

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 8

CX/PR 21/52/12-Add.1

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ORIGINAL LANGUAGE ONLY

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON PESTICIDE RESIDUES

52<sup>nd</sup> Session

(Virtual)

26-30 July and 3 August 2021

### 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 4)

*Comments at Step 3 of Australia, Canada, Chile, Egypt, Iran, Indonesia, Thailand,  
United States of America (USA),  
CropLife International and FoodDrinkEurope*

#### Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/38-PR issued in May 2021. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific paragraphs.
2. The comments submitted through the OCS are, hereby attached as an Annex and are presented in table format.

**GENERAL COMMENTS**1. **General Comments** on overall structure and content of the Guidelines and its readiness for adoption at Step 5.

COMMENTS/RATIONALE	MEMBER/OBERSER
<p>Australia suggests that the title of the document should be changed to “Guidelines for the recognition of active substances or authorized uses of active substances of low public health concern that are considered exempted from the establishment of Maximum Residue Limits or do not give rise to residues”. This is more consistent with the title of Section 3, but also incorporates the fact that some of these active substances are not expected to give rise to residues. Deletion of ‘Codex’ is recommended since Australia believes that the Guidelines are intended for a wider audience than Codex.</p> <p>Australia has no comments on the overall structure of the document, but believes that the examples should not remain in the final document. Some compounds in Criterion 1 are listed as without hazardous properties, which is inaccurate. We understand that the TOR c) specified to “Provide examples of compounds that meet the criteria to facilitate the development of the guidelines (such examples will not necessarily remain in the final document).” On the basis that the examples are removed, Australia supports progression of the Guidelines to Step 5.</p>	Australia
<p>As part of the EWG, Canada offered several comments on the guidelines. Canada has also contributed to the list of biopesticides that are registered on food crops (and for which MRLs are not required or exempted). As such Canada has no further comments on the structure and content of the Guidelines.</p>	Canada
<p>Chile agradece las propuesta presentada por el Grupo de trabajo por medios electrónicos presidido por Chile y copresidido por la India y los Estados Unidos de América, y apoya que las Directrices para los compuestos de baja preocupación en materia de salud pública que podrían estar exentos del establecimiento de CXL o que no dan lugar a residuos, se avancen en el tramite 5/8, para su posterior adopción por la Comisión del Codex Alimentarius. No hay observaciones específicas que realizar al documento.</p>	Chile
<p>Egypt appreciates the approach taken by the CCPR, and would like emphasize the previous comments sent before.</p>	Egypt
<p>Indonesia supports draft 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 by adding examples of natural pesticide substances to 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”, namely: saga seed oil, basil and chili extract.</p> <p>Indonesia proposes that particular attention should be paid to substances that are genotoxic carcinogenic and, if possible, a list of these substances should be made. For example, castor oil taken from <i>Jatropha</i> (<i>Ricinus communis</i> seed oil) and <i>Jatropha curcas</i> seed oil contain Toxalbumin (a toxic protein) so it is not edible.</p>	Indonesia
<p>Structure of guideline is well established and it is ready for adoption at Step 5.</p>	Iran
<p>In case Codex definitions exist, the definition used in the guideline should be the same with the existing. Definitions and criteria should be clear and able to use in consideration on low public health concern. For basic substances and active substances without hazardous properties identified, their quantities or concentration should be mentioned since they are the factors affecting health.</p> <p>In addition, we suggest to remove the Annex on the Example of Substances because this Annex might lead to misunderstanding that only the substances/microorganisms in the Annex can be exempted from Codex MRL establishment.</p>	Thailand

COMMENTS/RATIONALE	MEMBER/OBSERVER
<p>The United States would like to provide the following comments in response to Circular Letter CL 2021/38-PR (Request for comments on the Guidelines for compounds of low public health concerns that could be exempted from the establishment of Codex maximum residue limits or do not give rise to residues).</p> <p>The United States supports the work of the electronic Working Group (EWG) and recognizes the important role that compounds of low public health concern, such as biopesticides, play in plant protection. There is a concern that if such compounds are not being viewed as “safe” or covered by Codex standards, then growers will be reluctant to incorporate these important tools into their farming practices.</p> <p>The EWG has made important progress in developing guidelines for compounds of low public health concern. The proposed draft guidelines for consideration by the 52nd Session of the Codex Committee on Pesticide Residues (CCPR52) provide an important foundation for international harmonization by introducing proposed definitions and criteria for compounds that are of low public health concern.</p> <p>In response to the specific questions asked on the various sections of the draft Guidelines, the United States believes the following:</p> <ul style="list-style-type: none"> <li>(i) the preface and scope reflect the intent of the Guidelines;</li> <li>(ii) the definitions listed – both in terms of the number and content – are useful and should be considered in light of existing definitions and Codex texts; and</li> <li>(iii) the criteria listed are appropriate for consideration.</li> </ul> <p>The United States does not have additional suggestions for further improvements at this time. Given the progress to date, the United States strongly supports continued work in this area.</p>	<p><b>USA</b></p>

**SPECIFIC COMMENTS**

2. **Specific Comments** on the various sections of the Guidelines e.g. (i) whether the scope clearly reflect the intent of the guidelines; (ii) whether there is need for more definitions and/or the current definitions need further improvements; (iii) whether there is need for more criteria or the current criteria need further improvements; (iv) other comments that Codex members and observers may feel relevant to improve the current draft.

