European Union Positions for the 43rd Session of the Codex Committee on Pesticide Residues
Beijing, China, 4 - 9 April 2011

AGENDA ITEM 5:
DRAFT AND PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES IN FOODS AND FEEDS AT STEPS 7 AND 4

COMMENTS AT STEPS 6 AND 3

GENERAL REMARKS REGARDING THE EXTRAPOLATION PRACTICES OF JMPR

Setting MRLs for crop groups is also considered as a form of extrapolation to a range of commodities which belong to a defined class of commodities. However, it is noted that setting MRLs by extrapolation is introducing an additional source of uncertainty in the MRL setting process, leading to possible over- or underestimations of the “real” residue level expected in the treated crops. In order to limit the uncertainties and the consequences of the over- or underestimation of the MRL level, the extrapolation and/or setting of group tolerances should be restricted to the following cases:

- The GAPs for commodities for which the MRL setting is envisaged have to be notified. (No MRL should be set unless it is needed).
- The GAPs for the individual crops for which the MRLs should be comparable.
- The residue behaviour on the crops should be comparable, taking into account crop morphology such as surface texture, wettability, shape, plant growth habits, rate of growth, surface/weight ratio etc.
- Sufficient residue trials have to be available for crop which is used for the extrapolation (usually trials are available for major crops).

These preconditions for extrapolating MRLs are in line with the recommendations in the FAO Manual (Section 6.7). JMPR also noted that setting of group maximum residue levels for large crop groups should be avoided. In addition, JMPR recommends having adequate residue data for at least one major commodity for a crop group.

Sound scientific data which justify the extrapolation from one specific crop to other crops are not easy to be found because there are many
variables which may have an impact on the final residue concentration in different crops. The final residue concentration might be in the same range for crops for which a similar residue concentration is measured on day zero. Assuming that the degradation rate is the same on different crops belonging to the same crop group and other factors like crop growth and translocation or accumulation in certain plant tissues are not of relevance, residue concentrations measured for one crop may be a good indicator whether an extrapolation to other crops is possible. Thus, if the initial residue deposit on day-zero is comparable, the final residue at short PHIs may be expected in the same concentration for certain crops. In the recently published article of Maclachlan D.J. and Hamilton D. summarises the normalised residue concentrations measured in a wide range of crops on day zero. The data presented in this document could give indications if the initial residue concentration on crops is expected to be in same magnitude or if significant differences are expected which are resulting mainly from the crop morphology. The data presented in the article could give also an indication that the terminal residues are expected to be different because there are already significant differences in the initial residue deposit on day zero.

Although setting of group tolerances might be justified for certain crop groups, the setting of individual MRLs for crops for which sufficient trials are available is the preferred option because the uncertainties regarding the residue behaviour are reduced.

Setting group tolerances for crops for which no MRL is actually needed or setting MRLs at higher levels than necessary (e.g. by extrapolation of residues from one crop within a group which showed the highest residues to all other crops which belong to the same crop group) is not acceptable, because this practice is blocking a certain percentage of the ADI in the chronic risk assessment. Thus, future uses may have to be rejected because the chronic risk assessment leads to a full exhaustion of the ADI.

For the above reasons, the EU does not support the advancement of certain draft and proposed draft MRLs. Furthermore, in cases of high concern due to unacceptable risk for the EU consumers, the EU does not support the advancement of several draft and proposed draft MRLs until these concerns are raised.

### 219 Bifenazate

The EU would like to introduce a reservation to the advancement of the proposed MRL for Legume vegetables (7 mg/kg). The residue levels found on shelled beans (up to 0.15 mg/kg) and peas (up to 0.17 mg/kg) are much lower than the residues found on podded beans (up to 1.8 mg/kg) and peas (up to 3.7 mg/kg). The morphology of beans and peas with pods is not comparable with shelled beans and peas. There are sufficient trials data which would allow establishing MRLs for beans and peas in pods and succulent shelled beans and peas. The commodity group legume vegetable is too inhomogeneous to justify the setting of a group tolerance.

