European Union Comments

Beijing, China, 6 – 11 May 2013

Agenda Item 6 a
Draft and proposed draft maximum residue limits for pesticides in foods and feeds at Steps 7 and 4
Comments at steps 6 and 3
(CX/PR 13/45/5)

European Union Competence
European Union Vote

025 DICHLORVOS (R)

The EU would like to introduce a reservation to the proposed draft MRLs for the following commodities:
- poultry meat
- poultry fat
- poultry, edible offal of
- eggs
- rice
- wheat

At CCPR 44, the EU made a reservation for the ADI and ARfD recommended by JMPR because of a methodological disagreement about the use of human studies.

At EU level, only tentative toxicological reference values have been derived for dichlorvos, as the toxicological data package was considered
insufficient to address the genotoxic and carcinogenic potential of dichlorvos.

JMPR did not assess the nature of residues in processed commodities. Since the MRL proposals refer to commodities which are consumed exclusively after processing, this information is indispensable to assess the safety of MRL proposals.

For poultry, a metabolism study reflecting oral exposure is required to derive a final residue definition.

For rice and wheat, a chronic consumer risk concern has been identified (2540% of EU ADI, refined calculation 243%). Moreover, an acute consumer risk concern has also been identified (rice: 3278% of EU ARfD, refined calculation husked rice 524%; wheat 2962% of EU ARfD, refined calculation wholemeal 1185% and wheat flour 296%).

The MRL proposals for rice bran and polished rice are too high, considering the results of the processing studies.

**026 DICOFOL (T, R)**

The EU supports the withdrawal of the existing CXLs for dicofol.

The EU would like to introduce a reservation to the proposed draft MRLs for the following commodities:
- tea, green, black (black, fermented and dried)

Some evidence suggests that dicofol might hydrolyse to its benzophenone metabolites, which could also generate chloroform. Before concluding on the safety of the MRL proposal for tea, the possible formation of these degradation products (benzophenone and chlorophorm) needs to be addressed. Chloroform is indicated as 'reasonably anticipated to be a human carcinogen' in the 12th Report on Carcinogens, U.S. Department of Health and Human Services.

**081 CHLOROTHALONIL (R)**

The EU would like to introduce a reservation to the proposed draft MRLs for the following commodities:
- banana
- chard

Considering that the ARfD established for the metabolite SDS-3701 is significantly lower than the ARfD established for the parent
compound, the occurrence of SDS-3701 should also be assessed in raw plant commodities. Since no information on the concentration of SDS-3701 was provided for the above mentioned commodities, the MRL proposals are not acceptable.

**096 CARBOFURAN (R)**

The EU supports the lowering of the MRL in banana. However, the EU would like to comment that even for the proposed lower MRL, the data available is not sufficient to exclude a consumer risk. Thus, further evidence should be provided with radiolabelled studies that confirm the no residue situation for carbofuran and 3-OH carbofuran and the conjugates.

**112 PHORATE (R)**

The proposed draft MRL for the following commodity is not acceptable. A concern form will be submitted:

- potato
An acute consumer risk concern has been identified (max. 871% of ARfD, refined calculation 113%).
Moreover, some evidence suggests that under processing conditions the formation of toxicologically relevant degradation products such as formaldehyde may occur. Before concluding on the safety of any MRL proposal for potato, the possible formation of these degradation products needs to be addressed. Formaldehyde is indicated as 'known human carcinogen' in the 12th Report on Carcinogens, U.S. Department of Health and Human Services, and classified as Category 2 carcinogen in the EU (Annex VI to Regulation (EC) No 1272/2008).

**119 FENVALERATE (T, R)**

As the residue definitions for both fenvalerate and esfenvalerate comprise the same compounds, the EU proposes that all MRLs for fenvalerate and esfenvalerate are combined and assessed against the lowest toxicological reference values of esfenvalerate.

The EU supports the withdrawal of CXLs as proposed by JMPR, however it first needs to be assessed whether the proposed MRLs for esfenvalerate e.g. in cereal grains, cotton seed, tomato, wheat bran, flour, and wholemeal (currently at step 7) are reflected adequately. Furthermore, it is also necessary to first derive MRLs for esfenvalerate in commodities of animal origin before withdrawing the corresponding CXLs for fenvalerate.
The proposed draft MRL for the following commodity is not acceptable. A **concern form** will be submitted:
- **Chinese broccoli**

An acute consumer risk concern has been identified (211% of ARfd), considering the consumption of broccoli, which is the crop to which the MRL would apply at EU level.

