

European Union comments

CODEX COMMITTEE ON PESTICIDE RESIDUES

Codex Circular Letter CL 2021/38-PR:

“Proposed 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”

European Union Competence

European Union Vote

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 guideline.

General Comments:

The EU acknowledges that the document provides a good basis for further discussions at the forthcoming CCPR meeting.

Specific comments:

SECTION 2. DEFINITIONS

Paragraph 18 Biological pesticide: “Active substance made from...”

Paragraph 19 Botanical pesticide: “Active substance that consists of...”

Paragraph 25 Microbial pesticide: “Active substance used for...”

The EU proposes that these definitions are revised as proposed below:

“Biological pesticide (Biopesticide): A pesticide containing active substances made from living or dead microorganisms such as bacteria...”

“Botanical pesticide: A pesticide containing active substances that consist of one or more components found in plants and obtained by subjecting plants...”

“Microbial pesticide: A pesticide containing active substances used for the control or management of pests such as invertebrates...”

SECTION 3. CRITERIA FOR THE RECOGNITION OF COMPOUNDS OF LOW PUBLIC HEALTH CONCERN THAT ARE CONSIDERED EXEMPTED FROM THE ESTABLISHMENT OF CODEX MAXIMUM RESIDUE LIMITS (CXLs)

Criterion 2

The EU suggests specifying the title of Criterion 2 as follows:

'Active substances for which it is not possible to differentiate between the exposure associated with its use as pesticide, with its natural background exposure levels, or its other uses in the food chain'.

Paragraphs 39-42

The EU notes that residues from the use of pesticides may not be distinguishable from residues of natural components or from other authorised uses of the substance in the food chain. In such cases, exemptions from establishing CXLs may be granted if the exposure resulting from pesticides use is not adding significantly to the exposure from natural background levels or other authorized uses. Case by case considerations are needed taking into account the specificities of each substance and the exposure levels.

The EU suggests considering the following addition to paragraph 42:

'Measurable background levels should be assessed carefully and taken into consideration when deciding on the use of this criterion. For instance, where the exposure through residues from pesticides use does not add significantly to the exposure from natural background levels or other authorised uses, exemptions from establishing CXLs may be granted. Case by case considerations are needed taking into account the specificities of each substance and the exposure levels.'

Criterion 4

The EU suggests reversing the order of paragraphs 44 and 45.

The EU notes that the text of Criterion 4 and paragraphs 44 and 45 refers to “mammalian toxins” and “human health concern”. Those terms used together do not make sufficiently clear to what taxonomic level (“mammalians” or “humans”) the concern for toxins refers. Therefore, in order to align the terms used in the text, the EU proposes to use the term “human and animal health concern” consistently in the text.

The EU proposes the following title for Criterion 4: “*Criterion 4. Microorganisms that are not of human or animal health concern*”

Under this title the order of paragraphs 44 and 45 should be reversed. The scope of both paragraphs should be clarified. It is proposed in paragraph 44 to deal with microorganisms that are either primary human or animal pathogens or are taxonomically close relatives to such microorganisms.

Paragraph 45 should then deal with microorganisms that produce toxins.

Paragraph 44

The EU proposes to re-phrase the paragraph as follows:

'This criterion also concerns ~~includes~~ microbial active substances that may potentially produce toxins/metabolites. ~~For microorganisms that are closely related to known toxigenic human pathogens, it~~

~~must be demonstrated that toxins/metabolites toxic to humans, animals are not likely to be produced by the microorganism, and should they be present in the products, Such microorganisms should only be included into the Annex, if it can be proven that such these toxins/metabolites should are not be present on edible parts of the treated crops, following application, at levels on or in the treated crop that will either exceed natural background levels or and potentially cause harm to human and animal public health.' Attention should be given to any mammalian toxins or other potentially toxic secondary metabolites of human health concern produced by microorganisms.~~

Paragraph 45

The EU agrees that microorganisms that are either primary human or animal pathogens or are taxonomically close relatives to such microorganisms should never be included in the Annex. For taxonomically close relatives to microorganisms that are primary human or animal pathogens, more information would need to be provided by the applicant to decide about their inclusion or non-inclusion in the Annex.

The EU has the following proposal for re-wording:

~~This 'eCriterion 4 excludes microorganisms from the inclusion in the Annex that are either primary mammalian human or animal pathogens or. For microorganisms that are taxonomically close relatives to such pathogen microorganisms, Annex 1 inclusion is possible only if evidence is provided to prove that they do not negatively affect human or animal health'. microbes that are primary mammalian pathogens.~~

ANNEX

Criterion 4

The EU is pleased to see the long list of examples in the Annex.

The EU suggests putting the examples of microorganisms in alphabetical order.