COMMENTS/RATIONALE	MEMBER/OBSERVER
<p>(iv) Other comments</p> <p>Annex – Examples should be deleted from the final document.</p> <p><u>PREFACE</u></p> <p>Paragraph 7 – Australia recommends that the paragraph terminates at “there are no internationally harmonized or internationally recognized criteria for MRL exemptions.” Delete “further, there is not a harmonized list of active substances for which exemption have been deemed appropriate.” A “harmonized list of active substances for which exemptions have been deemed appropriate” would not be suitable, because exemption would need to consider the usage of the substance.</p> <p>Paragraph 5 – Replace “in accordance with” with “based on” because there have been some instances where CCPR has advanced MRLs different to (i.e. not in accord with) those recommended by the JMPR.</p> <p>Australia believes that the proposed criteria are sufficient, but would prefer that Criterion 1 is renamed to: Non-toxic active substances and active substances without hazardous properties identified (very low or no toxicological concern).</p> <p><u>SECTION 1. SCOPE</u></p> <p>Australia suggests that the scope should clearly explain that uses of pesticides that are toxic but do not lead to residues harmful to consumers (e.g. uses of certain seed treatments, soil fumigants or pre-planting treatments for example) are not covered in the scope of the Guidelines. This is Australia’s understanding, based on Criterion 1.</p> <p>Australia also suggests that paragraph 11 be changed to ‘These criteria are presented to provide a consistent and harmonized approach for determining when an active substance is of low public health concern and or its authorized uses could be considered exempt from the establishment of MRLs.</p> <p><u>SECTION 2. DEFINITIONS</u></p> <p>Paragraph 17 (and paragraphs 36 and 39 in Section 3) – Australia has concerns with the term “Basic Substance” and would prefer using the term “Non-toxic active substance”. The term “basic” could be confused for “alkaline”.</p> <p><u>SECTION 3. CRITERIA FOR THE RECOGNITION OF ACTIVE SUBSTANCES OR AUTHORIZED USES OF ACTIVE SUBSTANCES OF LOW PUBLIC HEALTH CONCERN THAT ARE CONSIDERED EXEMPTED FROM THE ESTABLISHMENT OF CODEX MAXIMUM RESIDUE LIMITS (CXLs)</u></p> <p>Heading of Section 3 should be changed to indicate that the Guidelines are intended for an audience wider than Codex. Suggest “Section 3. CRITERIA FOR THE RECOGNITION OF ACTIVE SUBSTANCES OR AUTHORIZED USES OF ACTIVE SUBSTANCES OF LOW PUBLIC HEALTH CONCERN THAT MAY BE CONSIDERED EXEMPTED FROM THE NEED TO ESTABLISH MRLS.”</p>	<p><b>Australia</b></p>