<table>
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<th><strong>157 Cyfluthrin (R)</strong></th>
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<td>The EU <strong>supports</strong> the advancement of all the proposed draft MRLs.</td>
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<th><strong>169 Cyromazine (R)</strong></th>
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<td>The EU would like to introduce a <strong>reservation</strong> to the proposed draft MRLs for the following commodities:</td>
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<td>- chick pea (dry)</td>
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<td>- lentil (dry)</td>
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<td>- lupin (dry)</td>
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Considering that the metabolite melamine may be present at similar or even higher levels than parent cyromazine, a separate risk assessment for melamine is required. Moreover, a metabolism study on a representative third crop group (e.g. pulses) is still required to derive a general residue definition in plants and to finalise the risk assessment.

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<th><strong>173 Buprofezin (R)</strong></th>
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<td>The EU would like to introduce a <strong>reservation</strong> to the proposed draft MRLs for the following commodities:</td>
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<td>- tea, green</td>
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As tea is a major crop according to the EU guidelines, 3 additional residue trials would be required to have a complete dataset. Moreover, the potential formation of degradation products in tea infusions needs further investigation.
The EU **supports** the withdrawal of CXLs as proposed by JMPR and the advancement of all the proposed draft MRLs except for the following crops for which the EU would like to introduce a **reservation**:

- assorted tropical and sub-tropical fruits – inedible peel (except banana and kiwifruit)
- assorted tropical and sub-tropical fruits – edible peel
- currants, black, red, white
- potato
- stone fruits
- sunflower seed

For assorted tropical and sub-tropical fruits – inedible peel (except banana and kiwifruit), according to extrapolation rules agreed by CCPR the data would not be sufficient to set a MRL for the whole group.

For assorted tropical and sub-tropical fruits – edible peel, according to extrapolation rules agreed by CCPR the data would not be sufficient to set a MRL for the whole group.

For currants, the data package used to derive the MRL proposal is very inconsistent (11 trials reflecting different application rates, trials with/without spray shields). Thus, the MRL derived is not acceptable. Moreover, the MRL derived with the OECD calculator would be 0.8 mg/kg, instead of 1 mg/kg.

For potato, the MRL was derived from 7 trials reflecting the Brazilian GAP. The residue trials reflecting alternative GAPs differed significantly, without providing information what might have caused the different residue behaviour. An acute consumer risk was identified for the US GAP (HR 0.62 mg/kg) while for the Brazilian GAP the exposure was found to be acceptable. Moreover it is noted that from the Brazilian data a lower MRL of 0.05 mg/kg would be derived (instead of 0.1 mg/kg).

For stone fruits, the MRLs for individual crops would be the same for apricots and plums (0.15 mg/kg), while for cherries and peaches/nectarines lower MRLs could be derived (0.09 mg/kg for cherries and 0.1 mg/kg for peaches/nectarines).

For sunflower seed, the MRL proposal was derived by using the proportionality principle. However, for uses as desiccants, the proportionality approach is not a suitable approach.
The EU would like to **comment** on the proposed draft MRLs for the following commodities:
- banana,
- edible offal (mammalian),
- kiwifruit,
- lettuce, head and lettuce leaf,
- soyabean.
For these commodities, JMPR identified an acute intake concern for the proposed MRLs. The EU does not agree with the opinion of JMPR that additional considerations should be taken into account after an exceedance of the ARfD has been established. As a matter of principle, such considerations are not acceptable and corrode the risk assessment approach.

As regards **pome fruits**, the EU would like to mention that using the OECD calculator the proposed MRL should be 0.08 mg/kg instead of 0.1 mg/kg.

**176 Hexythiazox**

The EU would like to introduce a **reservation** to the draft MRLs for the following commodities:
- strawberries
At CCPR 44, the EU had introduced a reservation on all proposed draft MRLs on commodities that are consumed after processing, based on open questions on the toxicological profile of metabolite PT-1-3 and the behaviour of metabolites during processing. As strawberries are also consumed after processing, the EU maintains its position on this MRL.

