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European Union Comments
CODEX COMMITTEE ON PESTICIDE RESIDUES
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AGENDA ITEM 11

Discussion paper on the development of guidance for compounds of low public health concerns that could be exempted from the establishment of CXLs

CX/PR 19/51/16

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 discussion paper.

The EU welcomes the development of such guidelines in the light of the growing importance of low risk pesticides. In the EU a specific Annex with substances that do not require MRLs has been established and is constantly updated.

The EU would like to submit the following more detailed comments:

Diversification of national legislations (§16, page 2):

In the description of the EU rules (Annex IV of Regulation (EC) No 396/2005) reference should also be made to the related EU guidance document (SANCO/11188/2013¹) that goes into further detail on the criteria to be used when including substances in Annex IV.

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Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) N° 396/2005, available at:
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_sanco-2013-11188.pdf

Appendix II, Annex I Compounds of low public health concern considered exempt from the establishment of maximum residue limits (MRLs) and paragraph 13, p. 8

In paragraph 13, p. 8 in the description of the criteria for inclusion in Annex 1 it should be clearly stated that substances covered by the specific criteria are not necessarily safe just by the fact that they are falling under one of the criteria. They must have been assessed to be safe taking into account a given use. For some substances, a detailed description of the rationale to include it into Annex 1 may be needed alongside its inclusion.

Appendix II, Annex II Definitions (page 11):

For future discussions on the proposed guidelines in the first step, clarifications on the definitions in Annex II are needed. On the basis of these clarifications it will be easier to discuss the different criteria. More input is necessary to allocate substances to the right category with the aim to clearly assign candidates for the list in Annex I.

The EU suggests that all definitions are carefully reviewed. Here below just a few examples (to be considered non-exhaustive) for which the EU considers further clarifications most relevant:

- The definition of “biological pesticides” is questionable. This definition includes semiochemicals which themselves include synthetic analogues that cannot be considered as “biological”. Furthermore, in the draft guideline itself the term “pesticide of biological origin” is used.
- The category of "semiochemicals" includes synthetic analogues that are very different from naturally occurring substances. A common understanding is needed whether synthetic analogues are belonging to "semiochemicals" or to the group of substances produced by chemical synthesis.
- In case of "microbial pesticides" the differentiation between biological pesticides and biochemical pesticides is not very clear.
- The definition of "basic substances" would also profit from further clarifications.

Appendix II, Criteria 4: Substances of low public health concern for which there is a long history of equivalent level of exposure (similar to the level of exposure that would be incurred by the proposed use of the pesticide) to humans, e.g. 50 years or longer.

This criteria is too broad and opens the possibility for exemptions of broad and heterogeneous range of chemicals that may have critical health effects. The criteria should be defined more precisely or be deleted.

It covers, among others, products used as cosmetics which are covered by others legislation in Europe.