

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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**Agenda Item 6**

**CX/PR 02/6-Add.1**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX COMMITTEE ON PESTICIDE RESIDUES**

**Thirty-fourth Session**

**The Hague, The Netherlands, 13 - 18 May 2002**

#### **SUMMARY OF COMMENTS<sup>1</sup>**

#### **STEPS IN THE CCPR-CODEX PROCEDURE**

- |                |   |
|----------------|---|
| <u>Step 1</u>  | Recommendation of priority compounds by CCPR, involving the Ad Hoc Working group on Priorities  |
| <u>Step 2</u>  | 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) |
| <u>Step 3</u>  | Submission of the proposed Codex MRLs to governments for a first round of comments  |
| <u>Step 4</u>  | First discussion of the proposed MRLs by the CCPR in the light of the comments received   |
| <u>Step 5</u>  | Submission of the proposed Codex MRLs to the Codex Alimentarius Commission in the light of the CCPR-discussion, for consideration                         |
| <u>Step 6</u>  | Submission of the proposed Codex MRLs to governments for a second round of comments   |
| <u>Step 7</u>  | Final discussion of the proposed Codex MRLs by the CCPR in the light of comments received   |
| <u>Step 7A</u> | The proposed MRL is not further advanced in the procedure until a full ADI has been estimated by the JMPR   |
| <u>Step 7B</u> | The proposed MRL is referred back to the JMPR for reconsideration, in the light of new information provided   |
| <u>Step 7C</u> | The proposed MRL is not advanced, waiting for further information as specified  |
| <u>Step 8</u>  | Consideration by the CAC in view of adoption of the proposal as Codex MRL (CXL)   |

<sup>1</sup> Original language only, tables are not included in this document

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.

## CAPTAN (007)

### EUROPEAN COMMUNITY

In general, the EC is reluctant to accept MRLs that are based on a GAP where no PHI has been specified. From a general point of view, the EC does not support the establishment of MRLs based on a 0-day PHI, especially since Captan is classified as a skin sensitiser.

For captan animal feeding studies are required.

The EC questions the recommendation of JMPR of not setting an ARfD in view of the proposed high MRLs. What are the criteria for not setting an ARfD?

EC can not accept the proposal especially in relation to the dietary exposure of infants and young children. EC does not support the advancement of MRLs beyond step 6 before the issue of the acute intake has been solved .

#### Cherries (25 mg/kg)

The EC objects to an MRL of 25 because it is based on a mixture of trials with different PHIs varying from 0 to 8, while the proposal is mainly based on trials with a 0-day PHI.

#### Cucumber (3 mg/kg)

The MRL is not supported by the data: the highest residue is 1.5, 2 ppm would be sufficient.

#### Grapes (25 mg/kg)

For wine grapes, it is not clear why a PHI of 0 days is required. Such practice could affect the fermentation process this is not good GAP. The EC cannot accept the proposal.

#### Peach (20 mg/kg)

The EC has objections to such a high value in view of the 0-day PHI

#### Plums (10 mg/kg)

The MRL is based on trials with different GAPs which cannot be combined, and some of which have a 0-day PHI. The EC can therefore not accept the proposal.

#### Pome fruit (15 mg/kg)

The EC questions the JMPR policy of accommodating every data point in a MRL. For example, based on the trials data (42 trials) only 3 data points exceed a level of 10 mg/kg (13, 14 and 16 mg/kg) - therefore a level of 10 mg/kg would appear to be more appropriate. The EC can therefore not accept the proposal,

#### Strawberries (15 mg/kg)

The EC has reservations on a 0-day PHI,

#### Tomatoes (5 mg/kg).

The EC notes that only a limited number of trials data are available - particularly from those carried out under glass.

### SOUTH AFRICA

The proposed MRLs for peaches, pome fruits, strawberries and plums are supported. The withdrawal of the present 20mg/kg MRL on apples is supported.

### USA

The proposals of the 2000 JMPR are consistent with the data reviewed, including data from USA field trials. There are no chronic or acute dietary risk concerns for those uses registered in the US. The US supports advancement of all proposed MRLs.

Generally, US reevaluated tolerances will agree with the proposed Codex MRLs. Significant differences are due to use pattern. Several uses in the US are limited to seed treatment only, with a corresponding low tolerance value (0.05 ppm). These include cucumber, melons, potato, and cereal grains.

The US tolerances for apples and pears, 25 ppm, are higher than the proposed MRL for pome fruit, 15 mg/kg. In both cases, the use pattern is postharvest dip. The data are consistent with the JMPR recommendations, which were based on the evaluation of US data. The US values reflect harmonization with previous Codex MRLs.

## **CHLORMEQUAT (015)**

### **EUROPEAN COMMUNITY**

Based on the same data the EC propose 2 mg/kg for wheat, tricale and rye and 5 mg/kg for Oats.

For dry straw and fodder, dry of cereals the EC considers 20ppm as sufficient.

For oat and rye forage 100ppm should be sufficient.

The setting of above MRLs at the levels proposed by JMPR is unacceptable for the EC because of acute exposure concerns.

