRLs for cotton seed, tomato and wheat at Step 7 awaiting the phase-out of fenvalerate.

IMIDACLOPRID (206)**AUSTRALIA**

Australia supports the recommendations of the 2008 JMPR. Australia supports advancement of all MRLs to Step 5/8.

BRAZIL

ADI: 0–0.06 mg/kg bw
ARfD: 0.4 mg/kg bw

ADI Brazil: 0.05 mg/kg bw
not established

Imidacloprid is registered in Brazil for several commodities, however, related to the proposed commodities, MRL are established for only for peanut (0,05 mg/kg) and potato(0,5 mg/kg).

METALAXYL-M (212)**AUSTRALIA**

Australia notes the Committee decided to retain all the draft MRLs at Step 7, awaiting the periodic review of metalaxyl by JMPR in 2012 for toxicology and 2013 for residues

BIFENAZATE(219)**AUSTRALIA**

Australia supports the advancement of all MRL recommendations to Step 5/8.

BRAZIL

compound not registered in Brazil

BOSCALID (221)**AUSTRALIA**

Australia supports the advancement of all MRL recommendations to Step 5/8.

BRAZIL

ADI: 0 - 0,04 mg/kg bw

ADI Brazil: 0.04 mg/kg bw

ARfD: 0,5 mg/kg

not established

MRLs were not established for banana and kiwi.

AZOXYSTROBIN (229)**AUSTRALIA**

Australia supports advancement of all MRLs to step 5/8

BRAZIL

ADI: 0-0.2 mg/kg bw

ADI Brazil = 0.02 mg/kg bw

ARfD: unnecessary

Based on the proposed GAP several established MRLs in Brazil are lower than those proposed banana; barley; bulb vegetables (onion); citrus fruit; cotton seed; fruiting vegetables, cucurbits (cucumber), grape, legume vegetables (bean); lettuce, head; maize; mango; papaya; rice; root and tuber vegetables (potato); stone fruits (peach); strawberry; wheat

Some MRLs are not established: celery; berries, raisins, dry herbs, oat grain, pepper, chili dry, rye, sunflower, witloof chicory (sprouts)

MRLs for brassica, peanut and soybean are the same as proposed by JMPR.

CHLORANTRANILIPROLE (230)**AUSTRALIA**

Australia supports advancement of all MRL recommendations to Step 5/8 except for milk fat which has been set too low. Note that the milk fat and whole milk MRLs recommended are the same at *0.01 mg/kg.

The maximum dietary burden for beef and dairy cattle is 0.67 and 0.63 ppm respectively, so the levels of residues in tissues can be obtained from the 1 ppm feeding level. Maximum residues expected in tissues are: fat, muscle, liver and kidney are 0.0067 mg/kg ($0.01 \times 0.67/1$) and the mean residue for milk 0.0063 mg/kg. At the 3 ppm dose level, average residues of chlorantraniliprole were 0.015 mg/kg in cream and <0.01 mg/kg in whole milk (0.025 and 0.005 mg/kg respectively for cream and whole milk for the 10 ppm dose level at day 14). Expected residues in cream are 5× the residues in whole milk or $5 \times 0.0063 = 0.0315$ mg/kg. The fat content of cream is 40-60% and the Estimated mean residues for milk fat to be $2 \times 0.0315 = 0.063$ mg/kg.

The maximum residue level for milk fat should be 0.1 mg/kg with an STMR of 0.047 mg/kg.

BRAZIL

ADI: 0–2 mg/kg bw

ADI Brazil: not established

ARfD: Unnecessary

Compound not registered in Brazil.

UNITED STATES OF AMERICA

A concern form will be submitted for the recommended MRL of 1 mg/kg for **grapes** requesting further details on the basis for this recommendation. The data set consists of 17 supervised field trial results. The statistical calculation gave a value of 1.4, which JMPR would round to 2 mg/kg. The 1 mg/kg was selected based on “experience.” The U.S.A. requests a more transparent and detailed explanation than that this was based on experience or revision of the estimate to 2 mg/kg in accordance with the statistical result.

A concern form will be submitted for the recommended MRL of 20 mg/kg for **leafy vegetables** requesting further details on the basis of this recommendation. JMPR based the estimate on U.S. data for spinach, where the high residue was 8.9 mg/kg. The statistical spreadsheet produced an estimate of 14.2 mg/kg, or 15 mg/kg rounded. Apparently because only 7 trials were available, the JMPR selected the value of 20 mg/kg based on experience. Please detail the experience beyond a rejection of the spreadsheet for too few data points. A value of 20 seems excessive based on the spreadsheet and the highest residue, and a clear explanation for the selection should be provided, or preferably the value should be revised to 15 mg/kg.

