

European Union comments

CODEX COMMITTEE ON PESTICIDE RESIDUES

Codex Circular Letter CL 2020/14-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.

The EU would like to submit the following comments:

TITLE

The EU notes that the title and the background in paragraph 1 implicitly seem to suggest that “*compounds that do not give rise to residues*” could be exempted from the establishment of CLXs. However, the EU believes that a compound does not give rise to residues should always be accompanied with insignificant toxicological characteristics, before CXL exemption can be granted.

PREFACE

Paragraph 4

The EU notes that the Guidance Document does not cover substances referred to as biofertilizers or bioregulators as well as invertebrates such as insects and nematodes or other macroorganisms.

In the European Union, Regulation (EU) 2019/1009 on the making available on the market of EU fertilising products¹ has defined a new category called plant biostimulants, which aim solely at improving the plants’ nutrient use efficiency, tolerance to abiotic stress, quality traits or increasing the availability of confined nutrients in the soil or rhizosphere. They are by nature more similar to fertilising products than to most categories of plant protection products.

The EU suggests for the reasons of clarity to exclude biostimulants from the Guidance Document and proposes the following: “*Therefore, substances referred to as biofertilizers, ~~or~~ bioregulators or biostimulants as well as invertebrates such as insects and nematodes or other macroorganisms are not covered by this Guidance Document.*”

Paragraph 7

The paragraph states that “*When authorized uses of pesticides do not produce residues or are identical and indistinguishable from certain natural components of the foods 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*

¹ Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1–114)

substance. However, there are no harmonized or internationally recognized criteria for MRL exemptions; further, there is not a harmonized list of substances for which exemptions have been deemed appropriate.” The EU notes that, though residues may not be distinguishable from natural components, they may prove to have hazardous properties. If the added residue levels through use of pesticides are comparable with natural backgrounds, exemption of MRLs may be granted. But if the added residue is significantly higher this might need broader consideration. This is addressed in paragraph 34.

SECTION 2. DEFINITIONS

Paragraph 13 Acceptable daily intake (ADI)

The EU notes that the definition of ADI is slightly different from the definition in the Report of the 1975 Joint FAO/WHO Meeting on Pesticide Residues, FAO Plant Production and Protection Series No.1 or WHO Technical Report Series No. 592.

The EU suggests to align the definition and clarify that although the ADI represents an estimate over a life-time exposure, it is expressed on a daily intake basis (mg/kg bw/day).

Paragraph 15 Active substance

Sometimes the active has to be metabolized to produce the pesticide action. The EU is not sure whether the wording “provides” sufficiently cover that situation as well. Therefore, the EU proposes to change into “*The component of the product that directly or indirectly (after metabolism) provides the pesticide action.*”

Paragraph 17, 18 and 19

For a better understanding of these definitions, the EU suggests to add one or two examples for each definition, as is done for paragraph 20 Food Group/Crop Group.

Paragraph 23 Maximum Residue Limit (MRL)

The EU acknowledges that the definition of Maximum Residue Limit is reproduced as provided in the Procedural Manual. However, toxicological acceptance includes comparison of both long-term and short-term exposure to the ADI and ARfD, respectively.

Therefore, the EU suggests to add the reference to the ARfD: “*Consideration of the various dietary residue estimates and determinations both at the national and international level in comparison with the ADI and the ARfD, should indicate that foods complying with Codex MRLs are safe for human consumption*”.

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)

The EU proposes to clarify the relation between the different criteria in the guideline, as it is not clear how do these 4 different criteria relate to each other i.e. should some/all criteria be fulfilled for an active substance?

Criterion 2

The EU considers that the criterion 2 could also specify that naturally occurring exposure levels of substances are taken into account.

Therefore, the EU suggests the following heading for criterion 2: “*Substances for which it is not possible to differentiate between the exposure associated with its use as pesticide and its other uses in the food chain or its naturally occurring exposure levels*”.

Criterion 4

Paragraph 37

The EU agrees that in the criterion 4 mentioned mammalian toxins or other potentially toxic secondary metabolites of human health concern should be taken into account. However, the paragraph 37 is not particularly clear. Therefore, the EU proposes the following:

“This approach could include microbial pesticides, excluding microorganisms that are either primary mammalian pathogens or are taxonomically close relatives to microbes that are primary mammalian pathogens. For microorganisms that are closely related to known toxigenic human pathogens, it must be demonstrated that toxins/metabolites of concern are not likely to be produced by the microorganisms, so as they are absent in final pesticide products and should there be present in the products, these toxins/metabolites should not be present on edible parts of the treated crops ~~are not likely to be produced by the microorganism, following application, at levels on or in the treated crop that will either exceed natural background levels or potentially cause harm to public health.~~

Attention should be given to any mammalian toxins or other potentially toxic secondary metabolites of human health concern produced by microorganisms.”

The EU proposes to add a consideration whether or not MRL exemption is exclusively linked to a certain pesticide GAP use. It can be GAP dependent whether or not residues are expected; or it can be GAP dependent what residue levels are expected, and what these levels are in comparison with possible background exposure. Therefore, every time a new use is requested, this 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).

Annex, page 9

The EU notes that the list of examples which is not exhaustive is presented to support better understanding of the provisions in the document.

The EU recognizes that a full harmonized list of all substances that would fall under one of these 4 criteria is not possible at the moment. Development of such a list in future would, however, be appreciated.

The EU suggests to delete azadirachtin and pyrethrins from the list of examples for criterion 2 as, according to agricultural practices, criterion 2 may not be fulfilled.

The EU also suggests to delete *Bacillus thuringiensis* from the list for criterion 4 as concerns about the potential contribution of *Bacillus thuringiensis* based pesticides to foodborne outbreaks is not yet ruled out. It might be that, in the future, some of the strains of *Bacillus thuringiensis* may need a MRL.