GSC CODEX MESSAGE CAC34/2011/23

23 June 2011

European Union comments on
Codex Circular Letter CL 2011/09-PR


PART A: MATTERS FOR ADOPTION BY THE 34TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

1. Draft Maximum Residue Limits for Pesticides at Step 8 (para. 31 - 81 and Appendix II);

   The EU supports the adoption at Step 8 of all the draft MRLs in Appendix II of REP 11/PR with the exception of the Draft MRLs for the substances/commodities below:

   **HALOXIFOP (194):** The EU does not support the adoption of the draft MRLs at Step 8 due to chronic dietary intake concerns. The EU has already forwarded a concern form to the Codex Secretariat and JMPR.

   The ADI and ARfD values derived by JMPR are in the same range as the EU toxicological reference values (EU ADI 0.00065 mg/kg bw/day, JMPR ADI 0.0007 mg/kg bw/day, both based on the same chronic study in mice, SF 100; EU ARfD 0.075 mg/kg bw, JMPR ARfD 0.08 mg/kg bw, both based on the developmental toxicity NOAEL in rabbits, SF 100). In the Risk assessment is used the EFSA PRIMo rev. 2. The exposure related to the CXL proposals amounts of up to 219 % of the ADI and is mainly driven by the CXL for milk (using the STMR in the exposure assessment). The ADI is exceeded for FR toddler, UK infant, NL child, UK toddler and FR infant.

   **FLUOPICOLIDE (235):** The EU and Switzerland already expressed their concerns due to acute intake concerns at the 42nd session of the CCPR. Therefore, the EU does not support the adoption at Step 8 of the draft MRLs.

   The EU has set a lower ARfD (0.18 mg/kg bw) than JMPR (0.6 mg/kg bw). Using EU endpoints and risk assessment methodologies, there are intake problems for head cabbage, scarole, kale, celery Chinese cabbage, witloof, lettuce; spinach, purslane. There is a problem even with the variability factor of 5. Even when using JMPR endpoints there are also intake problems for scarole, kale, celery and Chinese cabbage.

2. Proposed Draft Maximum Residue Limits for Pesticides at Step 5/8 (with omission of Steps 6/7) (paras. 31 - 81 and Appendix III);

   The EU supports the adoption at Step 5/8 of all the Proposed Draft MRLs in Appendix III of REP 11/PR with the exception of the Proposed Draft MRLs for the substances/commodities below:

   **CHLOROTHALONIL (81):**
- **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.

**Bifenthrin (178):**

- **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

**Novaluron (217):**

- **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 Maclauchlane 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.

**BIFENAZATE (219):**

- **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.

**BOSCALID (221):**

- **Leafy vegetables** (i.e., 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.

**CHLORANTRANILIPROLE (230):**

- **Brassica:** due to disagreement with the extrapolation used by the JMPR.

**CLOTHIANIDIN (238):**

- **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.

**FLUBENDIAMIDE (242):**

- **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

**THIAMETHOXAM (245):**

- **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.


**Editorial comment:**

The European Union would like to propose the deletion of the reference numbers (1), (2) and (3) in Appendix X of the CCPR Report (page 101 and 102) as the respective references are not included in the final Codex text.