codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 7 **CX/PR 06/38/5-Add.1**
March 2006

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES
Thirty-eighth Session
Hotel Vila Galé, Fortaleza, Brazil, 3 - 8 April 2006

SUMMARY OF COMMENTS at Steps 6 and 3

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 7A	The proposed MRL is not further advanced in the procedure until a full ADI has been estimated by the JMPR
Step 7B	The proposed MRL is referred back to the JMPR for reconsideration, in the light of new information provided
Step 7C	The proposed MRL is not advanced, waiting for further information as specified
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

USA

The US notes that the 2005 JMPR did not review certain requested pesticides for alternative GAP with adequate supporting field trial data, as requested by the 2005 CCPR. These particular pesticides have been returned to Step 5/6 for 3 or more years because of unresolved dietary intake concerns. The US agrees with the JMPR (2005 JMPR Report, General Consideration 2.7) that usually any such request would require the submission of updated GAP information and possibly new field trial data, where several years have elapsed from the initial JMPR review. The US supports the proposal from the 2005 JMPR that the JMPR should routinely consider alternative GAP when chronic and/or acute dietary intake concerns are found during the scheduled full evaluation or periodic review.

As discussed at the last CCPR session, the US supports granting interim MRL status to all MRL recommendations of the 2005 JMPR where no dietary intake concerns were signaled by the JMPR.

CAPTAN (007)

AUSTRALIA

Australia recommends that MRLs for captan be returned to Step 6, awaiting further consideration by JMPR in relation to inclusion of THPI in the dietary intake assessment.

CANADA

Canada has no objection to the advancement of the MRLs at Step 6. In Canada, the toxicology database for captan is under re-evaluation. The results of the re-evaluation can be made available when completed.

USA

The US notes that the the MRLs are being retained at their current steps (no advancement) pending an additional consideration of the THPI metabolite by the JMPR (2004 JMPR) and requests information of when the necessary studies will be submitted to and considered by the WHO experts of JMPR.

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 expresses reservations regarding the MRL recommendations for stone fruits and grapes, which should be returned to Step 6.

CANADA

Canada does not support the advancement of the MRLs currently at Step 6 because of health risk concerns (PDI > ADI) and the ongoing carbaryl re-evaluation.

USA

The US supports advancement of the MRLs for cherries, citrus fruits, dried grapes, grape pomace, grapes, and stone fruits (except cherry). The 2005 JMPR adequately addressed the question of the relatively high ARfD selected by the JMPR.

For the US, the acute dietary (food) risk estimate is below EPA's level of concern for its use and consumption patterns; that is, it is less than 100% of the aPAD for the general population and all population subgroups. Children (1-2years), the most highly exposed population group, are exposed to carbaryl at a level of 93% of the aPAD (0.01 mg/kg/day vs 0.2 mg/kg/day Codex) at the 99.9th exposure percentile. The non-cancer chronic dietary (food) risk estimate is significantly less than 100% of the cPAD for the general population and all population subgroups.

DIMETHOATE (027)

AUSTRALIA

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

Australia supports the progress of the MRLs for barley and citrus fruits.

It is noted that there is a recommendation for an MRL of 2 mg/kg for tomato, however in Annex 7 of the 2004 JMPR Report, *Corrections to the Report of the 2003 Meeting*, it is noted that the MRL for dimethoate in tomato is recommended for withdrawal. Australia requests clarification on the status of the MRL for dimethoate in tomato. Based on the dietary intake 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.

It is noted that a number of MRL revocations for dimethoate have been listed in Appendix VIII of Alinorm 05/28/24; these revocations (including tomato) should resolve the chronic intake concerns for the European diet. Australia proposes that the chronic intake calculations be revised in view of the revocations.

CANADA

Canada has no objection to the advancement of the MRLs at Step 6.

USA

The dietary intake calculations of the 2003 JMPR indicated dietary intake concerns for cabbages, lettuce, and peppers. These MRLs should not be advanced beyond Step 5/6. The US supports the 2005 JMPR position (2005 JMPR Report, General Consideration 2.7) that as residue data and GAP have not been reviewed by the JMPR since 1998, a request for consideration of alternative GAP by JMPR shouldbe accompanied by a call for new GAP and supporting field trial data. The US supports advancement of the MRLs for barley and citrus fruits where the risk assessment is acceptable.

ETHOXYQUIN (035)

CANADA

Canada has no objection to the proposed JMPR ADI and ARfD.

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 tentatively 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 has written to the CCPR Chairman to advise of plans to modify product labels. Australia is seeking clarification on the use pattern on stored grain, and trying to establish 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.

FOLPET (041)

CANADA

Canada has no objection to the advancement of the MRLs at Step 6, however folpet is under re-evaluation for toxicology, in association with captan. The results of the re-evaluation can be made available when completed.

USA

The US supports the advancement of all MRLs for apple, dried grapes, grapes, lettuce head, strawberry, and tomato, but notes that the proposed MRLs are substantially below the US tolerances.

MALATHION (049)

AUSTRALIA

The 36th 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.

Australia supports the advancement of malathion MRLs for apple, citrus and grapes to Step 8.

CANADA

Canada does not support the advancement of the MRLs at Step 6 because malathion is under re-evaluation for the dietary exposure. Since the definition of the residue of toxicological concern is also under revision, any change in this definition will impact the dietary exposure risk assessment. It is Canada's view that the chronic risk assessment is unacceptable (PDI > ADI), therefore we do not support the proposed MRL.

