CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 9 **CX/PR 22/53/11-Add.1**

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDES

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GUIDELINES FOR COMPOUNDS OF LOW PUBLIC HEALTH CONCERN THAT MAY BE EXEMPTED FROM THE ESTABLISHMENT OF CODEX MRLS OR DO NOT GIVE RISE TO RESIDUES (AT STEP 7)

Comments in reply to CL 2022/37-PR

Comments of Canada, Chile, Egypt, European Union (EU), Ghana, Kenya, Philippines, United Kingdom, Uruguay, United States of America (USA)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2022/37-PR[1] issued in May 2022. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached in the **Annex** and are presented in table format.

[1] Codex circular letter, including CL 2022/37-PR, are available on the Codex webpage/Circular Letters:
http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/
or on the dedicated Codex webpage/CCCF/Circular Letters:
https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCPR

Annex

GENERAL COMMENTS

COMMENT	MEMBER / OBSERVER
• Canada congratulates the EWG for the progress made in the development of the guidelines and is supportive of this work since products of low public health concern play a critical role in plant protection. • The proposed guidelines for consideration by CCPR53 provide the opportunity for global harmonization of definitions and criteria for qualifying compounds that are of low public health concern. • Canada agrees that the guidelines should advance to Step 8 for final adoption.	**Canada**
La delegación de Chile agradece el trabajo realizado por el GTE, y considera que el CCPR en su 53ª Reunión debería recomendar la aprobación de las Directrices en el trámite 8 por la Comisión del Codex Alimentarius en su 45º periodo de sesiones.	**Chile**
Egypt appreciates the work done in the document and agrees on it	**Egypt**
The European Union (EU) would like to thank the Electronic Working Group (eWG) chaired by Chile and co-chaired by India and the United States of America for the preparation of the guidelines. a) General Comments: The EU acknowledges that the document provides a good basis for further discussions at the forthcoming CCPR meeting. The EU notes that these guidelines are intended for countries' competent authorities that do not have established criteria for the MRLs exemption for active substances. This explicitly excludes the establishment of a Codex list of respective active substances. b) Specific comments: Paragraph 6 and paragraph 33, 34, 35 The EU notes that the scope of the guidelines includes, besides active substances of low health concern also certain authorised uses of active substances of low public health concern, since in some cases the exemptions apply to the authorised uses and not to the active substance. In order to provide best guidance "to be used by the countries competent authorities that do not have established criteria for the MRLs exemption for active substances or its authorised uses in their respective legislation" (paragraph 12), it would be useful to provide more details or some examples for such cases. c) Guidance on whether the Guidelines is ready for final adoption at Step 8 by CAC45 (2022) The EU supports the adoption of the guidelines.	**EU**
Position: Ghana commends and also supports the recommendation by the EWG for CCPR to agree with the revised proposal, to consider the establishment of a EWG to refine the work for consideration by CCPR54 (2023). Rationale: There are national data base for registered pesticides, therefore we can get monitoring data of the pesticides.	**Ghana**

