

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 4.6

CX/CAC 21/44/8 Add. 1

November 2021

Original Language Only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-fourth Session

COMMENTS ON DRAFT STANDARDS AND RELATED TEXTS SUBMITTED BY THE 52ND SESSION OF THE CODEX COMMITTEE ON PESTICIDE RESIDUES¹

BACKGROUND

This document compiles the comments on the draft standards submitted at Step 8 or Step 5/8 and the proposed draft standards submitted at Step 5 of the Procedure. The comments are those received through the Codex Online Commenting Systems (OCS), or via email by the time this document was issued. The comments are as shown in Appendix I.

OCS is an online tool that enables Codex Contact Points to submit comments on draft texts in a standardised way, thus providing more transparency and better management of comments on different Codex texts as requested through Circular Letters. Since its launching at CAC39 (2016), the OCS has been used for different Codex Committees.

EXPLANATORY NOTES ON APPENDIX I

The comments received are presented in a table format, with two columns as follows:

First column – Presents the comments with the rationale.

Second column – Presents the provider of the comments (name of country or observer)

¹ This document compiles comments submitted through OCS, or via email by the time this document was issued, in reply to CL 2021/74-PR

Appendix I

Comments in regard to: (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).

in reply to CL 2021/74-PR

Comments of: Australia, Canada, Chile, Costa Rica, Cuba, Ecuador, Egypt, European Union, Indonesia, Kenya, Uganda, THIE – Tea & Herbal Infusions Europe

COMMENT	MEMBER / OBSERVER
<p>In the Maximum Residue Limits for Pesticides in Food and Feed at Step 5/8, compound 296 cyclaniliprole (296) appears with an MRL of 0.45 (dw) in straw and fodder (dry) of cereal grains. The draft MRL at Step 4 was withdrawn by CCPR (as correctly recorded in REP21/PR Appendix VI). Therefore, there should be no CXL for cereal grain fodders and this line in the table should be in the table of revoked compounds.</p>	<p>Australia</p>
<p>REQUEST FOR COMMENTS ON TEXTS GOING FOR ADOPTION BY CAC (Adoption at Step 8 and Step 5/8)</p> <p>Canada Comments:</p> <p>(i) Maximum residue limits for pesticides in food and feed (At Step 5/8). Canada supports the adoption by CAC44 of the maximum residue limits for pesticides in food and feed (at Step 5/8) and recommends the adoption of the metaflumizone MRLs of 0.15 mg/kg and 0.6 mg/kg for mammalian fats (except milk fats) and milk fats, respectively, as recommended in the JMPR Report of the 2019 Extra Meeting.</p> <p>(ii) Revision of the Classification of Food and Feed (CXA 4-1989):</p> <ul style="list-style-type: none"> • 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). <p>Canada supports the adoption by CAC44 of the revised Class C (Primary Feed Commodities) and Class D (Processed Foods of Plant Origin), the corresponding Tables 7 and 8, respectively, which provide examples of the selection of representative commodities for these two classes, and the accompanying text.</p> <p>(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).</p> <p>Canada supports the adoption by CAC44 of the Guidelines for Compounds of Low Public Health Concern that may be exempted from the Establishment of CXLs or do not give rise to residues, the accompanying Annex Examples of Substances and the proposed text.</p>	<p>Canada</p>
<p>Request for comments on the:</p> <p>(i) Maximum residue limits for pesticides in food and food (At Step 5/8). Chile apoya la adopción.</p> <p>(ii) Revision of the Classification of Food and Feed (CXA 4-1989):</p> <ul style="list-style-type: none"> • Class C: Primary feed commodities and Table 7: Examples of representative commodities for Class C (At Step 5/8). 	<p>Chile</p>