Processed products from rye: (bran, flour and wholemeal) one study is not sufficient

For wheat: (bran, flour and wholemeal) the MRLs are not acceptable because based on 2 studies that differ widely. The processing factors are not comparable and therefore not to be used for deriving MRLs.

The MRL for pear, based on dutch and french trials should be withdrawn as all european authorisations have been withdrawn due an acute intake problem. It should be noted that the product is likely carried over to the next season in woody crops. The EU has a temporary MRL of 0.5 mg/kg to accommodate the residues due to carry over.

### **USA**

The US has no registered food/feed uses or established tolerances for chlormequat.

## **CHLORPYRIFOS (017)**

### **EUROPEAN COMMUNITY**

Alfalfa fodder, hay: 5 ppm

The analysis is made after harvest and gives maximum residues of 2,6 mg/kg (fresh weight) when taking into account 89% of dry matter, the  $(2,6/0,89 = 2,9)$  3 ppm should be sufficient.

The EC wonders whether any coordination has taken place between JMPR and JECFA about the MRLs for animal products. Not taking into account possible veterinary uses of this substance would be unacceptable for the EC

### **SOUTH AFRICA**

The proposed MRLs for pome fruit, bananas, carrots, grapes, maize, peaches, plums, tomatoes and wheat is supported.

### **USA**

The proposed MRLs generally agree with reevaluated US tolerances. Both US and JMPR chronic and acute dietary analyses have revealed no concerns with the respective uses and consumptions. However, the US requests that no proposed MRLs be advanced beyond step 6 until the completion of the US evaluation of the cumulative effect of the OP pesticides. Finalization of that process will be mid-2002.

The US notes a large discrepancy in the proposed MRLs for pome fruits, 1 mg/kg, and the US tolerances for apples and pears, 0.01 and 0.05 ppm, respectively. This is the result of different use patterns, dormant or delayed dormant use in the US and foliar application elsewhere with PHIs of 14 - 30 days.

### **2,4 D (020)**

#### **EUROPEAN COMMUNITY**

EC cannot accept results of trials data with a 0-day PHI as a basis for deriving the dietary burden of livestock animals and therefore has reservations for animal products except poultry. The EC oppose advancement beyond step 6 of these MRLs. The EC considers an LOD of 0.01 unrealistically low for routine monitoring.

### **DDT (021)**

#### **THE NETHERLANDS**

We are not in favour of using aspects of dietary intake in the decision of setting an ARfD. An ARfD should be based on toxicological findings only, i.e. the hazard assessment. Therefore, we do not agree with the argumentation of not setting an ARfD for DDT.

In fact, acute toxicological alerts are present. First, single oral exposure of rats (24 mg/kg bw) results in histopathological effects in the liver, including inflammatory infiltration (no effect after single oral dose of 12 mg/kg bw). Secondly, mice exposed early during the postnatal period show effects on behaviour in adulthood (dose not provided in JMPR). Although the relevance for humans of this effects is presently not clear, this effect may be relevant for an ARfD. Nevertheless, based on the liver effects in the single dose experiment in rats, an ARfD of 0.1 mg/kg bw can be proposed (NOAEL 12 mg/kg bw, assessment factor 100)

#### **SOUTH AFRICA**

The Proposed EMRL of 3 mg/kg is supported.

#### **THAILAND**

Thailand supports the setting of EMRL for DDT at the appropriate level which can ensure consumer safety but not too low to cause unnecessary trade problem. According to the 2000 JMPR evaluation based on the total data sets and the lowest violation rate, EMRL for DDT should be established at the level of 3 mg/kg for mammalian meat and 0.3 mg/kg for poultry meat.

### **DIAZINON (022)**

#### **EUROPEAN COMMUNITY**

The EC requires the setting of an ARfD and estimation of the acute risk for all relevant consumer groups for this substance, before MRLs can be advanced. As JMPR has set an ARfD of 0.03 mg/kg bw in the 2001 evaluations this can be done next year.

#### **USA**

Step 6 for cattle, goat, pig, sheep meat, liver, kidney.

An acute reference dose was established by the 2001 JMPR, and IESTI estimates revealed no concern for children or adults in any of the regional diets. Previous calculations indicated a possible chronic dietary intake concern. US calculations for its use patterns revealed neither chronic nor acute dietary intake problems. However, the US would prefer not to advance the step 6 MRLs for meat commodities until completion of the cumulative risk assessment for OP pesticides in mid-2002.

### **DIMETHOATE (027)**

#### **EUROPEAN COMMUNITY**

The EC opposes advancement of MRLs higher than LOD because of the exceedence of 2 regional diets in the calculations of the 1998 JMPR and because there are acute and chronic intake concerns. An ARfD needs to be agreed by JMPR. The residue definition and the plant metabolism need clarification. Omethoate should be included in the figures. This is metabolite is 7 times more toxic than the parent compound and appears

when longer PHIs are applied. The EU will reduce most of the MRLs by August 2002 because of acute and chronic intake problems. The ARfD applied by the EU is 0.03 mg/kg bw (UK).

### **FENTHION (039)**

#### **USA**

The US agrees with the JMPR recommendation to withdraw MRLs for meat and milk. Use in the US is limited to direct animal treatment in several southern states. Both chronic and acute dietary risk concerns do exist, with the main contributor to the risk being meat.