An additional reason for the EU's opposition to the advancement of the proposed draft MRL on strawberries at CCPR 44 was that the MRL proposal was derived using the proportionality approach. Given the progress in the discussions, the EU considers this second reason as addressed, provided that general agreement on the application of the proportionality approach is reached. The dataset used to derive the draft MRL using the proportionality principle fulfils the principles set out in paragraphs 32 - 40 of document CX/PR 13/45/6.

**179 Cycloxydim (R)**

The EU **supports** the advancement of all the proposed draft MRLs except for the following crops for which the EU would like to introduce a **reservation**:
- **brassica vegetables, head cabbage, flowerhead brassicas**
- **eggs**

For brassica, the available data would allow the setting of separate MRLs for flowering brassica (VB 0042) (4 mg/kg), head brassicas (VB2036) (5 mg/kg) and Brussels sprouts (9 mg/kg). It is not necessary to extrapolate from the most critical crop (i.e. Brussels sprouts) to the whole group.

For eggs, a MRL of 0.1 mg/kg would be derived from the feeding study.

The EU would like to **comment** on the proposed draft MRLs for the following commodities:

- **soya bean (dry)**

For soya bean (dry), a detailed assessment of the trials is required to identify the reasons for unusually high variations.

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**184 ETOFENPROX**

At CCPR 44, the EU opposed the advancement of the proposed draft MRL on **grapes**, as the MRL proposal was derived using the proportionality approach.

Given the progress in the discussions, the EU can now **support** the MRL proposal, provided that general agreement on the application of the proportionality approach is reached.

The dataset used to derive the draft MRL using the proportionality principle fulfils the principles set out in paragraphs 32 - 40 of document CX/PR 13/45/6.

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**197 FENBUCONAZOLE (T, PERIODIC REVIEW)**

The EU would like to **comment** on the toxicological reference values for this substance:

The lower ADI derived at EU level (0.006mg/kg bw per day) is based on the decreased body weight gain in females in the 1-year dog study with a NOAEL of 0.62 mg/kg bw per day.

For the ARfD, both JMPR and EU assessments considered maternal findings observed in rats and rabbits as a suitable basis for setting the
reference value. However, the difference appears to be the setting of an overall NOAEL in the developmental toxicity studies in rabbits; a higher NOAEL was identified in the EU evaluation (i.e. effects observed at 30 mg/kg bw per day in the developmental toxicity study in rabbits were not considered adverse). Thus, the EU ARfD was set at a level of 0.3 mg/kg bw, while JMPR derived a value of 0.2 mg/kg bw.

### 206 IMIDACLOPRID (R)

The proposed draft MRL for the following commodity is not acceptable. A **concern form** will be submitted:
- celery

For celery, an acute consumer risk concern has been identified (max. 184% of the EU ARfD (0.08 mg/kg bw), based on Dutch consumption data). The lower ARfD established in the EU assessment compared to the JMPR assessment is based on the selection of a different key study and a different NOAEL established in dogs.

For **pulses, dry (except soya beans)**, the EU can **support** the MRL proposals, provided that the GAPs for the other dry pulses are comparable to the GAPs reported for peas and beans.

### 209 METHOXYFENOZIDE (R)

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following commodities:
- **fruiting vegetables, cucurbits, except watermelons**
- **spring onions**

The datasets used to derive the proposed MRLs using the proportionality principle did not fulfil the principles set out in paragraphs 32 - 40 of document CX/PR 13/45/6.

The EU would also like to **mention** that in the EU a **lower ARfD** was derived based on a different toxicological study. In case the study had not yet been considered by JMPR, it should be made available for a possible future review.

### 211 FLUDIOXONIL (R)

The EU **supports the advancement** of the proposed draft MRLs.
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The proposed draft MRLs for the following commodities are not acceptable:
- celery,
- spinach.

Using the EU ARfD of 0.025 mg/kg bw an acute consumer health risk was identified for both celery and spinach. A concern form will be submitted.

Furthermore, the EU would like to introduce a reservation to the advancement of the proposed MRL for the following commodity:
- brassica vegetables.

The proposed MRL for the group brassica vegetables is based on extrapolation in combination with the use of the proportionality principle. This is leading to a high uncertainty of the proposed MRL.