COMMENT	MEMBER / OBSERVER
Comment: Kenya congratulates the EWG led by Chile and co-chaired by India and USA on the development of the guidelines. These guidelines support the recognition and use of these compounds in agricultural production systems to facilitate trade. The content of this document is appropriate for use. Kenya supports its adoption and advancement at step 8. Kenya wishes to propose provision for inclusion of more examples in the appendix II which should be maintained in the Codex website.	**Kenya**
The Philippines generally agrees with the overall content of the 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 MRL or do not give rise to residues. The country has not identified key issues that need further consideration and agrees on its readiness for final adoption.	**Philippines**
The UK would like to thank the Electronic Working Group (eWG) chaired by Chile and co-chaired by India and the United States of America for the preparation of the guideline. The UK supports the final adoption by the CAC 45.	**United Kingdom**
Uruguay agradece el trabajo realizado a través del Grupo de Trabajo electrónico presidido por Chile, y copresidido por Estados Unidos de América e India. Se apoya al avance de trámite de la "Directriz para el reconocimiento de sustancias activas o usos autorizados de sustancias activas de baja preocupación para la salud pública que se consideran exentas del establecimiento de límites máximos de residuos o no generan residuos".	**Uruguay**
The United States appreciates the efforts of the Electronic Working Group (EWG) in advancing further CCPR deliberation on the management of unsupported compounds without public health concerns. The United States has the following General Comments in response to CL 2022/37-PR. The United States served as co-chair on the discussion paper and supports this work since products of low public health concern, such as biopesticides, continue to play an increasingly important role in plant protection. There is a concern that if they are not being viewed as "safe" or included as part of Codex standards, then growers may be reluctant to incorporate these important tools into their farming practices. The EWG has made important progress in developing guideline s for compounds of low public health concern. The proposed guidelines for consideration by CCPR53 provide a foundation for international harmonization and help outline a clear set of definitions and criteria for compounds that are of low public health concern. As such, the United States believes the guidelines should advance to Step 8 for final adoption. The United States also has Specific Comments in the form of minor editorial edits and suggested clarifications in track changes provided directly in the document.	**USA**

PREFACE

COMMENT	MEMBER / OBSERVER
Position: Ghana does not support the removal of "CODEX" from the title of the document Rationale: Since it is a Codex document, Codex should be part of it for the title to read "The establishment of Codex 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 MRLs or do not give rise to residues" We also wish that the Codex Secretariat clarifies the issue concerning the removal of "CODEX" from the document. We commend the committee for a good work done by the EWG	**Ghana**
For the purpose of these Guidelines, p~~Among pesticides~~ esticides of biological origin, ~~a.k.a.~~ also known as biopesticides, ~~for the purpose of this Guidance Document, make reference to~~ include active substances based on microorganisms ~~(Microbial~~ (microbial pesticides), compounds made from plants like plant extracts ~~(Botanical~~ (botanical pesticides), pheromones ~~(Semiochemicals)~~ (semiochemicals) and substances of animal origin. ~~Therefore, substances~~ Substances referred to as biofertilizers, bioregulators or biostimulants as well as invertebrates such as insects and nematodes or other macroorganisms are not covered by this guidance document.	**USA**
Sometimes authorized uses of ~~the~~ pesticides on food crops result in residues. The Codex Alimentarius Commission (CAC) has set Maximum Residue Limits (MRLs) for pesticides on specific foodstuffs or food groups traded internationally to protect the health of consumers based on the recommendations of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). Some countries establish their own MRLs as a result of the evaluations carried out by national or regional agencies on risk assessment.	**USA**
Codex MRLs (CXLs) have been adopted based on the recommendations of the JMPR evaluations and in accordance with Good Agricultural Practices (GAP) data. Food resulting from commodities that comply with the MRLs will be toxicologically acceptable (are considered to be safe for consumers). These Guidelines establish criteria for the exemption of substances, or specific authorized uses of substances, from the establishment of MRLs when the establishment of MRLs is not necessary to protect consumer health. The question of whether an active substance or a specific authorised use of an active substance fulfills one or more criteria with the aim to exempt the substance or a specific authorized use of an active substance from the setting of maximum residue limits is the result of an evaluation of toxicology and residue behavior.	**USA**
When authorized uses of pesticides do not produce residues or result in residues that are identical and indistinguishable from certain natural components of the food commodities either considered to be of low or no toxicological significance, some regulations explicitly grant an exemption from the requirement to establish an MRL or state that an MRL is not required for the respective active substance or its authorized uses. However, there are no harmonized or internationally recognized criteria for MRL exemptions.	**USA**

