European Community comments on
Codex Circular Letter CL 2009/14-PR

SUBJECT: DISTRIBUTION OF THE REPORT OF THE FORTY-FIRST SESSION OF THE CODEX COMMITTEE ON PESTICIDE RESIDUES (ALINORM 09/32/24)

PART A: MATTERS FOR ADOPTION BY THE 32ND SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

The EC supports the adoption by the 32nd session of the Codex Alimentarius Commission of most of the draft and proposed draft MRLs forwarded for consideration by the 41st session of the Codex Committee on Pesticide Residues. However, the EC would like to make the following specific comments as it has still some concerns as regards the adoption of the draft and proposed draft MRLs for some substances/commodities:

1. DRAFT AND DRAFT REVISED MAXIMUM RESIDUE LIMITS FOR PESTICIDES AT STEP 8 (PARAS 60-130 AND APPENDIX II);

   CARBARYL (008): CITRUS FRUIT

   The EC does not support the adoption of the draft MRL for Carbary (008) in citrus fruit (15 mg/kg) at Step 8.

   The EC noted the response of the JMPR (2008) in relation to specific concerns raised by CCPR. However, there are important differences in toxicological endpoints set by JMPR and the European Food Safety Authority (EFSA), especially for ARfD, that result in completely different risk evaluations. The EC ARfD was established in 2006 as 0.01 mg/kg bw on the basis of neurotoxicity observed in dogs with a safety factor of 100. Following EFSA assessment, the EC considers the established EC ADI and ARfD to be still relevant for EC consumers.

   Accordingly, for the above reasons, in the event that the Codex Alimentarius Commission adopts the draft MRL for Carbary (008) in citrus fruits, the EC wishes to record its reservation to this decision in the report of the Codex Alimentarius Commission.

   FUSILAZOLE (165), EDIBLE OFFAL, APPLE AND PEAR

   The EC does not support the adoption of the draft MRLs for Fusilazole (165) in Edible Offal (2.8 mg/kg), Apple (0.3 mg/kg) and Pear (0.3 mg/kg) at Step 8.

   The EC noted the response of the JMPR (2008) on the EC review report which sets the 2 mg/kg/bw/day as the start of a dose response relationship. The JMPR did not consider the effects at that dose to be significant and reaffirmed the higher dose of 10 mg/kg/day to be such a start. The EC wishes to reconfirm the endpoint of 0.005 mg/kg/bw/day for the ARfD derived from the 2 mg/kg/bw/day dose level that was established in the EC peer review process in EFSA.
Accordingly, for the above reasons, in the event that the Codex Alimentarius Commission adopts the draft MRL for Fusilazole (165) in Edible Offal, Apple and Pear, the EC wishes to record its reservation to this decision in the report of the Codex Alimentarius Commission.

2. PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES AT STEP 5/8 – WITH OMISSION OF STEPS 6 AND 7 - (PARAS 60-130 AND APPENDIX III)

DIMETHOATE (027): PEPPERS AND LETTUCE

The EC does not support the adoption of the proposed draft MRLs for Dimethoate (027) in peppers (0.5 mg/kg) and lettuce (0.3 mg/kg) at Step 5/8.

Using EC endpoints and risk assessment methodologies, the proposed MRLs peppers are 164% of the ARfD. Although dimethoate residues for lettuce do not indicate an intake concern, omethoate is not included in the Codex residue definition for dimethoate. Omethoate is one of the degradation products of dimethoate, and it is 7 times more toxic than dimethoate. Hence, there may also be an intake concern for the proposed MRL for lettuce due to residues of omethoate.

Accordingly, for the above reasons, in the event that the Codex Alimentarius Commission adopts the proposed draft MRLs for Dimethoate (27) in peppers and lettuce, the EC wishes to record its reservation to this decision in the report of the Codex Alimentarius Commission.

MALATHION (049): WHEAT

The EC does not support the adoption of the proposed draft MRL for Malathion (049) in wheat (10 mg/kg) at Step 5/8.