The extrapolation is not in line with EU extrapolation guidelines. 4 trials on kohlrabi as well as 2 additional trials on cauliflower, 1 trial on head cabbage and 2 trials on Brussels sprouts would be needed to obtain a sufficient data set to derive a MRL.

With regard to the proportionality approach applied for trials on broccoli and head cabbage, the presentation of the details and results of the trials does not allow a detailed assessment whether the criteria set out in §§32 – 40 of document CX/PR 13/45/6 are fulfilled.
The EU would like to introduce a reservation to the advancement of the proposed draft MRL for the following commodities:
- **peppers:** the datasets used for deriving the proposed MRLs using the proportionality principle do not fulfil the criteria set out in § 31 of document CX/CL 13/45/6.
- **beans (dry),**
- **cherries.**

For **beans (dry) and cherries** the proposed MRLs were based on an intended US GAP using the proportionality principle. It is our understanding that this US GAP was finally not approved.

Furthermore, the EU would like to note that for **root and tuber vegetables** (potato, sugar beet) the proposed MRLs (0.03 mg/kg and 0.04 mg/kg, respectively) are derived from trials conducted as foliar applications on primary crop. These MRLs may not be sufficient to cover the residues expected from root/tubers grown as rotational crops. In the EU a default value of 0.1 mg/kg is currently used for rotational crops.

### 248 Flutriafol

At CCPR 44, the EU opposed the advancement of the proposed draft MRL on **grapes**, as the MRL proposal was derived using the proportionality approach.

Given the progress in the discussions, the EU can now support the MRL proposal, provided that general agreement on the application of the proportionality approach is reached.

The dataset used to derive the draft MRL using the proportionality principle fulfils the principles set out in paragraphs 32 - 40 of document CX/PR 13/45/6.

### 253 Amitoctradin (T, R)

The EU supports the advancement of the proposed draft MRLs with the exception of the MRLs for the following commodities for which the EU would like to introduce a reservation:

- **Brassica vegetables, head cabbages, flowerhead brassicas:** The extrapolation from broccoli and head cabbage to the whole group of head
and flowering brassica (MRL proposal: 9 mg/kg) is not acceptable according to EU guidelines. The data would allow setting individual MRLs for broccoli and head cabbage. The extrapolation is also not in line with the extrapolation rules discussed in the 2012 CCPR (Appendix XII of CCPR 2012 Report) as these would only allow extrapolation to flowering brassica (e.g. cauliflower) but not to other head brassica (kohlrabi, Brussels sprouts).

- **leafy vegetables:** the MRL proposal for leafy vegetables based on trials for mustard greens and spinach is not in line with the extrapolation rules discussed in the 2012 CCPR (Appendix XII of CCPR 2012 Report).

- **spring onions:** the proposed MRL for spring onions is based on 3 trials only. According to EU guidelines one additional trial would be required to complete the data set.

Finally the EU could like to mention that the codes for Amectotradin and Penthiopyrad should be verified as the same code is assigned to both substances.

### 253 PENTHIOPYRAD( R)

a) The EU **can not accept** the proposed draft MRLs for the following commodities due to **intake concerns:**

- Leafy vegetables, except brassica leafy vegetables (VL 0053)
- Mustard greens (VL 0485)

The EU has identified **intake concerns for scarole** (broad leaf endive) that falls within the category leafy vegetables as well as for **Chinese cabbage (mustard greens).** A **concern form** will be submitted.

The EU notes that also JMPR identified an **intake concern** as regards mustard greens.

b) The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following feed commodities and for those food commodities that can also be used as feed.
- alfalfa fodder, almond hulls, barley, barley straw, cabbage head, cotton gin trash, cotton seed, maize and maize related products, maize fodder (dry), millet, millet fodder, oats, oats straw and fodder (dry), pea hay, peanut, peanut fodder, rape seed, rye, rye straw, Sorghum, sorghum dry, soya bean, soya bean fodder, sugar beet, sunflower seed, triticale, triticale straw, wheat, wheat bran, wheat straw, wheat germ:

These commodities are feed items or food that can also be used for feed purposes. The EU concerns relate to the fact that the dietary burden estimated for ruminants exceeded the highest feeding level tested in the feeding study. Therefore JMPR could not derive MRL proposals for mammalian tissues and milk. The MRLs proposed for feed or for food that can be used for feed purposes should also not be advanced.

c) The EU would like to introduce a reservation to the advancement of the proposed draft MRLs for the following commodities:

- **stone fruits**: the proposed MRL for stone fruits was derived from residue data on cherries. According to EU rules the extrapolation from cherries to the whole group of stone fruits is not acceptable. Individual data sets on peaches and plums would allow to derive individual MRL proposal of 2 mg/kg and 1.5 mg/kg, respectively.