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When considering the JMPR ARfD, unacceptable acute risk was identified using European models for strawberries (358% IESTI 1 and 121% IESTI2), peppers (and brassica (100-128%). However when using the EU ARfD an unacceptable acute risk was identified for strawberries only. Therefore, the EU does not support the advancement of the proposed draft MRL for strawberries due to intake concerns. The EU would like to inform that a concern form has been submitted.

For rape seed, root and tuber vegetable, and tree nuts, the proposals are acceptable but should be indiced as a LOQ with an asterisk.

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

- For brassica (cole or cabbage) vegetables, Head cabbages, flowerhead brassicas, due to extrapolation problems, as the group of brassica contains crops with different morphology. According to Maclachlane et al. the normalised residue at day 0 after the last application are significantly different for crops belonging to this group, resulting from different surface texture and wettability, shape of the edible part of the crops and surface/weight ratio.

- For pulses due to the trials for the individual crops (beans, peas and soybeans) would allow setting of specific MRLs.

- For hops, tea, green and black, due to insufficient number of trials.

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

-Leafy vegetables (ie., leafy brassica, lettuce and other salad plants, spinach and similar leaves, water cress, chervil) as the proposed draft MRL was derived by extrapolating results from lamb’s lettuce to the whole group of leafy vegetables. This extrapolation is not foreseen at EU level. Specific residue levels for lamb’s lettuce, lettuce and red mustard could be derived.

-Stalk and stem vegetables, witloof (except fennel, leek): The proposed draft MRL was derived by extrapolating results from celery to the whole group of stalk and stem vegetables. This extrapolation is not foreseen at EU level.

The proposed draft MRL is only supported for celery.
230 CHLORANTRANILIPROLE

The EU supports the advancement for all commodities except for **brassica** for which the EU would like to introduce a **reservation** due to extrapolation rules not agreed in the EU.

81 CHLOROTHALONIL

The proposed draft **MRL for leeks (40 mg/kg)** is not acceptable, because of acute intake concern. A **concern form** has been submitted.

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

- **Cucumber, gherkin and summer squash (3 mg/kg)**: The proposed draft MRL for cucumber is not acceptable. The database is too small (5 trials outdoor in the US and 1 trial indoor in NL in cucumber). Extrapolation to gherkin and summer squash is also not acceptable.

- **Root and tuber vegetables (0.3 mg/kg)**: Extrapolation to the whole group of root and tuber vegetables requires in the EU also trials in sugar beet. Also the residue levels in carrots are higher than the residue levels found in potatoes. Therefore, extrapolation to the whole group of root and tuber vegetables is not acceptable.

- **Brussels sprouts (6 mg/kg)**: Using the OECD calculator the MRL should be 5 mg/kg.

238 CLOTHIANIDIN

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

- **Stone fruit**: There are sufficient trials data which would allow establishing separate MRL for plums, peaches and cherries resulting from the use of thiamethoxam. These data confirm the findings of Maclachlan et al. which postulate that for plums a lower MRL. For plums a MRL of 0.02 mg/kg would be sufficient. For cherries a MRL of 0.1 mg/kg is appropriate. For peaches and apricots the MRL of 0.2 mg/kg are proposed (the results from peaches could be extrapolated to apricots.).

- **Berries and other small fruits except grapes**: The morphology of various berries within the group is not comparable. There are residue data which would allow establishing separate MRLs for strawberries, blueberries, raspberries, blackberries, boysenberries, cranberries. There are no GAPs reported on other berries. Scientific studies indicate that initial residue deposits at 0 d PHI vary significantly between various berries (Maclachlan, 2010) thus introducing additional uncertainty to the extrapolation.
- **Brassica vegetables (flowering, head brassica and kohlrabi)**: Residue trials were available for broccoli and head cabbage. The results from cabbage were extrapolated to the whole group.