### **FOLPET (041)**

#### **EUROPEAN COMMUNITY**

The EC requires the setting of an ARfD and estimation of the acute risk for all relevant consumer groups for this substance, before MRLs can be advanced for apple (10 mg/kg), grapes (10 mg/kg) and lettuce head (50 mg/kg). For melons (3 mg/kg) the EC accepts the MRL-proposal as the residue will be predominantly on the peel

**For strawberry (5 mg/kg) the EC considers an MRL of 3 mg/kg to be sufficient, as the highest residue in the trials was 2.2 mg/kg.**

#### **USA**

Step 6 for strawberry, 5 mg/kg, and others advanced to Step 6.

The value for strawberry and some of other commodities (lettuce, onion) are in agreement with the reevaluated US tolerances (import only), and the US has no objection to their advancement. Insufficient data existed for the US evaluation of tolerances for cucumber, melons, and tomato. While an acute reference dose and associated acute dietary intake calculations have not been completed by the JMPR, the US has determined no chronic or acute dietary risk concerns for its use and consumption patterns. The US acute RfD (0.1 mg/kg bw/day) was based on developmental toxicity concerns and was applied as an acute PAD of 0.03 mg/kg bw/day to females.

### **MALATHION (049)**

#### **EUROPEAN COMMUNITY**

The EC does not accept advance of the MRLs for all feeding stuffs commodities before farm animal feeding studies are presented. The establishment of an ARfD is necessary.

In European countries there is a request for uses as Post Harvest treatments on wheat (MRL of 8ppm). The manufacturer will be requested to send the data to JMPR.

#### **USA**

The US opposes advancement of those MRLs at step 6, pending completion of the cumulative risk assessment of OP pesticides in mid-2002. The US supports the recommendations of the 2000 JMPR to withdraw MRLs on wheat processed commodities (wholemeal and bran), and has no objection to lowering the wheat flour MRL from 2 to 0.2 mg/kg. It is also noted that an acute reference dose and acute dietary intake analysis need to be considered by JMPR.

The proposed grain MRLs, including wheat, are significantly lower than US tolerances. This results from a postharvest use in the US not reflected in the data provided to JMPR in 1999. In fact the 1999 JMPR recommended withdrawal of the cereal grain MRL, 8 mg/kg, representing postharvest uses.

The US agrees with the decision to maintain those MRLs recommended for withdrawal by the 1999 JMPR for the four year period. The US has tolerances for most of the subject commodities and urges interested parties to submit requisite data within the four year period. The US will be completing a cumulative risk assessment of the OP pesticides in mid-2002.

### **MEVINPHOS (053)**

#### **EUROPEAN COMMUNITY**

The EC recommends also to withdraw Brussels sprouts as recommended by the 33<sup>rd</sup> session. Only three crops (cabbage head, common bean and leek) are left after the proposed withdrawals. The EC will withdraw mevinphos from its market in 2003. As the CXLs for cabbage head, common bean and leek are based on EC uses, these CXLs should also be withdrawn.

#### **USA**

The US has no active mevinphos products and supports the withdrawal of the MRLs, as proposed by the 2000 JMPR.

### **2-PHENYLPHENOL (056)**

#### **GERMANY**

The withdrawal of CXL for pears after 4 years period is supported if no new data become available

#### **THE NETHERLANDS**

We oppose advancement of the proposed MRLs in Step 6 awaiting the availability of new residue data from the USA and awaiting the JMPR evaluation of the comments of the Netherlands, provided to the JMPR in 2001, on the need to set an Acute Reference Dose for this compound.

#### **USA**

Withdrawal of CXL for pear (25 mg/kg) retained awaiting new data.

The US is aware of a data package being submitted in 2002 to the FAO Secretary of the JMPR and notes that it is scheduled for review in 2004.

### **PARATHION (058)**

#### **EUROPEAN COMMUNITY**

The EC opposes advancement of the MRLs for apple and barley because JMPR established acute intake concerns. MRLs for commodities that can be used as animal feeds should not be advanced before adequate animal feeding studies are presented. The EC is withdrawing parathion from its market because of operator exposure, and environmental concerns. All MRLs will be set at LOD by May 2003.

#### **USA**

The US has eliminated all uses, and the tolerances will be revoked. The US supports the withdrawal of MRLs as proposed by the 2000 JMPR and does not support the establishment/retention of any MRLs for parathion-ethyl.

### **PARATHION-METHYL (059)**

#### **EUROPEAN COMMUNITY**

The EC opposes MRLs for commodities that can be used as animal feeds before adequate animal feeding studies are presented. Evaluation of this compound in the EU is pending.

#### **SOUTH AFRICA**

The proposed MRL on apple is supported.

#### **USA**

The US opposes the advancement of any proposed MRL beyond Step 6, pending completion of the cumulative risk assessment for the OP pesticides in mid-2002.

The US has canceled uses on apple, artichoke, broccoli, Brussels sprouts, carrots, cauliflower, celery, cherries, collards, grapes, kale, kohlrabi, lettuce, mustard greens, nectarines, peaches, pears, plums, rutabagas, spinach, succulent beans, succulent peas, tomatoes, and turnips. Apples, peaches, pears, and grapes were the major contributors to acute dietary risk. Without the canceled uses, the chronic and acute dietary risk analyses showed no intakes of concern for either the general population or the most sensitive subpopulation, children. The acute dietary risk calculations of the JMPR indicated no concern for apples, peaches, and grapes.