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

Submitted by: USA			
Date: 03/06/2009			
Pesticide/ Pesticide Code Number	Commodity/ Commodity Code Number	MRL (mg/kg)	Present Step
chlorantraniliprole / 230	Grapes / FB0269	1	3
<i>Is this a Request for Clarification?</i> Yes			
<i>Is this a Concern?</i> No			
<i>Is this a Continuing Concern?</i> No			
<i>Concern</i> (Specific statement of reason for concern to the advancement of the proposed MRL).			
<i>Request for Clarification</i> (Specific statement of clarification requested). The MRL should be 2. A value of 2 mg/kg is in accord with the statistical calculation, based on 17 supervised trials. Explain the origin of the proposed 1 mg/kg estimate. Please detail the experience that leads to this estimate.			
<i>Do you wish this Concern to be Noted in the CCPR Report?</i> Yes			
<i>Data/Information</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.) No additional information/data, but a request for reconsideration of the supervised trial results and the MRL calculation.			

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

Submitted by: USA			
Date: 03/06/2009			
Pesticide/ Pesticide Code Number	Commodity/ Commodity Code Number	MRL (mg/kg)	Present Step
chlorantraniliprole / 230	leafy vegetables / VL 0053	20	3

Is this a Request for Clarification? Yes
Is this a Concern? No
Is this a Continuing Concern? No
Concern (<i>Specific</i> statement of reason for concern to the advancement of the proposed MRL).
Request for Clarification (<i>Specific</i> statement of clarification requested). The MRL should be 15 mg/kg, based on the statistical analysis of the results of the supervised trials for spinach. This is a reasonable value, given a HR (high residue) of 8.9 mg/kg. Please explain the selection of 20 mg/kg. What experience led to this estimate?
Do you wish this Concern to be Noted in the CCPR Report? Yes
Data/Information (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.) No additional information/data, but a request for reconsideration.

MANDIPROPAMID (231)

AUSTRALIA

Australia supports advancement of all MRLs to step 5/8.

BRAZIL

ADI: 0–0.2 mg/kg bw

ADI Brazil: 0.03 mg/kg bw

ARfD: Unnecessary

not established

Mandipropamid is registered in Brazil and has MRLs established for the proposed commodities.

PROTHIOCONAZOLE (232)

AUSTRALIA

Australia supports advancement of all MRLs to step 5/8

BRAZIL

ADI: 0 - 0.05 mg/kg bw

ADI Brazil: 0.001 mg/kg bw

ARfD: 0.8 mg/kg bw (woman of child bearing age)

ARfD not necessary (general population) not established

Prothioconazole - Desthio

ADI: 0–0.01 mg/kg bw

ARfD: 0.01 mg/kg bw (woman of child bearing age)

ARfD: 1 mg/kg bw (general population)

None of the proposed MRLs are established in Brazil. MRLs are established only for cotton seed (0,03 mg/kg), bean (0,05 mg/kg) and soybean (0,05 mg/kg).

Definition of the residue (for the estimation of dietary intake) for plant commodities: the sum of prothioconazole and prothioconazole-desthio expressed as prothioconazole.

UNITED STATES OF AMERICA

All U.S.A. supervised field trial data were discarded (except peanut) because the analytical method used determined a total residue based on the sum of prothioconazole and the metabolite desthio prothioconazole. The JMPR decided upon a residue definition of desthio prothioconazole only for plant commodities. This is most unfortunate, as U.S.A. GAPs are often the critical GAPs and would lead to higher MRLs, e.g., cereal grains. This presents a real trade barrier issue for U.S.A. exports. The following crops/commodities were affected by the failure to consider US field trials: pulses, sugar beet, cereal grains (wheat, barley), canola (rapeseed), soybean, and cereal forages/straws.

The JMPR residue definition decision is apparently based on their conclusion that prothioconazole is an insignificant portion (<10%) of the total residue. Therefore, including the U.S.A. supervised field trial results would have elevated the residue values by no more than 10%. This error is not significant when compared to all other errors and uncertainties involved in the supervised field trials, ranging from treatment to sampling to storage to analysis to estimation from the data set.

A review of the JMPR Report clearly indicates that in the plant metabolism parent prothioconazole is a very small part of the residue. Prothioconazole was consistently <5% of the total radioactive residue. Moreover, some trials conducted in Europe using different formulations containing prothioconazole, e.g., cereals (10 trials on wheat and 6 trials on barley) and vegetables (9 trials on onion, 16 trials on pulses), showed negligible levels of prothioconazole. Again, including prothioconazole in the residue definition and/or in the analytical measurement of the residue will have no significant effect on the residue levels and the subsequent estimation of the MRL.

