

CODEX ALIMENTARIUS COMMISSION

44th Session – 8 - 18 November 2021

European Union comments on

Codex Circular Letter CL 2021/74 PR (REV):

Request for comments on the:

(i) Maximum residue limits for pesticides in food and food (At Step 5/8)

(ii) Revision of the Classification of Food and Feed (CXA 4-1989):

- **Class C: Primary feed commodities and Table 7: Examples of representative commodities for Class C (At Step 5/8)**
- **Class D: Processed foods of plant origin and Table 8: Examples of representative commodities for Class D (At Step 5/8)**

(iii) Guidelines for Compounds for Low Public Health Concern that may be exempted from the Establishment of CXLs or do not give rise to residues (At Step 5)

*European Union Competence
European Union Vote*

(i) Maximum residue limits for pesticides in food and food (At Step 5/8)

The European Union (EU) supports the adoption of all the proposed draft maximum residue limits (MRLs) in Appendix II (step 5/8) of REP 21/PR with the exception of the draft MRLs for the substances/commodities below for which the EU requests that its reservations are included in the report of CAC44.

The EU has a policy in place whereby EU MRLs will be aligned with Codex MRLs if three conditions are fulfilled: (1) that the EU sets MRLs for the commodity under consideration; (2) that the current EU MRL is lower than the CXL; and (3) that the CXL is acceptable to the EU with respect to areas such as consumer protection, supporting data, and extrapolations.

Reservations address the cases where the EU considers the third criterion not to be met, with the aim to increase transparency and predictability regarding the impact of the work of the Codex Alimentarius Commission on EU legislation.

CARBENDAZIM (072). The EU confirms its reservation to the advancement of the proposed draft MRLs for Spices, seeds, Subgroup of as the compound is currently the subject of an ongoing review.

CYPERMETHRIN (INCLUDING ALPHA and ZETA-CYPERMETHRIN) (118). The EU confirms its reservation to the advancement of the proposed draft MRLs for dried ginseng, including red ginseng, as the compound is currently the subject of an ongoing review.

METHOPRENE (147). The EU confirms its reservation to the advancement of the proposed draft MRLs for peanut because a chronic risk for European consumers could not be excluded. Considering the significant background exposure from the existing EU MRLs, there is no scope to raise the MRLs. Further refinements of the chronic exposure calculation are possible; however the relevant data have not yet been assessed in the EU. Studies investigating the metabolic behaviour after post-harvest treatment and on the nature and magnitude of residues in processed products are lacking.

GLYPHOSATE (158). The EU confirms its reservation to the advancement of the proposed draft MRLs for dry beans (subgroup) and dry peas (subgroup), pending the outcome of the ongoing periodic re-evaluation in the EU.

PROPICONAZOLE (160). The EU confirms its reservation to the advancement of the proposed draft MRLs for peach. Following a recent EU evaluation, the active substance was not approved in the EU. In that framework, the consumer risk assessment could not be finalised due to data gaps, and no conclusion could be drawn on the genotoxicity and the general toxicity of several metabolites. Specifically on peaches, an acute consumer risk has been identified for European consumers. Moreover, the proposed Codex MRL is not acceptable because the number of residue trials is insufficient according to the Information Document on the Application of the Guidance to Facilitate the Establishment of MRLs for Pesticides for Minor Crops (referred to in Annex D to the Risk Analysis Principles applied by the Codex Committee on Pesticide Residues, Codex Procedural Manual).

BUPROFEZIN (173). The EU confirms its reservation to the advancement of the proposed draft MRLs for group of tree nuts, mammalian fats except milk fats, eggs, edible offal of poultry, poultry fats, and poultry meat. The EU identified a concern about the potential for the formation of aniline from residues of buprofezin in commodities which are subject to processing.

TEBUCONAZOLE (189). The EU confirms its reservation to the advancement of the proposed draft MRLs for oranges and mandarins as the periodic re-evaluation in the EU is ongoing.

TOLCLOFOS-METHYL (191). The EU confirms its reservation to the advancement of the proposed draft MRLs for potatoes because an acute consumer risk has been identified for European consumers. The EU has set an acute reference dose, based on a 9-month mouse study and an uncertainty factor of 100.