USA

The US does not support advancing the following animal commodity MRLs at Step 5 pending the review of a livestock feeding study by the JMPR: alfalfa fodder, alfalfa forage, clover, clover hay, grass forage, hay or fodder of grasses, maize fodder, wheat flour, wheat straw, and wheat fodder. The US requests information on when such a study will be made available and when it will be scheduled for review by the FAO JMPR. The US agrees with the opinion expressed by the JMPR in its 2005 Report:

The Meeting noticed that the highest contribution to the dietary burden of malathion came from crops grown specifically for feed. Residues of malathion in other feed and food commodities, including cereal grains and citrus dried fruit, are low (< 1 mg/kg) and are not expected to make any significant contribution to the animal dietary burden.

The US therefore supports advancement of the following MRLs to Step 8: cotton seed, sorghum grain, wheat grain, wheat flour, and maize grain.

The US further suggests deletion of the proposed MRLs for forage commodities of grass and alfalfa, based on the decision of the 2005 JMPR to make no recommendations for forage crops. (General Considerations, 2005 JMPR Report)

For its use and consumption patterns, the US found no acute or chronic dietary intake concerns for malathion (8/05). The acute dietary exposure to malathion from food alone is well below the level of concern for all population subgroups (20% aPAD for the U.S. population and 46% aPAD for children 1-2 yrs) at the 99.9th percentile. The chronic dietary exposure to malathion from food alone is well below the level of concern for all population subgroups (10% aPAD for the U.S. population and 27% aPAD for children 1-2 yrs). The acute RfD and aPAD are identical in this case, 0.14 mg/kg bw/day. The cPAD is 0.003 mg/kg bw/day, based on a ADI of 0.03 mg/kg bw/day. These contrast with the significantly higher Codex values of 0.3 mg/kg bw for ADI and 2 mg/kg bw/day for Acute RfD.

PARAQUAT (057)

AUSTRALIA

Australia supports the advancement of paraquat MRLs to Step 8.

GLYPHOSATE (058)

CANADA

Canada has no objection to the recommended JMPR MRLs at Step 3, and the proposed ADI.

USA

The US supports the advancement of all MRL recommendations from the 2005 JMPR. The US supports the decision to not set MRLs for forage crops. The US and Codex residue definitions are harmonized.

PARATHION-METHL (059)

AUSTRALIA

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

The 36th 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 that the JMPR has not yet evaluated animal transfer data for parathion methyl.

CANADA

Canada supports the advancement of the MRLs currently at Step 6.

USA

The US does not support advancing the animal feed commodity MRLs (at Step 5) for alfalfa fodder, alfalfa forage, bean forage, cotton seed, hay or fodder of grasses, maize, maize oil, pear hay or fodder, pea vines, rape seed, rape seed oil, sugar beet leaves or tops, wheat, wheat bran, wheat flour, and wheat straw until a livestock feeding study is received and reviewed by the JMPR. The US requests information on when the study will be made available and when it will be scheduled for review. For its use and consumption patterns, the US found no acute or chronic dietary intake concerns for parathion methyl (06/02). The US acute RfD is 0.0011 mg/kg/day, and the ADI is 0.002 mg/kg. A safety factor of 10 was applied to both to arrive at the

PADs. Exposure was at 75% aPAD for children, 60% for the general population, and at 8% cPAD for children and 4% cPAD for the general population.

PYRETHRINS (063)

AUSTRALIA

Australia supports advancement of the pyrethrin MRL for tree nuts to Step 5.

USA

The US supports advancement of the proposed MRL for tree nuts.

THIABENDAZOLE (065)

CANADA

Canada has no objection to the advancement of the MRLs at Step 6.

USA

The US supports maintaining the existing CXL of 10 mg/kg resulting from post harvest use on citrus pending review of new citrus data by the JMPR, as reported at the 2005 CCPR. The US requests clarification on the availability of the data and the scheduling for review by the JMPR.

CYHEXATIN (067)

CANADA

Canada has no objection to the recommended JMPR MRLs at Step 3, and the proposed ADI and ARfD.

USA

The US supports the advancement of the MRL for oranges and the withdrawal of the MRLs for citrus fruit, meat, milk products, and milks. The US notes that many tolerances have been canceled in the US (Fed Reg 9/21/05, 70 (182), 55269), including those for the proposed Codex MRLs for apple, pear, and grapes. This resulted from an apparent acute dietary intake concern for infants and children. The US has an acute reference dose of 0.007 mg/kg/day, based on a 13 week neurotoxicity study on rats with a LOAEL of 11 mg/kg/day. The effect was decreased body weight and food consumption and clinical signs. The JMPR evaluated the same study and decided that an acute reference dose for the general population (which includes children) was not warranted. Thus, the issue is a difference in interpretation of findings. The US notes the differences with respect to the JMPR evaluation but will not object to the advancement of the subject MRLs.

CARBENDAZIM (072)

AUSTRALIA

On the basis of the outcomes of the 2005 JMPR, Australia supports progression of all MRLs for carbendazim to Step 8 as listed in Appendix IX of ALINORM 05/28/24.

CANADA

Canada has no objection to the proposed ADI and ARfD.

Canada does not support the advancement of the MRLs at Step 6 due to health risk, and there is voluntary discontinuation of the registered product.

USA

The US supports advancement of the MRLs for the various commodities from the use of thiophanate-methyl. Carbendazim is not registered in the US, and all benomyl food use registrations will be revoked on or before January 1, 2008 as the result of a voluntary action from the manufacturer. The US notes substantially higher tolerances in the US for cucurbit vegetables (cucumber, etc) than the corresponding proposed Codex MRLs.