It is noted that field trial data for hops from the US could not be evaluated for lack of a relevant GAP (label). Reevaluated tolerances for wheat, wheat straw, and wheat bran agree with the proposed MRLs. Other reevaluated and retained tolerances are in general agreement with the proposed MRLs.

### **PHOSALONE (060)**

#### **EUROPEAN COMMUNITY**

The EC opposes advancement for pome and stone fruit pending establishment of an ARfD and acute intake assessment. As JMPR has set an ARfD of 0.3 mg/kg bw in the 2001 evaluations this can be done next year.

#### **USA**

The US requests retention of the MRLs for stone fruit and pome fruit at step 6 pending completion of the cumulative risk analysis for the OP pesticides. Acute and chronic dietary risk analyses for the US residue (imported commodities only) and consumption patterns revealed no concerns.

### **PYRETHRINS (063)**

#### **EUROPEAN COMMUNITY**

The databased available for the periodic review is very limited.

Metabolism: Pyrethrin 1 labelled in the cyclopropane moiety of the acid part only was used in all metabolism studies in plants and animals. No information about the fate of the alcohol moiety is available because linkage at the other side of the ester bond, e.g. in the cyclopentene moiety was not used in any metabolism study.

#### **Dried fruit (0.2 mg/kg)**

Only data for prunes, treated in a warehouse were available. The extrapolation of these data to all dried fruit is not acceptable.

#### **Pulses (0.1 mg/kg)**

Two trials each were made for dried peas and dried beans treated by foliar application. All residues were less than 0.04mg/kg (LOD). It is therefore not clear how the proposed draft MRL of 0.1mg/kg was derived. The proposal is not acceptable

The EC objects to withdrawal of postharvest treatments on cereals because that there are uses as Post Harvest Treatment on cereals in the EC. A German company is willing to submit data to the JMPR.

#### **USA**

The US supports advancement of the MRLs proposed by the 2000 JMPR.



**QUINTOZENE (064)****EUROPEAN COMMUNITY**

The EC is withdrawing quintozene from its market because of operator exposure, and environmental concerns. All MRLs except for peanuts will be set at LOD by December 2002.

**THIABENDAZOLE (065)****CÔTE D'IVOIRE****Step 3**

**papaya:** with a MRL set at 10 mg/kg which we support.

**melon:** for the time being, we lack quantified evidence to assess the proposed MRL, but would like the limit presently set at 1 mg/kg to be raised to that of 5mg/kg proposed for mango or at least aligned to that 3 mg/kg for pome fruit.

**EUROPEAN COMMUNITY**

This product no more allowed for foliar treatment in EU, only for post-harvest treatment are authorised due to problems of high persistence in soil.

**Melon:** 1 ppm is based on residues trials from Spain with according to the Spanish GAP but as it is not more registered in Spain the MRL should be withdrawn.

**Strawberry:** 5 ppm is based on residues trials from Spain with according to the Spanish GAP but as it is not more registered in Spain the MRL should be withdrawn

**SOUTH AFRICA**

The proposed MRL for avocado is supported.

**USA**

The US does not support advancement of the MRLs proposed by the 2000 JMPR, based on acute dietary intake risk concerns. The JMPR needs to establish an acute reference dose for thiabendazole and complete an acute dietary risk analysis. The preliminary acute dietary risk analysis conducted in the US (08/01) showed an unacceptable risk for children 1 - 6 at the 99.9<sup>th</sup> percentile, 117% of the aPAD. For the general population there was no concern. There were no chronic dietary intake concerns (1 - 2% cPAD). Risk management options are now under consideration in the US.

The MRLs proposed by the 2000 JMPR generally agree with the reevaluated US tolerances. The most significant difference is 10 ppm for citrus versus 3 mg/kg proposed MRL. Data for US postharvest treatment of citrus were not made available to the JMPR.

The proposed withdrawal of the MRLs for apples and pears and introduction of an MRL for pome fruit is in harmony with a US pome fruit tolerance.

**Step 3, mushroom 60 mg/kg**

The US previously opposed advancement of the proposed MRL based on the existence of a reduced application rate GAP and supporting data. The data reviewed by the JMPR (1997) were from the US and resulted in an MRL estimate of 60 mg/kg. A label (GAP) use change was pending in the US which would have eliminated the first application at 110 g ai/100 m<sup>2</sup> and would have retained the applications at 54 g ai/100 m<sup>2</sup>. Assuming no accumulation of residues between breaks (fruitings), the maximum residue from the lower application rate is 38 ppm, consistent with the US tolerance of 40 ppm. However, the pending US label change has not occurred. Therefore, the US supports advancement of the proposed 60 mg/kg MRL for mushroom to Step 6 only. There are acute dietary risk concerns.

**BENOMYL (069)****EUROPEAN COMMUNITY**

The toxicological studies for the benomyl group compounds are under review in the European Community especially with regard to the feasibility of setting ADIs. **Benomyl is no longer supported by the main notifier in the EC.** The following comments are therefore preliminary pending finalising the evaluations. Residue definition for plants and animal products.