BOSCALID (221). The EU confirms its reservation to the advancement of the proposed draft MRLs for pome fruits (subgroup). The OECD MRL calculator derives a lower MRL of 1.5 mg/kg.

METAFLUMIZONE (236). The EU confirms its reservation to the advancement of the proposed draft MRLs for grape because an acute consumer risk has been identified for European consumers in relation to grape. The EU has set an ARfD based on reduced body weight gain observed in a rat developmental study.

In addition, the EU recommends the adoption of the MRLs of 0.15 mg/kg and 0.6 mg/kg for mammalian fats (except milk fats) and milk fats respectively at Step 5/8.

DICAMBA (240). The EU confirms its reservation to the advancement of the proposed draft MRLs for cotton seed, maize and soya beans, pending the outcome of the ongoing periodic re-evaluation in the EU.

PENTHIOPYRAD (253). The EU confirms its reservation to the advancement of the proposed draft MRLs for cane berries, bush berries, edelberries and guelder rose because of the different residue definitions for risk assessment between the EU and JMPR and the extrapolation methods.

PICOXYSTROBIN (258). The EU confirms its reservation to the advancement of the proposed draft MRLs for sorghum grain, cottonseed, coffee bean, green and black tea, mammalian edible offal, mammalian fats, meat from mammals other than marine mammals, and milks due to several health concerns identified in the European Food Safety Authority peer review, including possible genotoxicity of picoxystrobin and its main plant metabolites.

FLUENSULFONE (265). The EU confirms its reservation to the advancement of proposed draft MRLs for citrus fruit (group); Pome fruit (group, except Japanese persimmon); stone fruit (group); small fruit vine climbing (subgroup); sugar cane; tree nuts (group); coffee bean; wheat, similar grains, and pseudo cereals without husks (subgroup); barley, similar grains, and pseudo cereals with husks (subgroup); maize cereals (subgroup); sweet corns (subgroup); rice cereals (subgroup); and sorghum grain and millet (subgroup). The metabolism studies are not representative for the residue behaviour observed in the residue trials. In addition, the EU is of the opinion that the genotoxic potential of MeS cannot be excluded and that further genotoxicity tests would be needed to follow up on the positive results in vitro.

TOLFENPYRAD (269). The EU confirms its reservation to the advancement of all proposed draft MRLs, pending the outcome of the ongoing import tolerance requests. Moreover, for mandarins, oranges and peppers, based on the toxicological reference values derived by JMPR, an acute consumer risk has been identified for European consumers.

ACETOCHLOR (280). The EU confirms its reservation to the advancement of the proposed draft MRLs for soya bean (dry) and mammalian edible offal because the enforcement residue definitions for plant and animal commodities in the EU differ from the definitions applied by JMPR.

FLONICAMID (282). The EU confirms its reservation to the advancement of the proposed draft MRLs for lemons and limes (subgroup); oranges (subgroup); and pumelo and grapefruit (including Shaddock-like hybrids) (subgroup) because the enforcement residue definition for plant commodities in the EU differs from the definition applied by JMPR. In addition, for oranges, an acute consumer risk has been identified for European consumers.

FLUAZIFOP-P-BUTYL (283). The EU confirms its reservation to the advancement of the proposed draft MRLs for elderberries because an extrapolation from blueberries to elderberries is not foreseen in the Codex extrapolation rules and for strawberry because an acute and chronic consumer risk has been identified for European consumers.

CYCLANILIPROLE (296). The EU confirms its reservation to the advancement of all proposed draft MRLs because the consumer risk assessment could not be finalised in a recent

EU evaluation and no conclusion could be drawn on the genotoxicity and the general toxicity of several metabolites. Moreover, for the subgroup of leaves of Brassicaceae, the number of trials were insufficient to recommend an MRL.

FOSETYL-ALUMINIUM (302). The EU confirms its reservation to the advancement of the proposed draft MRLs for coffee beans because of insufficient number of residue trials.

MANDESTROBIN (307). The EU confirms its reservation to the advancement of the proposed draft MRLs for rape seed because of the different residue definition for risk assessment in the EU.

PYDIFLUMETOFEN (309). The EU confirms its reservation to the advancement of all the proposed draft MRLs, pending the outcome of the ongoing approval procedure in the EU. In addition, for the subgroup of stems and petioles, an acute consumer risk has been identified for European consumers.