The revised US residue definition for thiophanate-methyl is harmonized with the Codex definition. The dietary risk posed by thiophante methyl (TM) and the carbendazim metabolite (MBC) is below the EPA's level of concern (both chronic and acute) for all population subgroups. Acute dietary risk estimates range from 5% to 22% of the acute PAD at the 99.9th percentile exposure for TM and from 4% to 89% for MBC. The highest chronic dietary risk estimates (children 1 –6 years of age) are 2% and 26% of the chronic PAD for TM and MBC, respectively.

DISULFOTON (074)

CANADA

Canada has no objection to the advancement of the MRLs at Step 6. It should be noted, however, that in Canada certain registrants have decided not to support the continued registration of this product which subsequently results in the discontinuation of registration[1]. Canadian use is therefore being phased out.

USA

The US notes the apparent acute dietary intake concerns found by the JMPR and therefore does not support the advancement of the MRLs. The US also notes that the 2005 JMPR did not consider an alternative GAP as requested by the 2005 CCPR. On the latter issue, the US supports requesting the JMPR to consider alternative GAPs on a *routine* basis when initially evaluating/reevaluating compounds with dietary intake concerns.

For the US use and consumption patterns, the acute and chronic dietary (food) risks are less than 100% of the aPAD and cPAD for the general U.S. population and all population subgroups. Children (1-6 years), the most highly exposed population group, are exposed to disulfoton at a level of 9.6% of the aPAD at the 99.9th exposure percentile and 3.5% of the cPAD. Numerous tolerances will be revoked based on voluntary cancellation of uses. However, for the Codex MRLs under consideration (broccoli, cabbages, cauliflower, and lettuce) the US tolerances remain.

FENAMIPHOS (085)

AUSTRALIA

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

Based on the acute dietary intake calculations of JMPR 2002, Australia has reservations about the MRLs for peppers, tomato and watermelon, which should be returned to Step 6.

CANADA

Canada supports the advancement of the MRLs currently at Step 6.

USA

The US does not have tolerances for the commodities under consideration (peppers, tomato, watermelon). As there is an apparent acute dietary intake concern reported by the JMPR, the US does not support advancement of the MRLs. The US also notes that the 2005 JMPR did not consider an alternative GAP as requested by the 2005 CCPR. On the latter issue, the US supports requesting the JMPR to consider alternative GAPs on a *routine* basis when initially evaluating/reevaluating compounds with dietary intake concerns.

For the US use and consumption patterns, the acute dietary (food) risk estimate is below the EPA's level of concern for the general U.S. population and all population subgroups. Infants (younger than one year of age), the most highly exposed subpopulation, are expected to be exposed to fenamiphos at a level less than or equal to 1% of the aPAD. The chronic dietary risk estimate is also below the Agency's level of concern for the general population and all population subgroups. The exposure is estimated to be equal to or less than 1% of the cPAD for all population subgroups including infants and children (from 1 to 6 years of age), the most highly exposed subpopulation.

CHLORPYRIFOS-METHYL (090)

AUSTRALIA

Australia notes the decision of the 35th CCPR to hold all draft MRLs at step 6 pending review by JMPR in 2008.

CANADA

Canada has no objection to the advancement of the MRLs at Step 6.

USA

The US has post-harvest uses on barley, oats, and rice with tolerances lower than the proposed MRLs. However, noting the dietary intake concerns expressed by Codex, the US will not support advancement of the MRLs. Perhaps JMPR will be able to resolve the issue when it is considered at its scheduled periodic review date (2008/2009 JMPR).

METHOMYL (94)

AUSTRALIA

Based on the acute dietary calculations of JMPR 2001, Australia proposes that the MRLs for apple, brassica vegetables, celery, watermelon (from the cucurbit group), grapes and leafy vegetables be returned to Step 6.

Australia considers that MRLs for cucumbers, summer squash and melons (except watermelon) can be supported, and proposes that the Committee request JMPR to recommend separate MRLs for these commodities on the basis of trial data, rather than hold up the current MRL recommendation for the crop group fruiting vegetables, cucurbits. The MRL for fruiting vegetables, cucurbits should be returned to Step 6 awaiting further recommendations from JMPR for individual cucurbit commodities.

CANADA

Canada does not support the advancement of the MRLs at Step 6 because of health risk (PDI > ADI; ARfD different).

USA

The US notes the apparent acute dietary intake concern reported by the JMPR and therefore supports holding the subject MRLs (apple, brassica vegetable, celery, fruiting vegetables cucurbit, grapes, leafy vegetables, and pear) at Step 5. It is noted that for the group *cucurbit fruiting vegetables*, watermelon was the only commodity with an acute dietary intake concern (JMPR Report 2001). The acute dietary intakes were <100% for the general population and for children for cucumber, summer squash, and melons (except watermelon) (JMPR Report 2001). Adequate field trial data were reviewed by the JMPR for these commodities (JMPR Report 2001). The US supports retaining the cucurbit group at Step 5 and introducing MRLs for summer squash, melons (except watermelon), and cucumber, each at 0.1 mg/kg, and advancing these specific commodity MRLs to Step 8.

For US use and consumption patterns, the results of the probabilistic acute dietary exposure analyses, for methomyl only, indicate that there are adequate margins of exposure for the general U.S. population (MOE=958), children 1 to 6 years of age (MOE=417), and infants (MOE=1117) from the application of methomyl. For this analysis, percent crop treated information and field trial residue data were utilized for all commodities. The results of the chronic dietary risk evaluation system (DRES) analyses, for methomyl only, indicate that the anticipated residue contribution for infants occupies 67% of the RfD. For children 1-6 years old 62.6% of the RfD is occupied and for the general U.S. population, 35% of the RfD is occupied.