COMMENTS/RATIONALE	MEMBER/OBSERVER
<p>(i) Whether the scope clearly reflect the intent of the guidelines; The scope is clearly reflects the intent of the guideline.</p> <p>(ii) Whether there is need for more definitions and/or the current definitions need further improvements; Definitions are sufficient and well-defined.</p> <p>(iii) Whether the there is need for more criteria or the current criteria need further improvements; Current criteria are sufficient.</p>	Iran
<p><u>SECTION 3. CRITERIA FOR THE RECOGNITION OF ACTIVE SUBSTANCES OR AUTHORIZED USES OF ACTIVE SUBSTANCES OF LOW PUBLIC HEALTH CONCERN THAT ARE CONSIDERED EXEMPTED FROM THE ESTABLISHMENT OF CODEX MAXIMUM RESIDUE LIMITS (CXLs)</u></p> <p>(32) To grant the exemption from the establishment of MRLs to an active substance and / or its authorized uses, active substances mandatorilly must meet the requirements indicated in Criterion 1 <del>and-or</del> must <del>also</del> meet the requirements indicated at least for one of the other criteria as appropriate.</p> <p><u>Comment:</u> CropLife International recommends to replace "and" with "or", based on generally accepted scientific principles and regulations for national tolerance exceptions (e.g. USA, Australia): tolerance exemption occurs when mammalian toxicity is negligible, or when negligible exposure is expected.</p>	CropLife International
<p>(37) Active substances and their relevant metabolites for which, according to risk assessments, it has been considered that it is not necessary to establish <del>Guidance Values</del> <u>guidance values</u> for <del>Human Health</del> <u>human health</u> (ADI/ARfD). It should be <del>taken into account excluding cases</del> that there are active substances that do not have ADI / ARfD established because they are genotoxic substances or due to lack of data to define these values.</p> <p><u>Comment:</u> "Guidance Value" are not defined under the Glossary, neither are commonly used in typical scientific jargon for toxicity and risk assessment. CropLife International suggests to take the capital letter out to avoid confusion of introducing new terms. Also, the sentence about incomplete tox-datasets can be misleading and CropLife International suggests to change "taken into account" to "excluding cases".</p>	CropLife International
<p>(38) Active substances and relevant metabolites that do not bioaccumulate or do not have the capacity to cause significantly toxic effects such as, corrosive, sensitizing, neurotoxic, immunotoxin, carcinogenic, mutagenic, reproductive, developmental or endocrine disrupting effects, among others at</p> <p><u>Comment:</u> It seems confusing to associate toxic effects with environmental background levels (defined in Glossary as "Background exposure: Natural levels of substances and levels arising from past human activities present in the environment (e.g. agriculture), in situations relevant for the respective environmental compartment."). It is generally accepted by existing regulations that toxic effects should be associated with environmentally relevant levels. CropLife International suggests to replace "background" by "relevant". environmental <del>background-relevant</del> levels.</p>	CropLife International
<p>(41) Food and/or feed items which are known allergens should be <del>considered carefully</del> <u>subject to additional requirements, not related to risk from pesticides</u>.</p> <p>Since there are no specific requirements for allergenicity of pesticides, it is advisable that this numeral should be further clarified to replace "considered carefully" by a more explanatory note. For example, it could be subject to additional requirements, not related to risk from pesticides.</p>	CropLife International

COMMENTS/RATIONALE	MEMBER/OBSERVER
<p><u>SECTION 2. DEFINITIONS</u></p> <p>FoodDrinkEurope welcomes the intention to establish guidelines at Codex Alimentarius level to exempt substances of low concern from Codex maximum residue levels (CXLs) for plant protection products. We also see it as positive that terms such as "biopesticides" are defined for the first time and that "bio-pesticides" are assigned to different subcategories such as "microbial pesticide", "botanical pesticide", etc., for which definitions have also been proposed.</p>	FoodDrinkEurope
<p><b>Pest:</b> means any species, strain or biotype of plant, animal or pathogenic agent injurious to plants and plant products, materials or environments and includes vectors of parasites or pathogens of human and animal disease and animals causing public health nuisance.</p> <p>We have considerable reservations about the very broad interpretation of the terms "pest" (28), "pesticide" (29) and "pesticide residue" (30). This means that almost every organism in almost every material is called a "pest", every agent on the other hand is a "pesticide" and every residue is a "pesticide residue".</p> <p>From our point of view, this would cover a multitude of different legal areas, which would go far beyond the current range of tasks of the CCPR, which, to the best of our knowledge, has so far mainly or exclusively covered residues from plant protection products (residues from PPP). Consequently, it would have to be clarified that only pesticide residues are meant when referring to the CCPR with "pest", "pesticide" and "pesticide residue".</p> <p>Although the definition of "pesticide" already excludes certain areas: "in these guidelines, the term excludes fertilizers, plant and animal nutrients, food additives and animal drugs", on the one hand, fertilizers, nutrients and food additives cannot be, or are not, generally considered as pesticides. On the other hand, human medicine, cleaning agents, sanitizers and disinfectants as well as other groups of biocidal products, which according to the European understanding belong to the main groups I, II and IV of Regulation (EU) No. 528/2012 on biocidal products, have not been excluded so far.</p>	FoodDrinkEurope
<p><b>Pesticide residue:</b> Pesticide Residue means any specified substance in food, agricultural commodities, or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities considered to be of toxicological or ecotoxicological significance. The term "pesticide residue" includes residues from unknown or unavoidable sources (e.g. environmental contamination) as well as known, authorized uses of the chemical.</p> <p>The comment above on biocidal products also applies by analogy to the term "pesticide residue". Here the term is defined even more broadly: "The term "pesticide residue" includes residues from unknown or unavoidable sources (e.g.) environmental contamination) as well as known, authorised uses as chemical".</p> <p>Even though this may be the approach to also take into account such sources of input, it should also be taken into account when defining CXLs.</p> <p>Other sources of input such as "environmental contamination" must not simply be referred to as "pesticide residue" if they had nothing to do with a "pesticide use".</p> <p>This would mean that the definition of "pesticide residue" and the description of the process of which input sources are to be considered in the CXLs would have to be separated from each other.</p> <p><u>Conclusion:</u></p> <p>The three terms "pest", "pesticide" and "pesticide residue" would have to be limited to pesticide residues from Plant Protection Product - or at least in the sense of the work of the CCPR, the other areas of regulations- especially in the definitions -these would have to be explicitly excluded.</p>	FoodDrinkEurope