The following residue definition for enforcement purposes is proposed:

"Sum of benomyl, carbendazim and thiophanate-methyl expressed as carbendazim"

Justification: The metabolism studies in plants show clearly that the residue definition for the individual compounds should be:

- benomyl: sum of benomyl and carbendazim expressed as carbendazim
- carbendazim: carbendazim
- thiophanate-methyl: sum of thiophanate-methyl and carbendazim expressed as carbendazim

For enforcement purposes we agree to use the same residue definition for animal products as in plants with the clarification discussed above.

The suggested residue definitions clearly indicate for the enforcement laboratories how to handle the sample.

**Berries and other small fruits 1 mg/kg (Step 6)**

The proposed withdrawal of this MRL is acceptable. But the European Community wants to point out again to the fact that very recently new residue data for use in blackberries and raspberries became available. The evaluation by JMPR 2003 has to be waited for.

**Cereal grains (0.5 mg/kg B.C.Th (Step 6)**

The proposal to replace this MRL by MRLs for specific crops is acceptable. Extrapolation from wheat to rye is supported by the European Community.

**Lettuce, head 5 mg/kg (Step6)**

Withdrawal of the MRL is acceptable on condition that an alternative MRL is fixed. The EC had already informed the Committee in the 33<sup>rd</sup> Session that new residue data became available. The evaluation by the JMPR 2003 has to be waited for.

**Cucumber**

MRL proposal of 0.05\* mg/kg from evaluation is acceptable. Recently new indoor trials with carbendazim became available to the European Community showing that a MRL of 1 mg/kg is necessary.

**Garden pea, Shelled**

The proposed MRL of 0.02 mg/kg is not acceptable.

The number of trials is insufficient. Furthermore garden peas are also traded with shells so that data for peas with pods are necessary. The proposal setting an MRL lower than the practical limit of determination of 0.05 mg/kg will imply practical problems in enforcement.

**Oranges, Sweet, Sour**

The reported 6 trials with one application from USA and Brazil seems to be insufficient to cover the wide range of agricultural and climatic conditions. Furthermore results on citrus fruits without stating the distribution of the residues between pulp and peel is not acceptable. Therefore the MRL proposal of 1 mg/kg cannot be accepted.

**Rye**

The extrapolation from wheat to rye is supported by the European Community

**CARBENDAZIM (072)****EUROPEAN COMMUNITY**

The toxicological studies for the benomyl group compounds are under review in the European Community

especially with regard to the feasibility of setting ADIs. **Benomyl is no longer supported by the main notifier in the EC.** The following comments are therefore preliminary pending finalising the evaluations. Residue definition for plants and animal products.

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- carbendazim: carbendazim
- thiophanate-methyl: sum of thiophanate-methyl and carbendazim expressed as carbendazim

For enforcement purposes we agree to use the same residue definition for animal products as in plants with the clarification discussed above.

The suggested residue definitions clearly indicate for the enforcement laboratories how to handle the sample.

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Withdrawal of the MRL is acceptable on condition that an alternative MRL is fixed. The EC had already informed the Committee in the 33<sup>rd</sup> Session that new residue data became available. The evaluation by the JMPR 2003 has to be waited for.

#### Cucumber

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#### Garden pea, Shelled

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The number of trials is insufficient. Furthermore garden peas are also traded with shells so that data for peas with pods are necessary. The proposal setting an MRL lower than the practical limit of determination of 0.05 mg/kg will imply practical problems in enforcement.

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#### Rye

The extrapolation from wheat to rye is supported by the European Community

#### **USA**

The USA has no registered food/feed uses for carbendazim.

### **DISULFOTON (074)**

#### **EUROPEAN COMMUNITY**

The EC refers to its comment made on Agenda ITEM 5(a)

## USA

Step 6, numerous commodities.

In general, proposed MRLs have lower values than the corresponding US tolerances, which were reevaluated in 1998. An acute intake assessment has been performed (CX/PR 02/03, 03/2002) with concerns for both adults and children. Moreover, there is a chronic dietary intake concern for the European diet. The MRLs should not be advanced. The US also repeats its opposition to advancement of the MRLs pending completion in mid-2002 of the cumulative risk assessment.

As stated to the 33<sup>rd</sup> CCPR, the US has determined that there is no chronic or acute dietary intake concerns for the pesticides with US use patterns and food consumption patterns. Tier 3 level refinements, including extensive use of monitoring data, were required for both the chronic and acute dietary calculations.

## THIOPHANATE-METHYL (077)

### EUROPEAN COMMUNITY

The toxicological studies for the benomyl group compounds are under review in the European Community especially with regard to the feasibility of setting ADIs. **Benomyl is no longer supported by the main notifier in the EC.** The following comments are therefore preliminary pending finalising the evaluations.

Residue definition for plants and animal products.

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The suggested residue definitions clearly indicate for the enforcement laboratories how to handle the sample.

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Withdrawal of the MRL is acceptable on condition that an alternative MRL is fixed. The EC had already informed the Committee in the 33<sup>rd</sup> Session that new residue data became available. The evaluation by the JMPR 2003 has to be waited for.