ACEPHATE (095)

AUSTRALIA

See under methamidophos. Also note revised acephate ADI and ARfD at 2005 JMPR reduced the number of exceedances of ARfD by one MRL.

CANADA

Canada has no objection to the proposed JMPR ADI and ARfD for acephate.

Canada has no objection to the advancement of the MRLs currently at step 6. Acephate is under re-evaluation in Canada, and is also associated with the review of methamidiphos[1]. We are willing to share the results of the evaluation when completed.

USA

The US notes that the 2005 JMPR established a new ADI and a new ArfD for acephate and performed new dietary intake analyses (Report 2005 JMPR). However, there continues to be apparent acute dietary intake concerns for flowerhead brassicas, mandarins, nectarines, peaches, peppers, and pome fruit, and therefore the US supports retaining these MRLs at Step 5. The US supports the advancement of the MRL for beans to Step 8.

The US notes that it has no tolerances for mandarins, nectarines, peaches, or pome fruit. The US RfD (0.0012 mg/kg/day) and population adjusted ARfD (0.005 mg/kg/day) are an order of magnitude below the most recent JMPR values, 0.03 mg/kg/day and 0.1 mg/kg/day.

No apparent chronic or acute dietary intake concerns exist for the US use and consumption patterns. Acute and chronic dietary risk analyses for acephate were conducted with the Dietary Exposure Evaluation Model

[1] In accordance with Section 19 of the Regulations to the Pest Control Products Act, all pesticides, both active ingredients and formulated end-use products that were registered prior to 1995 are subject to re-evaluation by PMRA to ensure that their continued acceptability is examined using current scientific approaches. Since the initiation of the re-evaluation program, certain registrants have chosen not to support the continued registration of particular active ingredients resulting in the discontinuation of the registration of their technical active ingredients and any end-use products formulated with that active ingredient. In such cases, the PMRA does not schedule the pesticide for further review, and Canadian use is phased out by establishing a last date of use (i.e., the expiry date) for existing product.

(DEEM™). Residues used for the exposure analyses wer highly refined and included anticipated residues generated from field trials, USDA Pesticide Data Program (PDP) and FDA monitoring data, adjustments for the percent crop treated, washing and cooking factors, and a probabilistic acute analysis.

CARBOFURAN (096)

CANADA

Canada does not support the advancement of the MRLs at Step 6 due to health risk (PDI > ARfD).

USA

The US notes the rationale used by the WHO JMPR in selection of the critical toxicology study (JMPR 2006 Report, General Item 2.12) and expresses continued concern with the exposure from dietary intake of carbofuran. The US opposes advancement of the MRLs and requests that more recent toxicology data be made available to the JMPR for evaluation. The 2005 JMPR did not consider newer data described below.

The 2001 JMPR established an **ARfD of 2.0 mg/kg bw** based on a NOEL of 3.8 mg/kg bw/day identified from cholinesterase inhibition in a 5-week dietary study in dogs. The US acute RfD was based on a recently submitted comparative ChE study in the rat (**2005**). A benchmark dose analysis (BMD) was performed on the data. The acute RfD was derived from the BMDL10 value of 0.03 mg/kg/day from the rat pup brain ChE data from the oral gavage acute comparative sensitivity study. A total uncertainty factor of 500 is appropriate: 5X database uncertainty (ratio of BMD for brain ChE/RBC ChE inhibition), 10X for variability among individuals; and 10X for interspecies extrapolation). A special FQPA safety factor of 1X is appropriate because the endpoint and dose is based on pup brain ChE data from the comparative ChE study (most sensitive effect in the most sensitive species/population). The results of this study demonstrated that the pups were more sensitive than the adults to the inhibitory effects of carbofuran. The database uncertainty factor of 5X was based on the results of EPA studies that have characterized time-course and dose-response relationships of ChE inhibition (RBC, plasma, and brain) in adult rats acutely treated with several N-methyl carbamate pesticides including carbofuran (USEPA 2005). While the comparative ChE study demonstrated a dose-response relationship for inhibition of *brain* ChE in adults and pups, there was no such relationship in the *RBC* data (FMC 2005). Other carbofuran toxicity studies have demonstrated dose-response relationships for RBC ChEI. Since BMD analyses in the adult rats have indicated lower BMD values for RBC in comparison to the brain (USEPA 2005), the apparent lack of dose-response in RBC (FMC 2005) cannot be discounted. In the case of carbofuran, for adult rats, BMD10 levels for RBC (0.15 mg/kg) were five times lower than the BMD10 for brain (0.03 mg/kg). Therefore, for pups, a factor of 5X is applied to the pup brain BMDL10 (0.03 mg/kg) to derive a value of 0.006 mg/kg to account for the uncertainty in the RBC data. The additional intraspecies (10X) and interspecies (10X), and special FQPA factor (1X) result in an acute RfD and acute **PAD of 0.00006 mg/kg/day** for the general population and all population subgroups.

The US can immediately supply its review of the new data and will arrange for submission of the relevant studies to the 2006 JMPR.

Carbofuran is currently undergoing review in the USA. The US and Codex residue definitions are harmonized with the deletion of three phenolic metabolites from the US residue definition during the reregistration process. It is noted that US tolerances are approximately 2X the corresponding Codex MRLs. The Codex ArfD and ADI are about 10% of the corresponding US values. Preliminary US risk assessments indicated both acute and chronic dietary intake concerns for the US use and consumption patterns. Most of the estimated acute dietary exposure is from drinking water. However, estimated dietary exposure to carbofuran (02/2006) from food alone also exceeds the US level of concern for all population subgroups (770% of the aPAD for the U.S. population and 1300% of the aPAD for children, 1-2 yrs. old, the subgroup with the highest estimated exposure to carbofuran from food alone).