AFIDOPYROPEN (312). The EU confirms its reservation to the advancement of all the proposed draft MRLs due to their concern on the evaluation of metabolites, an acute consumer risk concern for European consumers for leaves of Brassicaceae, and the representative crop selection for herbs.

METCONAZOLE (313). The EU confirms its reservation to the advancement of all the proposed draft MRLs, pending the outcome of the ongoing periodic re-evaluation in the EU. In addition, the EU believes that the proposed draft MRL for peach should be lower (according to the OECD calculator) and that the number of residue trials were insufficient to support an MRL for plums (subgroup). The EU also noted that for cherries, sunflower and sugar beet, fewer residue trials had been considered by JMPR than by the EU for import tolerance requests for the same commodities. The EU also considers that JMPR should base its recommendations on the most comprehensive dataset possible.

(ii) Revision of the Classification of Food and Feed (CXA 4-1989):

- **Class C: Primary feed commodities and Table 7: Examples of representative commodities for Class C (At Step 5/8)**
- **Class D: Processed foods of plant origin and Table 8: Examples of representative commodities for Class D (At Step 5/8)**

The European Union supports the adoption of the Revised Classification of Food and Feed, Class C – primary feed commodities and of the Revised Classification of Food and Feed, Class D – Processed food of plant origin.

Regarding Class C: Primary feed commodities and Table 7: Examples of representative commodities for Class C (At Step 5/8), Appendix VII, the EU would like to propose the following changes:

Type 11 Primary feed commodities of plant origin, Group 050, Group Letter Code AL

For AL 3509 *Leucaena*, forage; AL 3510 *Leucaena*, silage; AL 3526 *Leucaena*, hay and/or straw and AL 3534 *Leucaena*, leaf meal with the scientific name *Leucaena leucocephala* (Lam.) de Wit and the synonym *Acaciella glauca* (L.) L. Rico. The EU, based on the

Mansfeld's Database (<http://mansfeld.ipk-gatersleben.de/apex/f?p=185:3>) suggests considering the synonym *Acacia glauca* (L.) Willd instead of *Acaciella glauca* (L.) L. Rico.

Type 11 Primary feed commodities of Plant origin, Group 052, Group Letter Codes AM (hay and processed products) AV (forage)

The EU notes that in the draft REP21/PR-Appendix VII the new code numbers of Cotton gin trash, Cotton seed, hulls and Cotton seed, meal are not consistent and therefore suggests the changes as follows:

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Subgroup 052C: Miscellaneous Processed feed products (such as meal, hulls, dried pulp)

AM 3587 Cotton gin trash

Gossypium spp.

- Cotton gin, see AM ~~3587~~ 357787 Cotton gin trash

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Processed commodities transferring from Class D (Food) to Class C (Feed):

Transferring commodity	Existing code	Number of CXLs	New code	Action
Cotton gin trash	AB 1204	1	AM 3587 <u>357787</u>	Adapt code in database
Cotton seed, hulls	AB 0691	1	AM 357888 <u>357888</u>	Adapt code in database
Cotton seed, meal	AB 1203	2	AM 357989 <u>357989</u>	Adapt code in database

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Commodities with code changes (not all commodity codes are used in the existing classification, some codes have been added over time). For the following commodities the code in the database has to be adapted:

Commodity	Existing code	New code	Number of CXLs
....			
....			
Cotton gin trash	AB 1204	AM 357787 <u>357787</u>	1
Cotton seed, hulls	AB 0691	AM 357888 <u>357888</u>	1
Cotton seed, meal	AB 1203	AM 357989 <u>357989</u>	2

Regarding Class D: Processed foods of plant origin and Table 8: Examples of representative commodities for Class D (At Step 5/8), Appendix VIII, the EU would like to propose the following change:

Type 12, Secondary food commodities of plant origin, Group 056, Group Letter Code DV

For “Chervil, dried, *Anthriscus cerefolium* L. Hoffmann”, the code DV 0465 is at the end of the line before chervil, dried. The EU suggests placing it in the same column as are other codes and making it bold.

(iii) Guidelines for Compounds for Low Public Health Concern that may be exempted from the Establishment of CXLs or do not give rise to residues (At Step 5)

The European Union supports the adoption of the proposed draft Guidelines.