

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Items 8, 13

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ORIGINAL LANGUAGE ONLY

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON PESTICIDE RESIDUES

52<sup>nd</sup> Session

(Virtual)

26-30 July and 3 August 2021

Comments submitted by Japan

#### Agenda Item 8

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Japan appreciates the work of EWG chaired by Chile and co-chaired by USA. Japan would like to comment on CX/PR 21/52/12.

#### SPECIFIC COMMENTS

Para. 1

Japan proposes to delete this paragraph because the proposed definition is different from that in the Procedural Manual. It should also be noted that pesticides are defined differently among countries.

Para. 7

Even if residues are not detectable (e.g. less than LOQ in supervised trials), Codex establishes MRLs based on the recommendation by JMPR. The current procedure covers such cases properly and therefore there is no need inclusion in the GL. Japan therefore proposes that the first sentence should read:

When authorized uses of pesticides result in residues that do not produce residues or are identical and...

Paras 13 and 14

ADI and ARfD are terms used in risk assessment and defined by JMPR. To avoid confusion, the same definition should be used in CCPR rather than re-define the term in this document.

Paras 23 and 24

We do not see the necessity to define JMPR and MRL in this document as they have already defined in other documents.

Paras 29 and 30

"Pesticide" and "pesticide residues" have already been defined in Procedural Manual. To avoid confusion and inconsistency when the definitions in Procedural Manual are revised, this document should not include definitions for these terms.

Paras 37 and 38

We agree to the sentences. However, it is difficult to judge if a substance meets the criteria without risk assessment and further instruction should be elaborated.

Para. 39

To avoid the possibility that the term "Low-toxicity of no public health concern" would be interpreted in various ways, it should be defined.

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**Agenda Item 13**

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Japan appreciates the work of EWG chaired by Chile and co-chaired by Australia, India and Kenya. Japan would like to comment on CX/PR 20/52/17 rev.1 for further discussion.

GENERAL COMMENTS

Japan reiterates that procedure to periodically re-evaluate safety of pesticides should be in place in order to protect consumers' health. Toxicological reviews long years ago (e.g. 25 years) become outdated and needed reassessment in view of current science and knowledge. Even if no report on health concern is available, it does not mean that they are still safe.

SPECIFIC COMMENTS

Para. 4

With regard to transferring data to other parties, it should be noted that data package and dossier are intellectual properties of the company which conducted the study. It is generic manufacturers and/or members that are responsible to obtain necessary data from their owner. Codex is not at the position to order the owner to transfer data to other parties. It should be noted that the data in JMPR monograph, which contains most of the data provided from the data owner, should not be used for re-evaluation because it clearly states that "a registration authority should not grant a registration on the basis of an evaluation unless it has first received authorization for such use from the owner of the data submitted for the JMPR review".

Para. 10

With regard to the identification of missing data by FAO/WHO, periodic re-evaluation is based on data provided by sponsors. If there is no sponsor, no data for thorough risk assessment is available. It should be noted that data provided to previous JMPR evaluation are no longer available to current JMPR because of data ownership.

Para. 12

It may be possible for governments to provide evaluation, but the data themselves are owned by sponsors. Without permission of sponsors, data cannot be submitted to Codex/JMPR/FAO/WHO.

Para. 21

No report about public health concerns does not mean the pesticide is safe. It is necessary that pesticides should periodically be re-evaluated to ensure they are still safe based on updated science.

Paras 22 and 23

Even if an active substance is registered in several countries, it is not clear if its formulation type and/or usage (application method, dose, timing, number of applications etc.) is the same. It should be noted that CXL is based on GAP. If GAP used under the current situation is different from that are used for previous JMPR evaluation, the CXL should be considered to be no longer valid.

Para. 25

JMPR does not take "what has been changed" approach. In re-evaluation process, JMPR thoroughly looks at all data provided and evaluates pesticides as if it is newly nominated.

Considering the period for studies, the longest, chronic toxicology, generally requires 2 years. Japan is of the view that 4 years, in line with current "4-year rule", is enough. To ensure safety of pesticides, deferring 10 years is too long.