METHAMIDOPHOS (100)

AUSTRALIA

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

Based on the acute dietary intake calculations of JMPR 2003 for both acephate and methamidophos, Australia has reservations about all of the MRLs listed in Appendix IX of ALINORM 05/28/24 for methamidophos and acephate, except for beans. All other MRLs should be returned to Step 6.

CANADA

Canada has no objection to the advancement of the MRLs at Step 6. However, in Canada, certain registrants have chosen not to support the continued registration hence the product's registration in Canada is discontined and its use in Canada is being phased out.[1]

USA

Given the apparent acute dietary intake concerns of Codex, the US does not support advancing the subject MRLs at Step 5.

The US notes that its acute and chronic reference doses (population adjusted) are an order of magnitude below those promulgated by Codex. The US has no chronic dietary or acute dietary intake concerns for its use and consumption patterns.

PHOSMET (103)

AUSTRALIA

Based on the acute dietary intake calculations of JMPR 2002, Australia has reservations about the MRLs for blueberries, citrus fruits, nectarine and pome fruits, which should be returned to Step 6.

It is noted that apricot has not been included in the IESTI calculations of the JMPR 2002, as the MRL was first proposed by the 1997 JMPR. Therefore an acute dietary intake calculation has not been conducted on apricot. Australia proposes that the MRL for apricot also be returned to Step 6, and an acute dietary intake calculation be performed in accordance with current procedures.

Note: Using Australian food consumption data the acute RfD is exceeded for apricot.

CANADA

Canada supports the advancement of the MRLs currently at Step 6.

USA

The US does not support advancing the subject MRLs at Step 6, based on acute dietary intake concerns (JMPR 2002) for blueberries, citrus fruits, nectarine, and pome fruits. The US requests clarification on the dietary intake calculation status of apricot. An inspection of the 2002 JMPR Report shows no data that would support a reduced MRL with possible acceptable dietary intake.

Phosmet is registered for use on these commodities in the USA. There are no chronic or acute dietary intake concern for the US use patterns and consumption habits. Revised acute and chronic dietary risk analyses for phosmet were calculated using the Dietary Exposure Evaluation Model (DEEM™). The regulated residues consist of parent phosmet and its metabolite, phosmet oxygen analog (oxon). For the revised phosmet risk assessment, the EPA conducted highly refined (Tier 3) acute (probabilistic) and chronic dietary exposure

analyses which were based almost entirely on the available monitoring data, and incorporated additional refinements such as processing and cooking factors and percent of crop treated.

DITHIOCARBAMATES (105)

AUSTRALIA

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

IMAZALIL (110)

CANADA

Canada has no objection to the proposed JMPR ADI.

PHORATE (112)

AUSTRALIA

Australia supports advancement of phorate MRLs except potato to step 5. Unless the acute intake concern for potato is resolved, this MRL should not proceed past step 6 as per current CCPR policy.

CANADA

Canada has no objection to the proposed JMPR ADI and ARfD, and the recommended MRLs at Step 3.

USA

The US supports all MRL recommendations of the 2005 JMPR and notes good agreement between US tolerances and the JMPR recommendations. The ArfD of Codex and the US are comparable, 0.0025 mg/kg bw/day and 0.003 mg/kg bw/day, respectively. The ADI of Codex and the US are comparable, 0.0007 mg/kg bw/day and 0.0005 mg/kg bw/day. Both chronic and acute dietary intake concerns are well below the level of concern for the US.

ALDICARB (117)

AUSTRALIA

Australia has concerns over the acute dietary intake of aldicarb from potatoes (JMPR 2001) and bananas (JMPR 2002) and recommends that the MRLs are returned to Step 6.

CANADA

Canada does not support the advancement of the MRLs at Step 6. Canada is re-evaluating Aldicarb and its uses are being recommended for phase-out because of acute health risk concerns. Canada is willing to share the results of the evaluation when completed.

USA

The US does not support the advancement of the MRLs for banana and potato at Step 6 based on acute dietary intake concerns reported by the JMPR. The US also notes that the 2005 JMPR did not consider an alternative GAP as requested by the 2005 CCPR. On the latter issue, the US supports requesting the JMPR to consider alternative GAPs on a *routine* basis when evaluating/reevaluating compounds with dietary intake concerns.

The US has a registered use for potato, but not for banana. The US and Codex residue definitions are harmonized. Aldicarb is under evaluation in the US.

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.

CANADA

Canada has no objection to the advancement of the MRLs at Step 6.

USA

The US does not support the advancement of the MRLs for citrus fruits, cucumber, melons, and peppers at Step 6, based on acute dietary intake concerns expressed by the JMPR 2002. The MRLs in question are based on US field trial data and GAP. The JMPR did not receive other GAPs and/or supporting field trial data (Evaluation, 2002 JMPR).

The US and Codex definitions are harmonized. The US has tolerances for all of the commodities under consideration, and has no dietary intake concerns for its use patterns and consumption habits. Acute dietary risk is below the Agency's level of concern based on a highly refined, acute probabilistic dietary exposure analysis using the DEEM model which incorporates percent crop treated information, PDP, FDA monitoring data, and field trial data. The percent aPAD value is 81% based solely on food for the most highly exposed population subgroup, children 1-6 years old. The EPA did not perform a chronic risk assessment because oxamyl induced ChEI reverses within 2 to 3 hours.