- **flower head brassicas**: the proposed MRL was based on residue data for broccoli only. According to EU guidelines, the extrapolation from broccoli to cauliflower is not acceptable since at least 4 trials on cauliflower would be needed.

- **leafy vegetables**: the MRL proposal is based on extrapolation from spinach to the whole group of leafy vegetables. This is not acceptable according to EU guidelines. Furthermore, according to the CCPR 2012 extrapolation rules the extrapolation to leafy greens (VL 2050) would be possible, but not the extrapolation to the wider group of leafy vegetables (VL 0053).

d) The EU notes that the codes for Amectotradin and Penthiopyrad should be verified as the same code is assigned to both substances.

**254 CHLORFENAPYR (T, R)**

The EU shares the view of JMPR that no MRL can be proposed. In the absence of an ADI/ARfD for the metabolite CL 303268 the safety can not be assessed.
255 DINOTEFURAN (T, R)

The EU would like to introduce a reservation to the advancement of the proposed draft MRLs for the following commodities:

- **brassica vegetables, head cabbages, flower head brassica**: The MRL proposal is not sufficiently supported by residue data. According to EU guidelines extrapolation to the whole group of brassica not acceptable. The proposal also not in line with extrapolation rules discussed in the 2012 CCPR (Appendix XII of CCPR 2012 Report) as trials on kohlrabi would be needed to derive a group tolerance.

- **fruiting vegetables, cucurbits**: the MRL proposal is acceptable as regards cucurbits with edible peel. However, the EU cannot support the MRL as regards cucurbits with inedible peel as it is based on combined datasets for cucurbits with edible peel and cucurbits with inedible peel which is not possible according to EU extrapolation guidelines. Two additional trials on melons would be required according to EU guidelines to extrapolate from melons to the whole group of cucurbits with inedible peel.

- **fruiting vegetables other than cucurbits**: according to the EU guidelines on extrapolation, extrapolation from tomatoes is only possible to aubergines. As sufficient data are available for peppers, EU extrapolation rules would lead to a MRL of 0.7 mg/kg for peppers and 0.3 mg/kg for tomatoes and aubergines.

- **leafy vegetables (except water cress)**: according to EU rules the available data allow for deriving more specific MRLs: a MRL of 4 mg/kg for leaf lettuce (and the whole group of lettuce and other salad plants), 6 mg/kg for spinach and similar crops (e.g. chard) and 0.8 mg/kg for head lettuce could be derived.

256 FLUXAPYROXAD (T, R)

The EU supports the advancement of the proposed draft MRLs except the MRL for the following commodity for which the EU would like to introduce a reservation:

- **stone fruits**: The EU extrapolation rules do not allow the pooling of data for cherries, peaches and plums. The EU proposes separate MRLs for cherries (3 mg/kg), peaches/nectarines (1.5 mg/kg) and plums (1.5 mg/kg) as sufficient data are available to derive those. For apricots no MRL can be derived as the residue trials are not sufficient.

As regards **oilseeds** the EU would like to mention that using the OECD calculator the proposed MRL should be 0.8 mg/kg instead of 1.5 mg/kg.
257 MCPA (T, R)

The EU can support the proposed draft MRLs. However, the EU proposes that JMPR reconsiders the residue definition for enforcement. The EU noted that the JMPR residue definition for enforcement does not include the salts, esters and conjugates of MCPA. Due to the analytical method used to analyse the samples, the MRL proposals for MCPA for cereals, edible offal (mammalian), mammalian fat and meat as well as for feed items may overestimate the actual MCPA residues.

258 PICOXYSTROBIN (T, R)

The EU shares the view of JMPR that no MRLs can be proposed in the absence of sufficient toxicological data on the plant metabolites INH8612 and 2-(2-formylphenyl)-2 o xoacetic acid.

259 SEDAXANE (T, R)

The EU supports the advancement of the proposed draft MRLs.