

CODEX ALIMENTARIUS COMMISSION



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DISCUSSION PAPER ON THE DEVELOPMENT OF GUIDANCE FOR COMPOUNDS OF LOW PUBLIC HEALTH CONCERNS THAT COULD BE EXEMPTED FROM THE ESTABLISHMENT OF CXLS

Comments submitted by Australia, European Union and Kenya

Australia

Introduction

1. This CRD is intended to correct a misunderstanding concerning Australia's regulatory system for biopesticides.

Comment

2. In discussion paper CX/PR 19/51/16, paragraphs 20 – 26 discuss the Australian Food Standards Australia and New Zealand (FSANZ) process for managing low levels of Agricultural chemicals without MRLs, known as P1027.
3. The purpose of P1027 is to consider an 'all other foods except animal food commodity' MRLs to cover the potential for low levels of unintended and inadvertent residues for pesticides in which MRLs are currently established in Schedule 20 of the Australian Food Standards Code. The pesticides considered all have MRLs established for directly treated plant commodities and have Health Based Guideline Values established. A dietary exposure estimate is undertaken as part of the consideration of an appropriate level for the MRL.
4. Australia suggests that the discussion on P1027 is out of context for this discussion paper on compounds of low public health concern, which aims to address the direct use of compounds on crops which should not produce residues of toxicological significance.
5. Australia notes that the Australian Pesticides and Veterinary Medicines Authority (APVMA) can set Table 5 entries in the APVMA MRL Standard. Table 5 lists uses of substances where MRLs are not necessary. MRLs are not necessary in situations where residues do not or should not occur in foods or animal feeds (and an MRL is not required for control of use purposes); or where the residues are identical to or indistinguishable from natural food components; or otherwise are of no toxicological significance. The APVMA considers the inclusion of proposed use patterns of active constituents including biologicals in the Table 5 list on a case by case basis.

European Union

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.

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.

Kenya

Comment: Kenya appreciates the EWG for this project paper and supports the recommendations to; Forward for approval this item as new work by CAC42 (2019) and to establish an EWG to prepare guidelines for compounds of low public health concerns that could be exempted from the establishment of CXLs

¹ 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