AZOCYCLOTIN (129)

CANADA

Canada has no objection to the recommended JMPR MRLs at Step 3, and the proposed ADI and ARfD.

USA

The US supports the advancement of the MRL for oranges and the withdrawal of the MRLs for citrus fruit, meat, milk products, and milks. The US notes that many tolerances have been canceled in the US (Fed Reg 9/21/05, 70 (182), 55269), including those for the proposed Codex MRLs for apple, pear, and grapes. This resulted from an apparent acute dietary intake concern for infants and children. The US has an acute reference dose of 0.007 mg/kg/day, based on a 13 week neurotoxicity study on rats with a LOAEL of 11 mg/kg/day. The effect was decreased body weight and food consumption and clinical signs. The JMPR evaluated the same study and decided that an acute reference dose for the general population (which includes children) was not warranted. Thus, the issue is a difference in interpretation of findings. The US notes the differences with respect to the JMPR evaluation but will not object to the advancement of the subject MRLs.

METHIOCARB (132)

AUSTRALIA

Australia supports the advancement of methiocarb MRLs to Step 5.

CANADA

Canada does not support the recommended MRLs at Step 3, and the proposed ADI and ARfD as we have health concerns related to the use of this product.

USA

All US tolerances for food use of methiocarb have been revoked (Fed Reg 63 (206), 57067, 10/26/98). The US will not oppose the advancement of the subject MRLs, deferring to the risk assessment of the 2005 JMPR, Annex 3 and Annex 4.

PROCHLORAZ (142)

AUSTRALIA

Australia proposes that the MRL be retained at Step 6, due to acute dietary concerns with mushrooms.

METHOPRENE (147)

AUSTRALIA

The mammalian MRLs for methoprene appear to have been set too low based on the intake and feeding studies. The JMPR report results from feeding studies carried out at dose levels equivalent to feeding at 0.1 to 167 ppm in the diet. For studies evaluated by JMPR, transfer factors (TF; residues in tissues ÷ residues in diet) for fat ranged from 0.02 to 0.1 depending on the feeding study and dose level. There is no consistent pattern with dose; rather the variation is suggestive of biological variation. For example the TF for fat was 0.096 at the 1 ppm feed level, 0.022 at 16.7 ppm, 0.07 at 33 ppm and 0.05 at 167 ppm. When taken as a whole the data indicate a higher transfer factor than that used by the 2005 JMPR is appropriate. Australia considers a TF of 0.1 or 0.07 is justified, rather than 0.022 used by the 2005 JMPR.

The 2005 JMPR estimated dietary burdens of 6.2 and 7.7 ppm for beef and diary cattle respectively. As meat is derived from dairy cattle, the higher of the two estimates should have been used in estimating residues in tissues. Using the estimated dietary exposure of 7.7 ppm combined with a transfer factor of 0.1 gives a highest residue in fat of 0.77 mg/kg (7.7×0.1) suggesting an MRL of 1 mg/kg for meat (mammalian) (fat) may be more appropriate. Australia considers there is justification for CCPR to request JMPR to revisit their animal commodity recommendations for mammalian meat and offal.

Australia supports advancement of methoprene MRLs, except those for animal commodities, to Step 5.

USA

The US supports the advancement of all recommendations of the 2005 JMPR. The US decided that tolerances are not required for methoprene as no chronic or acute reference doses are necessary.

PROPAMOCARB (148)

CANADA

Canada has no objection to the proposed JMPR ADI and ARfD.

BENALAXYL (155)

CANADA

Canada has no objection to the proposed JMPR ADI and ARfD for benalaxyl.

CLOFENTAZINE (156)

CANADA

Canada has no objection to the proposed JMPR ADI. In Canada, the toxicology database is under re-evaluation for clofentazine and Canada will be pleased to share the results with the Committee when available.

GLYPHOSATE (158)

AUSTRALIA

Australia supports the advancement of glyphosate MRLs to Step 5.

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.

MRL proposals for all other commodities listed in ALINORM 05/28/24 Appendix IX are supported and should be progressed to Step 8.

Australia supports advancement of MRLs for barley, barley straw and fodder, cauliflower, potato, rye, rye straw and fodder, sugar beet, sugar beet leaves and tops, wheat, wheat straw and fodder to Step 8.

CANADA

Canada does not support the advancement of the MRLs at Step 6 due to health risks (chronic and acute exposures).

USA

The US supports advancing the following MRLs to Step 8; cattle fat, common bean, cotton seed, eggs, kale, kohlrabi, lemon, meat of cattle, pigs, and sheep, milks, pig fat, poultry fat, poultry meat, and sheep fat. The proposed MRLs are in agreement with reevaluated US tolerances. The US does not support the advancement of MRLs for those commodities determined by the JMPR to have possible acute dietary intake concerns: apple, cabbages, grapes, oranges, and pear. The US notes that requesting JMPR to consider alternative GAPs would not be useful, as the review was conducted in 1998. New data (field trial and/or GAP) would need to be requested for the crops in question.

The US tolerances for apple, grapes, and pear have been recommended for revocation. The US has no chronic or acute dietary intake concerns for its use patterns and consumption habits. Revised acute and chronic dietary risk analyses for ODM were conducted with the Dietary Exposure Evaluation Model (DEEM™).The Tier 3 acute analysis included use of weighted average percent crop treated data and anticipated residues developed using residue data from available crop field trials and livestock feeding studies, and USDA/PDP and FDA monitoring data. The Tier 3 chronic dietary analysis included use of weighted average percent crop treated data, anticipated residues developed using residue data from available crop field trials and livestock feeding studies, PDP data from USDA, and FDA monitoring data.