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### Garden pea, Shelled

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Oranges, Sweet, Sour

The reported 6 trials with one application from USA and Brazil seems to be insufficient to cover the wide range of agricultural and climatic conditions. Furthermore results on citrus fruits without stating the distribution of the residues between pulp and peel is not acceptable. Therefore the MRL proposal of 1 mg/kg cannot be accepted.

Rye

The extrapolation from wheat to rye is supported by the European Community

**AMITROLE (079)****EUROPEAN COMMUNITY**

Grapes (0.05) should be without asterisk. In EC for grapes an LOD of 0.05 and considered as achievable and an MRL for grapes of 0.01 is in discussion. For all other vegetables and LOD of 0.01\* is considered appropriate. Therefore the EC proposes an MRL for grapes of 0.01.

**DODINE (084)****THE NETHERLANDS**

It is unclear why for this compound an ARfD has been established based on the NOAEL of 20 mg/kg bw in a 1 year dog study. The toxic profile of the compound shows, beside the LD50 of 660 mg/kg bw, no consistent effects relevant for acute exposure. The only possible acute toxic alert from the database is 'emesis' observed in dogs. However this effect is considered not relevant as it occurred mainly just before treatment, and as such is not relevant for acute risk assessment. Using a dose from a study without effects appears not to be justified. In our opinion the ARfD should be based on the lowest LD50 value and using a assessment factor of 1000 (10 interspecies, 10 intraspecies, and 10 for extrapolating the LC50 to LC0). The ARfD is than 0.6 mg/kg bw.

**FENAMINPHOS (085)****EUROPEAN COMMUNITY**

In view of the concerns about acute dietary intake by the Executive Committee it seems not appropriate to advance any of the MRLs. (e.g. bananapulp 160%, peppers 1060% of ARfD)

**DINOCAP (087)****EUROPEAN COMMUNITY**

The MRL proposal for strawberries is no more supported by the notifier.

For EC it is not acceptable to have different ARfDs different groups in the general population. The ARfD for the general population is therefore 0.008 mg/kg bw.

According to a risk assessment by Austria using Portuguese trials (JMPR 2001) on table grapes, children are estimated to be exposed at about 100% of the ARfD. The EC can thus accept advancement the MRL for grapes.

**CHLORPYRIFOS-METHYL (090)****EUROPEAN COMMUNITY**

The European Community proposed the deferral of discussions on the proposed MRLs until the dietary

intake concerns are resolved. The dietary calculations should consider all the commodities together. The proposed level for cereals need to be in line with the results from feeding studies that led to very low MRLs for milk and other products of animal origin. An ARfD needs to be established.

## **USA**

Pending completion of the cumulative risk assessment of the OP pesticides, the US does not support advancement of the step 6 MRLs for barley, oats, and rice. The USA has tolerances of 6.0 ppm for chlorpyrifos-methyl in barley, oats, and rice from postharvest use. The 10 mg/kg proposed MRLs may result from the JMPR rounding process (See Report 2001, 2.3). From the many data used to establish the USA tolerances, only one residue exceeded 6.0 ppm, at 6.9 ppm on rice. This latter value decreased to 6.1 ppm 3 days after treatment.

USA labels have been amended to specify one post-harvest treatment only and to provide a method for pretreatment testing of the grain to verify that it had not been treated previously.

Chronic and acute dietary risk analyses indicated no concerns for the any population group for US use and consumption patterns. However, a data call-in was issued for acute, subchronic and developmental neurotoxicity studies. The registrant is considering voluntary cancellation of uses.

## **CARBOFURAN (096)**

### **EUROPEAN COMMUNITY**

The European Community notes that no acute RfD will be established for this compound before 2002 and considers that in the absence of an acute RfD it is not possible to fully assess the consumer safety of the proposed MRLs. For this question of principle, the EC proposes not to advance the MRLs of this cholinesterase-inhibiting compound to the next step. The EC has set a provisional ARfD.

### **Cantaloupe (0.2 mg/kg, step 6)**

The European Community found that the monograph is over-summarised for this commodity making an appraisal of the JMPR proposal impossible. The European Community cannot accept the proposal.

## **USA**

Step 6, numerous commodities.

The USA notes that an acute reference dose has not been established by the JMPR and opposes advancement of the MRLs pending an acute dietary intake analysis. The US has performed both chronic and acute dietary risk assessments (05/01) and has concluded that there is no dietary risk concern for any population group, including the most sensitive group, children (1 – 6 years). Monitoring data were used in both analyses, and very extensive refinement of the risk analysis was required in the acute exposure case. The problematic commodities for the latter were potatoes, grapes, and cucumbers. The US believes that it would be prudent for JMPR to conduct an acute dietary risk assessment before advancing the proposed MRLs.

The US tolerance definition has been aligned with the Codex definition; three non-carbamate phenol metabolites were deleted. The US has no registered uses on citrus and will introduce a cucurbit group tolerance at 0.6 ppm to replace tolerances for cucumber, etc.

## **METHAMIDOPHOS (100)**

### **EUROPEAN COMMUNITY**

The EC requires the setting of an ARfD and estimation of the acute risk for all relevant consumer groups for this substance, before MRLs can be advanced beyond step 6. The periodic reevaluation by JMPR 2002 (toxicology) and 2003 (residues) has to be awaited.