- **Root and tuber vegetables (including sugar beet roots)**: GAPs were reported for carrots, potatoes, radishes and sugar beet. (in addition, GAPs for clothianidin were reported for carrots, chicory roots, tuberous and corm vegetable and sugar beet, but they were less critical than the use of thiamethoxam.) The GAPs were not comparable: seed treatment for sugar beets, foliar application for the other crops, different application rate for carrots and radishes compared with potatoes.

### 239 Cyproconazole

The EU would like to state that the residue definition recommended in the JMPR report for risk assessment for milk is the parent molecule, free and conjugated.

### 224 Difenoconazole

On **legume vegetables** the EU would like to introduce a **reservation** as no GAPs were notified for legume vegetables except the use on beans with pods. Therefore setting a group tolerance is not justified. The proposed draft MRL should therefore only be recommended on beans with pods (VP 0061).

### 193 Fenpyroximate

The EU has a **reservation to the proposed draft MRL for fruiting vegetables other than cucurbits** as no GAPs were notified for fruiting vegetables other than tomatoes and peppers. Therefore, the EU considers that setting a group tolerance is not justified.

### 242 Flubendiamide

The EU supports the advancement of all the proposed draft MRLs except for the following crops for which the EU would like to make a **reservation** for:

- **Stone fruits**: Extrapolation of residue data from cherries to the whole group of stone fruit is not acceptable in EU. There are sufficient trials data which would allow establishing separate MRLs for peaches/nectarines, plums and cherries. Scientific studies indicate that initial residue deposits at 0 d PHI vary significantly between stone fruits (cherries/plums) (Maclachlan, 2010). Thus the extrapolation is scientifically not valid.
- **Fruiting Vegetables**: Both tomatoes and peppers are considered major crops in the EU, eight residue trials would be required in each crop for MRL calculation. The data sets on which the proposed draft MRL is based are insufficient.

- **Cucurbits (edible and inedible peel)**: There are sufficient trials data which would allow establishing MRL for courgettes, cucumbers (6 trials) and melons (6 trials). Residues in cucurbits-edible peel would allow deriving lower MRL proposal than in cucurbits-inedible peel, maybe due to differences in surface texture. Residue extrapolation from cucurbits-inedible peel to cucurbits-edible peel (or vice-versa) are not acceptable at EU level due to different surface/weight ratios of the crops (gherkins vs. water melons) as well due to variations of the surface texture between various species of cucurbits (rough and smooth surfaces). Furthermore, since both melons and cucumbers are considered major in the EU, eight residue trials would be required in each crop for MRL calculation.

- **Brassica**: There are sufficient trials data which would allow establishing separate MRLs for head cabbage, Brussels sprouts, broccoli and cauliflower. Scientific studies indicate that initial residue deposits at 0 d PHI vary significantly between Brassica vegetables (Brussels sprouts/broccoli) (Maclachlan, 2010). Thus the extrapolation is scientifically not valid.

- **Legume vegetables**: Extrapolation of residue data from peas with pods to the whole group of legume vegetables is not acceptable in the EU. The morphology of beans and peas with pods is not comparable with shelled beans and peas. Extrapolation not compliant with regard to “one GAP” principle (FAO, 2009). There are sufficient trials data which would allow establishing separate MRLs for beans (with pods), peas (with pods) and beans (without pods).

- **Tea**: is considered major in the EU, and thus eight residue trials would be required.

**244 MEPTYLDINOCAP**

The RD derived by JMPR and at the EU level are not directly comparable. An additional problem results from the overlap of residue definition for meptyldinocap with the RD for dinocap.

The EU would like to introduce a **reservation for melons** as the proposed draft MRL is not sufficiently supported by data.

**217 NOVALURON**

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

- **Stone fruits**: The CXL proposal was derived by extrapolating results from cherries to the whole group of stone fruits (except prunes). The
group of stone fruit contains crops with different plant morphology, surface texture, wettability and surface/weight ratio (cherries vs. peaches). Therefore, the extrapolation from cherries to the whole group of stone fruit is scientifically not valid. This fact is also substantiated by the findings of Maclachlane et al., that the normalised residue concentrations on day 0 are significantly different for the different stone fruit crops.