<p>• Class D: Processed foods of plant origin and Table 8: Examples of representative commodities for Class D (At Step 5/8). Chile apoya la adopción.</p> <p>(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). Chile apoya la aprobación en el trámite 5.</p>	
<p>Costa Rica would like to thank the Gte and CCPR for the work done. We would also like to confirm that the proposed MRLs indicated in this document are ready for adoption.</p>	Costa Rica
<p>Cuba agradece poder responder a la carta circular 2021/74-PR y en principio, apoya los LMR propuestos de plaguicidas en alimentos y piensos, la revisión de las categorías C y D, los cuadros 7 y 8, así como las Directrices para los compuestos de baja preocupación en materia de salud pública que pueden estar exentos del establecimiento de cKL o que no dan lugar a residuos.</p>	Cuba
<p>Ecuador agradece a la Secretaría del Codex por la oportunidad de presentar nuestros comentarios a la Carta Circular CL 2021/74-PR, reafirmando las conclusiones emitidas en la 52.ª REUNIÓN DEL COMITÉ DEL CODEX SOBRE RESIDUOS DE PLAGUICIDAS, Ecuador apoya la aprobación del documento de Revisión de la Clasificación de alimentos y piensos, así como la aprobación del documento de Directrices para compuestos de baja preocupación para la salud pública que pueden estar exentos del establecimiento de CXL o que no dan lugar a residuos.</p>	Ecuador
<p>Egypt agrees with the adoption of the MRLs for pesticides in food/feed, the revised Class C and D and corresponding Tables 7 and 8 and the Guidelines for compounds for low public concern that may be exempted from the establishment of CXLs or do not give rise to residues.</p>	Egypt
<p>(i) Maximum residue limits for pesticides in food and food (At Step 5/8)</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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-</p>	European Union

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:

- Page 21
Subgroup 052C: Miscellaneous Processed feed products (such as meal, hulls, dried pulp)
AM 3587 Cotton gin trash
Gossypium spp.
- Cotton gin, see AM 3587 Cotton gin trash

- Page 59
Processed commodities transferring from Class D (Food) to Class C (Feed):
Transferring commodity Existing code Number of CXLs New code
Action

Cotton gin trash database	AB 1204	1	AM 3587	Adapt code in database
Cotton seed, hulls database	AB 0691	1	AM 3588	Adapt code in database
Cotton seed, meal database	AB 1203	2	AM 3589	Adapt code in database

- Page 60
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 3587	1
Cotton seed, hulls	AB 0691	AM 3588	1
Cotton seed, meal	AB 1203	AM 3589	2

Regarding Class D: Processed foods of plant origin and Table 8: Examples of

<p>representative commodities for Class D (At Step 5/8), Appendix VIII, the EU would like to propose the following change:</p> <p>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.</p> <p>(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)</p> <p>The European Union supports the adoption of the proposed draft Guidelines.</p>	
<p>Indonesia agrees that the MRL for pesticides in food and feed at step 5/8; the revision of the classification of food and feed at step 5/8 and guidelines for compounds for low public health concern at step 5 are ready for adoption by CAC44.</p>	Indonesia
<p>Kenya supports adoption of the MRLs at step 5/8 by CAC44.</p>	Kenya
<p>A. Maximum residue limits for pesticides in food and food (At Step 5/8). Uganda is in support of the advancement of the proposed MRLs for all the commodities evaluated but had reservations on the following MRLs.</p> <p>1) Bifenthrin (178). We express our reservation for the proposed MRL for strawberry, due to exceedance in the Acute Reference dose for the general population and Children.</p> <p>B. Revision of the Classification of Food and Feed (CXA 4-1989):</p> <p><input type="checkbox"/> Class C: Primary feed commodities and Table 7: Examples of representative commodities for Class C (At Step 5/8). Uganda agrees with the current structure of Class C. The revision that has been made accommodates all the processed feed commodities that have been moved from class D to Class C. The revised structure of Class C is as was agreed during CCPR50 and CCPR51. It will ultimately improve the calculation of animal dietary burden, to support establishment a maximum residue limits (MRLs), for animal commodities. Uganda would also like to propose the inclusion of sweet potato (<i>Ipomoea batatas</i>) vine, silage and hull and agreed with the decision of CCPR inclusion of these commodities.</p> <p><input type="checkbox"/> Class D: Processed foods of plant origin and Table 8: Examples of representative commodities for Class D (At Step 5/8). Uganda is in agreement with the adoption of the evaluated commodities. Uganda also agrees with the list of representative commodities listed in Table 7. Examples of selection of representative commodities, Class C, Type 11 Primary Animal Feed Commodities. We also agree with Table 8 Example of the selection of representative commodities Class D, Processed Foods of Plant Origin. Justification: The proposed representative commodities allow for the setting of group and subgroup MRLs to help facilitate trade in variety of food commodities. The Principles and Guidance on the Selection of Representative Commodities for the extrapolation of Maximum Residue Limits for Pesticides to Commodity Groups have been followed</p> <p>C. 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). Uganda is in agreement with the advancement of the guidelines to the next step of 5- so that member countries can give the document more scrutiny.</p>	Uganda
<p>As regards REVISION OF THE CLASSIFICATION OF FOODS AND ANIMAL FEEDS (CXA4 – 1989) CLASS D – PROCESSED FOODS OF PLANT ORIGIN (At Step 5/8) - Dried vegetables Class D Type 12 Group 056 dried vegetables we would like to not that for all commodities the plant part concerned needs to be specified as the plant parts may be affected by different pests, require different plant protection products which show different residue behaviours. Example: DV 0474 dandelion, dried - herbs and roots are used in commerce.</p>	THIE – Tea & Herbal Infusions Europe