Peach (1 mg/kg, step 6), Pome fruits (0.5 mg/kg, step 6), Tomato (1 mg/kg, step 6)

In view of the potential acute dietary risk the European Community cannot accept the proposed MRLs. EC proposes not to advance the MRLs beyond step 6.

**USA**

Step 6, peach, pome fruit, tomato.

The US repeats its opposition to the advancement of the proposed MRLs. Methamidophos is one of the most acutely toxic OPs. The MRLs should not be advanced, pending consideration by the 2002/2003 JMPRs. Special attention should be given to the acute dietary intake, including both acephate and methamidophos.

**PHOSMET (103)****GERMANY**

Awaiting the outcome of the review by JMPR and the proposed amendment of the draft MRL for apricots before submitting a further comment concerning acute dietary intake.

**USA**

Step 6, apricot, 10 mg/kg

As previously indicated, the USA holds that 5 mg/kg is a more appropriate value, but will not object to its advancement on these grounds. The USA notes that phosmet is subject to the cumulative risk assessment for OP pesticides, which will be completed in mid-2002 and would prefer retention of the MRL at Step 6.

**ETHEPHON (106)****CÔTE D'IVOIRE**

Côte d'Ivoire questions the logic behind the criteria for setting MRLs for ethephon given that dried grapes are consumed whole, while in the case of pineapples, all the integument containing 80% of the residue, is removed before consumption.

Côte d'Ivoire fails to understand the reasons for this distortion and remains firmly opposed to a MRL of 6ppm, indeed of 5 ppm, of ethephon in dried grapes, which we consider to be arbitrarily high.

**EUROPEAN COMMUNITY**Dried grapes (=currants, raisins and sultanas) (5 mg/kg, step 6)

Based on the mean processing factor of 3.7, an MRL of 3 could be proposed. Based on the highest processing factor (5.3), an MRL of 5 seems reasonable.

**SOUTH AFRICA**

At the 33<sup>rd</sup> Session of the CCPR some delegates expressed reservations on the MRL for grapes due to the lack of processing studies. The 1999 JMPR report indicated that a processing factor of 2.7 was used for raisins. South Africa would support the advancement of dried grapes in the Codex procedure unless reasons can be given that the processing factor is not correct.

**IMAZALIL (110)****THE NETHERLANDS**

For this compounds there are 2 acute alerts:

The LD50 is quite low: 227 mg/kg bw. Furthermore, in developmental studies with a short period of exposure, dams die at levels of 80 mg/kg bw and above (mice, 13% at 80 mg/kg bw, 30% at 120 mg/kg bw) or at 10 and 20 mg/kg bw (rabbits). This indicates that mortality occurs within the same dose range after a single and subacute exposure.

In addition, resorptions and decrease in number of live pups in developmental toxicity studies in rats, rabbits and mice. Although fetal deaths and resorptions occur mainly at maternal toxic dosages in most studies (except for 1 study in mice), these effects are, in combination with maternal lethality, indicative for serious toxicity after acute and short term exposure. It is proposed to use 5 mg/kg bw as NOAEL for serious maternal toxicity in rabbits. This dose also accounts for fetotoxicity in the various experiments. Using an assessment factor of 100, the ARfD is 0.05 mg/kg bw.

### **ALDICARB (117)**

#### **EUROPEAN COMMUNITY**

The EC opposes advancement of this MRL before a definitive Acute intake assessment is done

#### **USA**

Step 6, potato, 0.5 mg/kg

The proposal is a replacement for the existing 1 mg/kg CXL. The 2001 JMPR reported unacceptable acute dietary risks for aldicarb-treated potatoes. The USA supports replacement of the 1 mg/kg value with the 0.5 mg/kg value but urges refinement of the acute dietary intake calculation (Report, 2001 JMPR). The US tolerance for potatoes has been reevaluated from 1 to 0.2 ppm and reflects the use of PDA equipment only.

The acute dietary risk analyses are incomplete in the US at this time.

Regarding the residue on bananas, per the 2001 JMPR, the US notes that similar results have been found in numerous trials reported from Central America from the application of 0.8 g ai/tree with an approximate 180 day PHI. Residues are equally distributed between pulp and peel, but combined residues were consistently <0.01 mg/kg, versus 0.01 - 0.10 mg/kg for the trials (2 g ai/plant) considered by the JMPR (Guadeloupe, Martinique, Ivory Coast).

### **BITERTANOL (144)**

#### **EUROPEAN COMMUNITY**

The EC accepts the proposal of 3 mg/kg for tomatoes at step 5, but makes a reservation on the fixing by JMPR of processing factors and STMRs for tomato juice, preserve and paste on the basis of one single processing study. The present single study is not sufficient to derive those values.

#### **GERMANY**

Awaiting the outcome of the result of proposed extrapolation from peaches to apricots.

#### **USA**

CXL apricot

The USA has only one use, an import tolerance for bananas.