- **Brassica vegetables (except leafy brassica)**: The group of brassica contains crops with different morphology. According to Maclachlane et al. the normalised residue at day 0 after the last application are significantly different for crops belonging to this group, resulting from different surface texture and wettability, shape of the edible part of the crops and surface/weight ratio. Thus, the extrapolation to the whole crop group is scientifically not valid.

- **Fruiting vegetables, cucurbits**: At EU level an extrapolation is not possible between cucurbits with edible peel and inedible peel because of differences regarding the surface textures and the surface/weight ratios. It is noted that according to Maclachlan et al. these differences are confirmed

- **Fruiting vegetables other than cucurbits (except sweet corn)**: It is noted that the residue trials on peppers and tomatoes belong to the same population (Kurskal-Wallis H Test). Since a GAP was notified for the whole crop group of fruiting vegetables, an extrapolation would be acceptable. However, it should be clarified if the GAP is relevant also for fungi.

### 245 THIAMETHOXAM

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

- **Citrus fruits** (only valid for oranges)

- **Stone fruits** (only valid for cherries): The group of stone fruit contains crops with different plant morphology, surface texture, wettability and surface/weight ratio (cherries vs. peaches). Therefore, the extrapolation from cherries to the whole group of stone fruit is scientifically not valid. This fact is also substantiated by the findings of Maclachlane et al., that the normalised residue concentrations on day 0 are significantly different for the different stone fruit crops. There are sufficient data available which allow the setting of MRLs for plums, peaches and cherries. For apricots, the data from peaches could be extrapolated.

- **Berries and other small fruits** (only valid for strawberries): The group of berries and other small fruit contains crops with different plant morphology, surface texture, wettability and surface/weight ratio (e.g. grapes, strawberries, raspberries). The data published by Maclachlan demonstrate that the initial residue deposit is expected to be significantly different. Extrapolation from strawberries to the whole group is
therefore scientifically not valid.

- **Brassica vegetables** (only valid for head cabbage): The group of brassica contains crops with different morphology. According to Maclachlane et al. the normalised residue at day 0 after the last application are significantly different for crops belonging to this group, resulting from different surface texture and wettability, shape of the edible part of the crops and surface/weight ratio. Thus, the extrapolation to the whole crop group is scientifically not valid.

- **Cucurbits** (only valid for those of edible peel): At EU level an extrapolation is not possible between cucurbits with edible peel and inedible peel because of differences regarding the surface textures and the surface/weight ratios. It is noted that according to Maclachlan et al. these differences are confirmed.

- **Fruiting vegetables other than cucurbits** (only valid for peppers): No GAPs were notified for fruiting vegetables other than peppers. Therefore, the setting of a group tolerance is not justified.

- **Leafy vegetables** (only valid for lettuce and/or spinach): Residue trials were available for leafy lettuce, head lettuce, spinach and mustard greens. The group tolerance is based on the trials on leaf lettuce where the highest residues were observed. For the other crops lower MRLs could be derived. The fact that on lettuce lower residues are expected can be explained by the crop morphology.

- **Root and tuber vegetables** (only valid for potatoes): Taking into account that the GAPs are not comparable (see also clothianidin) an extrapolation from potatoes to the whole group is not acceptable. There are sufficient data to set individual MRLs for carrots, potatoes, radishes, sugar beet. It is not clear if for other crops belonging to the group GAPs were notified and whether the setting of MRLs is necessary.

### 143 TRIAZOPHOS

Although the proposed draft MRL is sufficiently supported by data, it is **not acceptable for rice, husked** because it exceeds the ARfD. The EU will submit a **concern form**. The impact on consumer safety derived from the potential residues in animal products could not be determined.
The EU opposes the advancement of the proposed MRLs because the EU ADI of 0.00065 mg/kg bw/day is exceeded with up to 233 %. The ADI of 0.0007 mg/kg bw/day established by JMPR was exceeded with 217 %.