Using STMR, the proposed draft MRL for wheat is 427% of EU ADI (no acute exceedance from malathion plus maleoxon residues). Furthermore, the EC has concerns about possible levels of desmethyl-malathion, malathion monocarboxylic acid and malathion dicarboxylic acid, which were not measured in supporting residue trials and are considered to be of toxicological relevance in the draft 2009 EU evaluation.

Accordingly, for the above reasons, in the event that the Codex Alimentarius Commission adopts the proposed draft MRLs for Malathion (049) in wheat, the EC wishes to record its reservation to this decision in the report of the Codex Alimentarius Commission.

METHOMYL (094): GRAPES AND TOMATO

The EC does not support the adoption of the proposed draft MRLs for Methomyl (094) in grapes (0.3 mg/kg) and tomato (1 mg/kg) at Step 5/8.

Using the EU ARfD at 0.002 mg/kg/bw/day and EU risk assessment methodologies, the proposed MRLs for grapes is 524% of the ARfD. For tomato it is 1698% of the EU ARfD. Using the JMPR ARfD it would be 212%.

Accordingly, for the above reasons, in the event that the Codex Alimentarius Commission adopts the proposed draft MRLs Methomyl (094) in grapes and
tomato, the EC wishes to record its reservation to this decision in the report of the Codex Alimentarius Commission.

CYPERMETHRINS (118): CAULIFLOWER, SCAROLE, APPLES AND PEACHES

The EC does not support the adoption of the proposed draft MRLs for Cypermethrins (118) in cauliflower (1 mg/kg), scarole (0.7 mg/kg), apples (0.7 mg/kg) (covered by pome fruits) and peaches (2 mg/kg) (covered by stone fruits) at Step 5/8.

The JMPR residue evaluation has been reviewed by the ECMS and based on the global toxicological end points for cypermethrins, the chronic and acute dietary intake calculation was performed according to EFSA PRIMO.

Using the HR values in the EFSA PRIMO, there is an acute intake concern for children for the following crops:

- Peaches (102.2% ARfD-VF=5)
- Apples (101.1% ARfD-VF=5)
- Cauliflower (107% ARfD-VF=5)
- Scarole (broad-leaf) (113% ARfD-VF=5).

No processing data on pome fruit and stone fruit were available in order to perform a refined dietary intake risk assessment.

Accordingly, for the above reasons, in the event that the Codex Alimentarius Commission adopts the proposed draft MRLs for Cypermethrins (118) in cauliflower, scarole, apples and peaches, the EC wishes to record its reservation to this decision in the report of the Codex Alimentarius Commission.

CYALOTHIRIN (146): APRICOTS, PEACHES, NECTARINES, TOMATOES, PEPPERS, SWEET CORN, BROCCOLI, CAULIFLOWER, HEAD CABBAGE AND MILK

The EC does not support the adoption of the proposed draft MRLs for Cyathorin (146) in apricots (0.5 mg/kg), peaches (0.5 mg/kg), nectarines (0.5 mg/kg), tomatoes (0.3 mg/kg), peppers (0.3 mg/kg), sweet corn (0.02 mg/kg), broccoli (0.5 mg/kg), cauliflower (0.5 mg/kg), head cabbage (0.3 mg/kg )and milk (0.2 mg/kg) at Step 5/8.

The EC ADI (0.005 mg/kg bw) and ARfD (0.0075 mg/kg bw) for lambda-cyhalothrin was established in 2001 on the basis of neurotoxicity observed in dogs, NOAEL 0.5 and 0.75 mg/kg bw/day respectively and a safety factor of 100.

Using the EFSA model, the proposed MRLs with STMR and HR identified by JMPR, the EU ADI and ARfD, acute intake concern was identified for the following MRL proposals:

- apricots (DE child 109%), peaches and nectarines (DE child 192%), tomatoes (BE child 101%), peppers (DE child 108%), sweet corn (DE child 126%),
broccoli (BE child 166%), cauliflower (NL child 264%, NL general population 127%), head cabbage (NL child 119%), milk and milk products from cattle (UK Infant 133%).