### **CARBOSULFAN (145)**

#### **EUROPEAN COMMUNITY**

The European Community notes that no acute RfD will be established for this compound before 2002 and



considers that in the absence of an acute RfD it is not possible to fully assess the consumer safety of the proposed MRLs. For this question of principle, the EC proposes not to advance the MRLs of this cholinesterase-inhibiting compound to the next step. The EC has set a provisional ARfD.

#### Cantaloupe (0.2 mg/kg, step 6)

The European Community found that the monograph is over-summarised for this commodity making an appraisal of the JMPR proposal impossible. The European Community cannot accept the proposal.

#### **USA**

The USA has no registered food/feed uses.

### **OXYDEMENTON-METHYL (166)**

#### **EUROPEAN COMMUNITY**

The EC requires the setting of an ARfD and a reevaluation the data base and estimation of the acute risk for all relevant consumer groups for this substance, before MRLs can be advanced. The EU will reduce most of its MRLs by August 2002 because of acute and chronic intake problems. The ARfD applied by the EU is 0.005 mg/kg bw (Germany).

#### Grapes (0.1 mg/kg, step 6)

Pending evaluation of the acute risk the EC opposes advancement of the MRL

#### Lemon (0.2 mg/kg, step 6)

#### **Pending evaluation of the acute risk the EC opposes advancement of the MRL Oranges, Sweet, Sour (0.2 mg/kg, step 6)**

Pending evaluation of the acute risk the EC opposes advancement of the MRL

#### **USA**

Step 6, many commodities.

The USA requests that the proposed MRLs remain at Step 6 pending completion of the cumulative risk analysis for OPs in mid-2002. Acute and chronic risk analyses conducted in the USA revealed no risks for the general population and subpopulations. The USA list of tolerances is more extensive than the Codex list, when CXL withdrawal recommendations are considered. The US also opposes advancement until an acute reference dose is set and a JMPR IESTI performed.

The US has partially harmonized its residue expression for both tolerance and dietary intake concerns with the Codex definition. The US definition is ODM plus oxydemeton-methyl sulfone. Demeton-S-methyl, parent of ODM, is not considered.

Reevaluated US tolerances are in general agreement with proposed Codex MRLs, with the exception of pear (0.3 ppm vs 0.05 mg/kg), and lemons and oranges (1 ppm vs 0.2 mg/kg).

### **ABAMECTIN (177)**

#### **CÔTE D'IVOIRE**

Pre-extension tests have in theory been completed and which can therefore be considered as already approved in Côte d'Ivoire for the treatment of papaya mites. We are very interested in this active ingredient and request early Codex consideration of a MRL for abamectin in papaya.

As regards the proposed drafts presented **at step 6**, we question the proposed MRL for ethephon for dried grapes. A proposed MRL of 5 ppm was rejected at step 5/8 during the 24<sup>th</sup> Session of the Codex Alimentarius Commission.

We are surprised to find at step 6 a MRL of 6 ppm which is higher than the MRL submitted to the Codex Commission, against which Côte d'Ivoire registered its opposition and which was returned to step 5. Our opposition was all the more warranted by the fact that a severe MRL of 2 ppm had been proposed for pineapple.

### **CLETHODIM (187)**

#### **GERMANY**

Awaiting the revision of the method of analysis by the applicant. A new method is probably not available before end of 2002.

### **FENPROPIMORPH (188)**

#### **EUROPEAN COMMUNITY**

The ARfD proposed by JMPR 2001 is not acceptable to EU and detailed comments will be send to the JMPR by Germany.

### **FENPYROXIMATE (193)**

#### **EUROPEAN COMMUNITY**

The EC requires the setting of an ARfD and estimation of the acute risk for all relevant consumer groups for this substance, before MRLs can be advanced.

### **HALOXYFOP (194)**

#### **GERMANY**

The draft MRLs for peas, fresh (pods and succulant = immature seeds), cotton seed and sunflower seed are not acceptable.

The reasoning was already submitted for the 31<sup>st</sup> CCPR session, see ALINORM 99/24A para 102 and reiterated for the 33<sup>rd</sup> session, see comment on CL 2000/49-PR.

#### **THE NETHERLANDS**

We oppose advancement of all MRLs in Step 6 awaiting the Residue Evaluations of the 2001 JMPR .

#### **USA**

The USA has no registered food/feed uses.

### **TEBUFENOZIDE (196)**

#### **THE NETHERLANDS**

We oppose advancement of the MRL for grapes of 2 mg/kg as the outcome of an acute intake calculation exceeds the Acute Reference Dose.

**USA**

Step 6, grapes.

The US maintains an import tolerance of 0.5 ppm, compared with the proposed MRL of 1 mg/kg. The data reviewed by the JMPR are consistent with the proposed MRL, and the US favors advancement of the MRL. Tebufenozide has been identified as an alternative to OPs.

**KRESOXIM-METHYL (199)****EUROPEAN COMMUNITY**

For kresoxim-methyl, the EC has MRLs in products of plant and animal origin.

Barley :

Proposal for 0.1 mg/kg. The EU proposal is 0.05\* mg/kg.

The report indicates that the JMPR has considered 9 results below the LOD (0.05\*) and 2 results at 0.06 mg/kg but these were on ears. The EC considers results on ears not representative of the situation for the grain and these should therefore not be taken into account .