TERBUFOS (167)

AUSTRALIA

Australia supports advancement of terbufos MRLs to step 5.

CANADA

Canada does not support the recommended MRL for bananas.

As a result of re-evaluation in Canada, the use of terbufos on corn and rutabaga are no longer supported and its use on sugar beets will be revisited in 2006. In Canada, the ADI was calculated to be 0.00015 mg/kg bw based on a NOAEL of 0.15 mg/kg bw and an uncertainty factor of 1000. Bananas are the principal contributor to the acute dietary risk for terbufos. An import maximum residue limit (MRL) is recommended at 0.005 ppm based on the dietary risk assessment. This proposed MRL is supported by field residue data at GAP provided to Canada.

USA

The US supports the advancement of the 2005 JMPR MRL recommendations for terbufos, including the numerous withdrawal recommendations. The US has very few tolerances for this pesticide, and there is good agreement between the proposed Codex MRLs and existing US tolerances. The US supports the decision of the JMPR to not recommend MRLs for forage crops.

The US has no acute or chronic dietary intake concerns for its use and consumption patterns. The acute dietary risk from foods is below the level of concern, 86% of the ArfD (also the acute PAD) for the most exposed group (non-nursing infants). Chronic dietary risk from food is well below the level of concern ($\leq$ 9% of the chronic PAD, also the ADI). The US acute and chronic reference doses are a factor of 10 lower than those of the 2005 JMPR.

FENPROXYMATE (193)

CANADA

Canada has no objection to the advancement of the MRLs at Step 6.

USA

The US supports holding the MRLs for apple and grapes at Step 6, based on Codex acute dietary intake concerns. As the data and GAP were last reviewed by the JMPR in 1999, consideration of alternative GAP based on these findings would be inappropriate.

The US has no acute dietary intake concerns for its use and consumption patterns, which includes grapes and pome fruits. The US aPAD of 0.05 mg/kg bw/day, based on prenatal developmental toxicology effects, applies only to women 13 – 50 years of age.

HALOXYFOP (194)

AUSTRALIA

Australia notes the intake concerns expressed by the 2003 JMPR for haloxyfop (chronic) and plans for JMPR to establish an ARfD. Australia supports the retention of MRLs at Step 6.

In addition, Australia notes that the MRL for cattle meat should be set in the fat. The most recent review of haloxyfop 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.

MRLs for all animal feeds have been returned to Step 3 and should not advance beyond Step 6, until animal commodity MRLs are revised and advanced.Australia recommends that CCPR **formally** request JMPR to revisit the animal commodity MRLs with regard to the residue definition and fat solubility. This will also provide JMPR with the opportunity to extrapolate the cattle MRLs to other livestock species.

CANADA

Canada has no objection to the advancement of the MRLs at Step 3 and Step 6.

USA

The US has no registered food uses for haloxyfop..

CHLORPROPHAM (201)

AUSTRALIA

Australia proposes that the MRL for chlorpropham in cattle milk be returned to Step 6. This is due to the proposed value of 0.0005* F being an incorrect figure in accordance with the CCPR policy regarding expression of fat-soluble pesticides in milk and milk fats in cases where residue levels in fat are at or about the limit of determination. [Reference ALINORM 95/24A para. 180; ALINORM 95/24 Appendix II].

In accordance with this policy, if residues in milk fat are at or about the limit of analytical determination, the suffix should be deleted and the MRL set at or about the limit of determination. In this case the correct MRL should be for whole milk and the figure should be either 0.01* mg/kg or 0.05* mg/kg (JMPR 2001 periodic evaluation of chlorpropham).

Australia requests that the Committee apply this policy, while preferably taking note of the proposal of the 2004 JMPR (General Considerations Item 2.7 *MRLs for fat-Soluble pesticides in Milk and Milk Products*) and request that JMPR establish two separate MRLs for chlorpropham in milk; one for whole milk and one for milk fat. The Committee may then choose to review the separate MRLs at a later time.

Australia also notes that the CXL for diphenylamine in milk is incorrect for the same reasons as above; the CXL of 0.0004*F mg/kg should either be changed to 0.01* mg/kg in whole milk, or preferably reviewed according to the decision taken by the 2004 JMPR and two separate MRLs be recommended.

CANADA

Canada has no objection to the proposed JMPR ADI and ARfD. Canada has no objection to the advancement of the MRLs at Step 6.

USA

The US supports the advancement of all subject proposed chlropropham MRLs to Step 8, except milk as proposed. The 2005 JMPR set new ADIs and ArfDs and conducted dietary intake analyses. There are neither chronic or acute concerns.

The proposed milk MRL was estimated prior to the revised procedure for estimating the milk MRLs (JMPR Report 2004). Under the old procedure, the value determined for cream was divided by 25 (4%) to arrive at an estimate for milk. The JMPR decided in 2004 to set MRLs based on the whole milk and/or cream, depending on the data available, and not to make mathematical calculations based on assumed percentages of milk fat. The data available support an MRL of 0.05* mg/kg for milk. Data are also available to estimate an MRL for cream. The 2004 JMPR Report noted an LOQ of the analytical method of 0.05 mg/kg for each of milk and cream.

ESFENVALERATE (204)

AUSTRALIA

MRLs for esfenvalerate should be retained at Step 6 until fenvalerate MRLs are phased out.

CANADA

Canada has no objection to the advancement of the MRLs at Step 6.