This is especially a concern for roselle which is currently listed as dried vegetable DV 0446 and under herbal teas as DT 0446 Roselle, calyxes /blossoms, dried. For DV 0446 the plant parts needs to be specified as leaves.

Moreover, many of the dried commodities are present in the corresponding fresh produce groups i.e. 001 fruits, 009 vegetables, 027 herbs. We don't see the rationale for expanding the dried crop groups for commodities which are already covered in the fresh crop groups given that it is the fresh growing crop that the pesticides are generally applied to.

For the EU and UK there would be an issue if MRLs are set at Codex on the dried crop and not at the corresponding fresh crop, since there is no provision within the EU commodity crop groups for these crops dried; the MRL is set on the fresh product.

For tea it is proposed to amend the current classification for DT1114 for tea, black green (dried & fermented) and the sub DT1116 tea, green (dried) to include additional categories

DT 1115 purple tea

DT 1117 black tea

I would strongly argue against this sort of expansion.

- Most national authorities only have 1 cropgroup 'tea' so this will create issues of how to adopt MRLs into national systems if set at a subset level of green or purple tea.

- Tea is one botanical species and pesticides are applied to the growing crop in the same manner irrespective of whether the cultivar is purple or green or whether the leaf is to be processed into green, black, oolong or other processing types of tea.

- This is no different than having 1 crop code for apple and no subsets for different varieties of apple.

For consistency and clarity subgroup 66A teas- teas from camellia sinensis should have only 1 code DT 1114 and no other and the title can be amended to 'tea – black, green, other (dried and/or fermented)'

As regards REVISION OF THE CLASSIFICATION OF FOODS AND ANIMAL FEEDS (CXA4 – 1989)

CLASS D – PROCESSED FOODS OF PLANT ORIGIN (At Step 5/8) - TEAS Class D
Type 13 Derived edible products of plant origin Group 066 Group Letter Code DT:

For tea it is proposed to amend the current classification for DT1114 for tea, black green (dried & fermented) and the sub DT1116 tea, green (dried) to include additional categories

DT 1115 purple tea

DT 1117 black tea

We strongly argue against this sort of expansion. Most national authorities only have 1 crop group 'tea' so this will create issues of how to adopt MRLs into national systems if set at a subset level of green or purple tea.

Tea (Camellia sinensis) is one botanical specie and pesticides are applied to the growing crop in the same manner irrespective of whether the cultivar is purple or green or whether the leaf is to be processed into green, black, oolong or other processing types of tea. This is no different than having 1 crop code for apple and no subsets for different varieties of apple. For consistency and clarity subgroup 66A teas- teas from Camellia sinensis should have only 1 code DT 1114 and no other and the title can be amended to 'tea – black, green, other (whether fermented, dried otherwise treated)'

As regards GUIDELINES FOR COMPOUNDS OF LOW PUBLIC HEALTH CONCERN

THAT MAY BE EXEMPTED FROM THE ESTABLISHMENT OF CODEX MAXIMUM RESIDUE LIMITS OR DO NOT GIVE RISE TO RESIDUES (At Step 5) - Criterion 2 Active substances for which it is not possible to differentiate between the exposure associated with its use as pesticide with its background exposure levels or its other uses in the food chain:

We would like propose to make it more explicit in this criterion that it also

encompasses substances naturally present in the crop but also neo-formed during primary processing of crops which cannot be distinguished from use as a pesticide in addition to the rather vague 'other uses in the food chain'.	
---	--