SECTION 1. SCOPE

COMMENT	MEMBER / OBSERVER
Estas directrices tienen como objetivo hacer uso de los diferentes criterios utilizados por algunos países y organizaciones internacionales para decidir que no es necesario establecer LMR para una sustancia activa o un uso específico autorizado de una sustancias activa, porque una evaluación de riesgos ~~conluye~~ concluye que son de bajo riesgo y baja preocupación en materia de salud pública. Error en la palabra	**Uruguay**
These criteria are presented in an attempt to provide a consistent and harmonized approach for determining when an active substance or its authorized uses could be considered exempt from the need for establishment of MRLs.	**USA**
These guidelines are intended to be used by ~~the countries'~~ competent authorities in countries that do not have established criteria for ~~the MRLs exemption~~ MRL exemptions for active substances or ~~its~~ specific authorized uses of active substances in their respective legislation.	**USA**

SECTION 2. DEFINITIONS

COMMENT	MEMBER / OBSERVER
Active substances of low ~~Public Health~~ public health concern: Active substances and their relevant metabolites considered of low or no toxicity ~~to human and animal health~~ based on risk assessments Delete "to human and animal health" or limit to "consumer health risk in food" to stay within the Codex mandate	**USA**
Authorized use: Authorized use refers to the safe use of a pesticide based upon a use pattern determined at national level. It includes domestically approved, registered or recommended uses, which generally take into account public and occupational health and environmental safety considerations.	**USA**
Biological pesticide (Biopesticide): A pesticide containing active substances made from living or dead microorganisms such as bacteria, algae, protozoa, viruses and fungi (See ~~Microbial pesticides)~~microbial pesticides definition), pheromones and other semiochemicals (See ~~Semiochemicals pesticides)~~semiochemicals definition), and plants or parts of plants (See botanical ~~pesticides)~~pesticides definition), designed to repel, destroy or control any pest or regulate the growth of plants (For example *Bacillus amyloliquefaciens* strain FZB24, Trichoderma atroviride (formerly T. harzianum) strains IMI 206040 and T11).	**USA**
Environmental exposure: Levels of ~~substances and~~ substances, including levels arising from past human activities ~~present in the environment~~ (e.g. ~~.~~ ., agriculture), present in the environment in situations relevant for the respective environmental compartment.	**USA**
Food Group/Crop Group: A collection of foods/crops subject to MRLs that have similar characteristics and similar potential for residue for which a common group MRL can be set. Representative commodities can be used to establish MRLs on an entire crop group or subgroup. The ~~Codex classification~~ Classification of ~~food~~ Food and ~~animal feed commodities describe~~ Feed (CXM 4/1989) describes the various food groups moving in trade and lists commodities included in each group.	**USA**
Joint FAO/WHO ~~meeting~~ Meeting on ~~pesticide residues~~ Pesticide Residues (JMPR): The ~~"Joint~~ Joint Meeting on Pesticide ~~Residues"~~ Residues (JMPR) is an expert *ad hoc* body administered jointly by the Food and Agriculture Organisation and World Health Organisation. The JMPR has met annually since 1963 to conduct scientific evaluations of pesticide residues in food. It provides advice on the acceptable levels of pesticide residues in internationally traded food. The JMPR consists of experts who attend as independent internationally recognized specialists acting in a personal capacity and not as representatives of national governments.	**USA**
Maximum ~~residue limit~~ Residue Limit (MRL): A Maximum Residue Limit (MRL) is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. MRLs are based on good agricultural practice (GAP) data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.	**USA**
Pesticide residue: 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. Should be consistent with the Codex Procedural Manual.	**USA**