USA

The US has no tolerances for the commodities under consideration: cotton seed, tomato, and wheat. The US has no objection to advancing the MRLs, but notes the existence of higher MRLs for the same commodities for fenvalerate. The proposed esfenvalerate MRLs should not advance to Step 8 until the corresponding fenvalerate MRLs are withdrawn, as the residue definitions for esfenvalerate and fenvalerate are the same (see JMPR Report 2002).

METHOXYFENOZIDE (209)

AUSTRALIA

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

CANADA

Canada has no objection to the advancement of the MRLs at Step 6.

USA

The US supports retaining the MRL for spinach at Step 6 because of acute dietary intake concerns (JMPR Report 2003) for children (310% ArfD). There is no alternative spinach data and/or GAP (JMPR Evaluation 2003) upon which to base a different MRL.

PYRACLOSTROBIN (210)

AUSTRALIA

Australia supports advancement of pyraclostrobin MRLs to Step 8.

FLUDIOXONIL (211)

AUSTRALIA

Australia supports advancement of fludioxonil MRLs to Step 8.

METALAXYL-M (212)

AUSTRALIA

Australia supports advancement of metalaxyl-M MRLs to step 6 only. No CXLs are necessary for metalaxyl-M as they are covered by existing MRLs for metalaxyl. These should remain at Step 6 until such time as CXLs for metalaxyl are deleted.

TRIFLOXYSTROBIN (213)

AUSTRALIA

Australia supports advancement of trifloxystrobin MRLs to Step 8.

CANADA

Canada has no objection for the advancement of the trifloxystrobin MRLs to Step 6 as indicated in ALINORM 05/28/24, Appendix VI.

DIMETHENAMID-P (214)

AUSTRALIA

Australia notes that no residues are expected in any commodities as reflected by the maximum residue level recommendations and questions why this compound was scheduled for review. This compound does not meet the general criterion adopted by CCPR concerning the presence of residues in or on commodities in trade.

Australia supports the advancement of dimethenamid-P MRLs to Step 5 .

CANADA

Canada has no objection to the recommended JMPR MRLs at Step 3, and the proposed ADI and ArfD.

USA

The US supports the fast-tracking to Step 8 of the proposed MRLs for dimethenamid-P. The US notes that all residues are at the limit of quantitation and that there are no dietary intake concerns.

FENHEXAMID (215)

AUSTRALIA

Australia supports the advancement of fenhexamid MRLs to Step 5.

CANADA

Canada has no objection to the recommended JMPR MRLs at Step 3, and the proposed ADI.

USA

The US supports the fast track advancement of all proposed MRLs for fenhexamide, a reduce risk pesticide. There is excellent agreement between the US tolerances and the proposed Codex MRLs, and residue definitions are harmonized. The US has no dietary intake concerns for its use and consumption patterns.

INDOXACARB (216)

AUSTRALIA

The pesticide is fat-soluble. The JMPR have evaluated residues in milk according to the procedure outlined by the 2004 JMPR. However, Australia notes an error in the MRLs listed in CL 2006/2-PR and annex 1 of the 2005 JMPR Report. The 2005 JMPR proposal in the text of the appraisal contains recommendations for milks and milk fats (p 179). The listed MRLs are for ML 0106 Milks and FM 0812 Cattle milk fats;

Australia requests CCPR amends the proposal to be ML 0106 Milks and FM 0183 Milk fats (from milk of Buffalo, Camel, Cattle, Goat or Sheep) with the levels as recommended by the JMPR..

With the above changes, Australia supports the advancement of all indoxacarb MRLs except cabbage head to Step 5.

Unless the acute intake concern for head cabbages is resolved, this MRL should not proceed past step 6 as per current CCPR policy.

CANADA

Canada has no objection to the proposed ADI and ArfD. Indoxacarb is currently undergoing toxicology evaluation in Canada and we are willing to share the results of the evaluation when completed.

USA

The US supports the fast track advancement of all MRL recommendations from the 2005 JMPR, but notes significantly higher tolerances of broccoli and cauliflower than the corresponding proposed Codex MRLs. This is the result of no submission of relevant US data.

NOVALURON (217)

AUSTRALIA

Australia notes the pesticide in fat soluble and the treatment of residues in milk and milk fat according to the procedure outlined by the 2004 JMPR. However, Australia notes an error in the MRLs listed. The 2005 JMPR proposal in the text contains recommendations for milks and milk fats (p 225). The listed MRLs are for ML 0106 Milks and FM 0812 Cattle milk fats; Australia requests CCPR amends the proposal to be ML 0106 Milks and FM 0183 Milk fats (from milk of Buffalo, Camel, Cattle, Goat or Sheep) with the levels as recommended by the JMPR.

With the above changes, Australia supports the advancement of novaluron MRLs to Step 5.

CANADA

Canada has no objection to recommended JMPR MRLs at Step 3, and the proposed ADI. Canada would like to inform the committee that new toxicology studies are being reviewed in Canada, and the proposed toxicological end-points are subject to possible changes. We will share the results with the Committee when completed.

USA

The US supports the advancement of the all proposed MRLs for novaluron.

SULFURYL FLUORIDE (218)

AUSTRALIA

Sulfuryl fluoride is currently not registered in Australia. The JMPR note that the dietary risk assessment requires an evaluation of fluoride intake. Australia supports the advancement of the MRLs to step 5 and awaits the outcome of the dietary risk assessment for fluoride.

CANADA

Canada has no objection to the recommended JMPR MRLs at Step 3, and the proposed ADI and ARfD.

USA

The US supports advancement of all 2005 JMPR recommendations for MRLs for sulfuryl fluoride.