Accordingly, for the above reasons, in the event that the Codex Alimentarius Commission adopts at Step 5/8 the proposed draft MRLs for Cyalothrin (146) in apricots, peaches, nectarines, tomatoes, peppers, sweet corn, broccoli, cauliflower, head cabbage and milk, the EC wishes to record its reservation to this decision in the report of the Codex Alimentarius Commission.

3. PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR PESTICIDES AT STEP 5 (PARAS 79, 91, 116, 124 AND APPENDIX IV);

METHOMYL (094): APPLES

The EC does not support the adoption of the proposed draft MRL for Methomyl (094) in apples (0.3 mg/kg) at Step 5. The EC would like to record that a concern form for apples has been submitted to the JMPR.

Using EC endpoints (ARfD 0.0025mg/kg bw/day) and risk assessment methodologies (EFSA model PRiMo rev2), the proposed draft MRL for apples is 666% of the ARfD, using an HR value of 0.17mg/kg (15 trials). It is acknowledged that a higher ARfD of 0.01mg/kg bw/day is accepted by JMPR, based on a human volunteer study. Even using the JMPR ARfD with EC risk assessment methodologies, apples are 167% of the ARfD.

Accordingly, for the above reasons, in the event that the Codex Alimentarius Commission adopts the proposed draft MRL for for Methomyl (094) in apples, the EC wishes to record its reservation to this decision in the report of the Codex Alimentarius Commission.

TEBUCONAZOLE (189): BRASSICA, POMEFRUITS AND LETTUCE, HEAD:

The EC does not support the adoption of the proposed draft MRLs for Tebuconazole (189) in Brassica (1 mg/kg), Pome fruits (1 mg/kg), and Lettuce, Head (5 mg/kg) at Step 5.

The EC would like to inform the CAC that a revised concern form has been forwarded to the JMPR. The EC ARfD of 0.03 mg/kg bw/day was set (based on developmental LOAEL of 10 mg/kg bw/day obtained in the mouse teratogenicity study applying a safety factor of 300). No ARfD is allocated by JMPR.

Accordingly, for the above reasons, in the event that the Codex Alimentarius Commission adopts the proposed draft MRLs for Tebuconazole (189) in Brassica, Pomefruits and Lettuce, Head, the EC wishes to record its reservation to this decision in the report of the Codex Alimentarius Commission.

BOSCALID (221): BANANA AND KIWI

The EC does not support the adoption of the proposed draft MRLs for Boscalid (221) in Banana (0.6 mg/kg) and Kiwi (5 mg/kg) at Step 5.
The 2006 JMPR could not recommend STMR values for a large number of follow up crops (rotational crops) in which residues may be present above the LOQ and decided that any estimation of the long term intake would be unrealistic. The 2008 JMPR recommended new MRLs for banana and kiwi fruit, but again no long term intake calculations including follow up crops could be carried out.

Consequently, a long-term intake assessment including possible residues in follow up crops arising from the GAPs evaluated must be carried out at a future meeting before the MRL proposals made by JMPR can proceed.

The EC has concerns to adopt the proposed draft MRLs at Step 5 before a calculation of a long term dietary intake is made. Therefore, the EC proposes to use a conservative residue value of 0.5 mg/kg for all commodities from annual crops which are not treated directly but with possible residues by uptake from soil. Based on this worst-case approach a preliminary long-term intake assessment can be made to exclude any concerns for consumers. In addition JMPR may use all data available on rotational crops to propose more realistic MRLs for annual crops according the procedure described in the JMPR Report 2008.

**Accordingly, for the above reasons, in the event that the Codex Alimentarius Commission adopts at Step 5 the proposed draft MRLs for Boscalid (221) in Banana and Kiwi, the EC wishes to record its reservation to this decision in the report of the Codex Alimentarius Commission.**