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 MAXIMUM RESIDUE LIMITS

COMMENT	MEMBER / OBSERVER
Paragraph 6 and paragraph 33, 34, 35 The EU notes that the scope of the guidelines includes, besides active substances of low health concern also certain authorised uses of active substances of low public health concern, since in some cases the exemptions apply to the authorised uses and not to the active substance. In order to provide best guidance "to be used by the countries competent authorities that do not have established criteria for the MRLs exemption for active substances or its authorised uses in their respective legislation" (paragraph 12), it would be useful to provide more details or some examples for such cases.	**EU**
Este criterio también se refiere a las sustancias activas microbianas que potencialmente pueden producir toxinas/metabolitos. Dichos microorganismos solo deben considerarse exentos del establecimiento de LMR si se puede demostrar que dichas toxinas/metabolitos no están presentes en las partes comestibles de los cultivos ~~tratados,~~ tratados en ~~niveles sobre el cultivo tratado o en él~~ concentraciones que excedan los niveles ambientales relevantes y puedan potencialmente causar daño a la salud humana y animal. Se sugiere un cambio de redacción en la página 9, párrafo 44 a fin de mejorar el entendimiento del criterio 4.	**Uruguay**
To grant the exemption from the establishment of MRLs to an active substance or a specific authorized use, the active substances or the specific use ~~must~~ should meet the requirements of at least one of the following criteria. "Should" is more appropriate than "must" in a guidance document. This comment applies throughout this section, which seems to use "should" and "must" or other formulations interchangeably, so maybe it is an issue only in the English translation.	**USA**
Special consideration ~~must~~ should be ~~taken for~~ given in those situations where the MRL exemption is linked to a certain pesticide GAP use.	**USA**
It can be GAP dependent whether or not residues are expected; ~~in case~~ if residues are expected or will occur according to GAP expected/measured residue ~~levels have to~~ levels should be assessed in comparison with possible environmentally relevant exposure levels.	**USA**
Therefore, every time a new use is requested, ~~this~~ the new use should be assessed with regard to its exemption from MRLs (whether or not the active substance has already been exempted from MRL ~~setting)~~setting for other uses).	**USA**
According to the criteria ~~proposed~~ below, active substances or specific authorized uses for which a risk assessment process concludes that there are not immediate or delayed harmful effects on human or animal health, directly or through drinking water , foods, or through aggregate effects, may be exempted from the need to establish MRLs.	**USA**
Active substances and their relevant metabolites for which, according to risk assessments, it has been considered that it is not necessary to establish health based guidance values (ADI/ARfD). ~~It should be excluding cases that there are~~ This excludes active substances that do not have ADI/ARfD established because they are genotoxic substances or due to lack of data to define these values.	**USA**

COMMENT	MEMBER / OBSERVER
Criterion 2. Active substances for which it is not possible to differentiate between the exposure associated with ~~its~~ use as pesticide with ~~its environmental~~ environmentally relevant exposure levels or ~~its~~ other uses in the food chain	**USA**
Active substances which, by themselves, are food components or have low-toxicity ~~of~~ and present no human or animal health concern.	**USA**
Active substances for which environmental exposure associated with the food substance cannot be differentiated from the one linked to the use as a pesticide ~~(Botanical~~ (botanical pesticides, natural chemical substances)	**USA**
Measurable environmental levels should be assessed carefully and taken into consideration when deciding on the use of this criterion For instance, ~~where~~ when the exposure through residues from pesticides use does not add significantly to the exposure from environmentally relevant levels or other authorised uses, exemptions from establishing MRLs may be granted. Case by case considerations are needed taking into account the specificities of each substance and the exposure levels.	**USA**
This criterion includes substances such as pheromones and other semiochemicals dispersed through dispensers for mating disruption purposes where the consumer's exposure from the application ~~level~~ is similar to the environmental exposure level ~~of~~ to the substance.	**USA**
Criterion 4. Microorganisms that are not of human ~~or animal~~ health concern	**USA**
This criterion also concerns microbial active substances that may potentially produce toxins/metabolites. Such microorganisms should only be considered exempted from the establishment of ~~MRL~~ MRLs if it can be ~~proven~~ demonstrated that such toxins/metabolites are not present on edible parts of the treated crops, or are not present at levels on or in the treated crop that will either exceed ~~environmental~~ environmentally relevant levels and potentially cause harm to human and animal health.	**USA**
Microorganisms that are primary human or animal pathogens (excluding target species) ~~could~~ should not be considered exempted from the establishment of MRL. For microorganisms that are taxonomically close relatives to such ~~pathogen~~ pathogenic microorganisms, a MRL exemption would be possible only if evidence is provided ~~to prove~~ that they do not negatively affect human ~~or animal~~ health. We wonder if "target species" should be defined earlier in the Guidelines.	**USA**