The U.S.A. requests that the prothioconazole MRL estimations for plant commodities barley, wheat, rape seed, and cereal (barley, oat, rye, triticale, wheat) straw be returned to the 2009 JMPR for reconsideration and that the U.S.A. supervised field trials and corresponding GAPs be reconsidered. It is further requested that the US field trial data for pulses, sugar beet, and soybean be revisited with the possibility of making MRL estimates. A Concern form has been submitted.

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

Submitted by: USA			
Date: 03/06/2009			
Pesticide/ Pesticide Code Number	Commodity/ Commodity Code Number	MRL (mg/kg)	Present Step
prothioconazole / 232	pulses / VD 070	None	None
	sugar beet / VR 596	None	None
	barley / GC 0640	0.05	3
	wheat / GC 0654	0.05	3
	canola (rape seed) / SO 0495	0.05	3
	soybean / VD 0541	None	None
	cereal forages/straws / AS 051* (barley straw, oat straw, rye straw, triticale straw, wheat straw)	2	3
Is this a Request for Clarification? Yes			
Is this a Concern? Yes			
Is this a Continuing Concern? No			
<p>Concern (<i>Specific</i> statement of reason for concern to the advancement of the proposed MRL). JMPR defined the residue as desthio-prothioconazole (metabolite) and therefore dismissed all US field trial data which measured the sum of prothioconazole and desthio-prothioconazole. However, as the JMPR Report shows, prothioconazole is a very small part of the total residue (<10%), and therefore the total residue may be used to estimate MRLs based on the JMPR residue definition. We request a reconsideration of the US supervised field trial data for the crops listed above. This may lead to 3 new commodity MRLs and to a revision of 4 MRLs at Step 3. We note that an MRL was estimated for peanut based on US data.</p>			
<p>Request for Clarification (<i>Specific</i> statement of clarification requested). * The currently listed OS classification may be wrong, and should be replaced by AS.</p>			
Do you wish this Concern to be Noted in the CCPR Report? Yes			
Data/Information (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.)
No additional information/data, but a request for reconsideration.

SPINETORAM (233)

AUSTRALIA

Australia supports advancement of all MRLs to step 5/8

BRAZIL

ADI: 0–0.05 mg/kg bw

ARfD: Unnecessary

Spinetoram is not registered in Brazil.

UNITED STATES OF AMERICA

The U.S.A. notes that very few supervised trials were considered and very few MRL recommendations subsequently proposed for this compound. This is a very low risk pesticide, and many tolerances have been established in the U.S.A. from translation of supervised field trial data from the closely related compound spinosad. This is not a Concern submission to the JMPR, as that body is clearly unable to decide upon issues and data that are not presented to them. The U.S.A. notes that the manufacturer (Dow AgroScience) is giving consideration to a future scheduling of the compound for additional uses based on the translation of spinosad data and will include the rationale and bridging studies previously presented to the U.S.A.

SPIROTETRAMAT (234)

AUSTRALIA

Australia supports advancement of all MRLs to step 5/8

BRAZIL

ADI: 0–0.5 mg/kg bw

ARfD: 1.0 mg/kg/bw

Spirotetramat is not registered in Brazil

UNITED STATES OF AMERICA

A concern form will be submitted for the recommended MRL value of 0.5 for tree nuts requesting further details on the basis for this recommendation. The data base used by JMPR was U.S.A. trials (11 values). The calculator provided an estimate of 0.29 mg/kg, or 0.3 mg/kg rounded. An explanation of the experience or professional judgment used in arriving at 0.5 mg/kg is requested, or preferably an adjustment of the MRL to 0.3 mg/kg.

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

Submitted by: USA			
Date: 03/06/2009			
Pesticide/ Pesticide Code Number	Commodity/ Commodity Code Number	MRL (mg/kg)	Present Step
spirotetramate / 234	tree nuts / TN 085	0.5	3
<i>Is this a Request for Clarification? Yes</i>			
<i>Is this a Concern? No</i>			
<i>Is this a Continuing Concern? No</i>			
<i>Concern (Specific statement of reason for concern to the advancement of the proposed MRL).</i>			
<i>Request for Clarification (Specific statement of clarification requested). The MRL proposed by</i>			

JMPR (0.5 mg/kg) is not appropriate based on the field trial data considered. The statistical estimate based on 11 trials is 0.3 mg/kg. The MRL should be 0.3 mg/kg.

An explanation for the estimation of 0.5 mg/kg is requested. What experience or judgment led to replacing the 0.3 mg/kg estimate with 0.5 mg/kg? We note that of the 11 values, 9 were below 0.1 mg/kg, and the two highest values were 0.13 and 0.25 mg/kg. Thus, 0.5 mg/kg seems excessively high.

Do you wish this Concern to be Noted in the CCPR Report? Yes

Data/Information (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.)

No additional information/data, but a request for reconsideration.