

CODEX ALIMENTARIUS COMMISSION



**Food and Agriculture
Organization of
the United Nations**



**World Health
Organization**

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Agenda Items 8(a/b)

CX/PR 11/43/07-Add. 1

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

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DRAFT PRINCIPLES AND GUIDANCE FOR THE SELECTION OF REPRESENTATIVE COMMODITIES
FOR THE EXPOLATION OF MAXIMUM RESIDUE LIMITS FOR PESTICIDES FOR COMMODITY GROUPS

(At Step 6)

and

PROPOSED DRAFT ADDENDA TO THE DRAFT PRINCIPLES AND GUIDANCE
FOR THE SELECTION OF REPRESENTATIVE COMMODITIES
FOR THE EXPOLATION OF MAXIMUM RESIDUE LIMITS FOR PESTICIDES FOR COMMODITY GROUPS

(At Step 3)

COMMENTS at Steps 6 and 3 submitted by Canada, Cuba and Japan

CANADA

Canada has no objection to the proposed principles and guidance for the selection of representative commodities for the extrapolation of maximum residue limits. However, Canada notes that for a number of groups (and subgroups), the Codex revisions are different from those of the International Crop Grouping Consulting Committee (ICGCC). For example, the ICGCC has divided the Citrus Fruits Crop Group into 3 Subgroups:

- a. Orange (with orange or tangerine as the representative commodity),
- b. Lemon/Lime (with lemon or lime as the representative commodity), and
- c. Grapefruit (with grapefruit as the representative commodity).

In contrast, the Codex classification for the Citrus Fruits Crop Group proposes 4 Subgroups:

- i. Lemons and Limes (with lemon or lime as the representative commodity),
- ii. Mandarin (with mandarin as the representative commodity),
- iii. Oranges, Sweet, Sour (with orange as the representative commodity), and
- iv. Pummelos (with pummelo or grapefruit as the representative commodity).

In order to facilitate future use of the crop groupings, Canada recommends that Codex and the ICGCC work closely together to ensure revisions are done consistently.

CUBA

English

Cuba approves this document.

Spanish

En principio Cuba está de acuerdo con lo expresado en este documento.

JAPAN

We appreciate the efforts of the United States of America and the Netherlands in leading the electronic working group for preparing the Draft Principles and Guidance for the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides for Commodity Groups (CX/PR 11/43/7 and CX/PR 11/43/8). We would like to provide our comments as follows:

General Comments

1. Japan thinks it will take some time to reach an agreement on Table 1 for the following reasons:
 - i. Unless the revisions of the Codex classification of all fruit groups are finished, the contents of Table 1 are subject to change.
 - ii. The committee needs to check Table 1 thoroughly in order for examples of representative commodities to be consistent with the general principles in this document.

Therefore, the CCPR should first agree on the principles and guidance except Table 1, and then discuss the selection of example representative commodities for commodity groups.

Structure of the “Principles and Guidance for the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides for Commodity Groups”

2. Addenda I and II (CX/PR 11/43/8) provide useful information to elaborate Table 1, however, they are not the principles and guidance. In this regard, Addenda I and II should be developed as supportive documents and should not be included in the finalized document (CX/PR 11/43/7).
3. In addition to the above proposal, to make the document (CX/PR 11/43/7) simpler and easier to understand, we would like to propose the following amendments in balloons and track-change.

DRAFT PRINCIPLES AND GUIDANCE ON THE SELECTION OF REPRESENTATIVE COMMODITIES FOR THE EXTRAPOLATION OF MRLS TO COMMODITY GROUPS

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INTRODUCTION

Residue extrapolation is the process by which the residue levels on representative commodities are utilized to estimate residue levels on related commodities in the same commodity group or subgroup for which trials have not been conducted. ~~Representative commodities are chosen based on their commercial importance and the similarity of their morphology and residue characteristics to other related commodities in the group or subgroup. Ideally representative commodities are the most economically important commodities in production and/or consumption in a group or subgroup and have a greater dietary burden and have residue characteristics similar to other members of the group or subgroup.~~ Residue extrapolation is a common consideration utilised by regulators internationally for ensuring that data requirements are only at a level that is scientifically justified in conducting risk assessment and to ensure the regulatory process does not become unnecessarily burdensome especially for minor crops.

OBJECTIVES

The objective of this document is to: (1) propose criteria for the selection of representative commodities; and (2) propose example representative commodities; ~~and (3) provide a detailed justification for the selection of the representative commodities (Addendum I).~~ Additional background information regarding the status of representative commodities is provided in Addendum II to this document.

GENERAL PRINCIPLES

Representative commodities within each Codex Classification commodity group and subgroup will be selected and proposed, based on consideration of all available information. The following principles will be used for the selection of representative commodities:

- A representative commodity is most likely to contain the highest residues;
- A representative commodity is likely to be major in terms of production and/or consumption; and;
- A representative commodity is most likely similar in morphology, growth habit, pest problems and edible portion to the related commodities within a group or subgroup.

The application of the three principles in the selection of representative commodities is based on the assumption that all of the commodities, covered by the commodity group MRL, are produced following the same use pattern or Good Agricultural Practice (GAP).

To facilitate the global use of the commodity groups for MRLs, alternative representative commodities may be selected giving flexibility for use of residue research conducted in different countries or regions that may vary due to regional differences in dietary consumption and/or areas of production for certain commodities.

Note: Table 1 in this document is provided to (1) separate the selection of representative commodities from the Codex Classification itself; (2) propose examples of representative commodities in parallel with the respective Codex commodity grouping classification revisions; (3) provide flexibility on the selection of representative crops and (4) provide guidance not only to CCPR and CCPR members, but also to JMPR, product manufacturers and other data generators.

~~Addendum I to this document provides detailed background information (Citrus Fruit, Pome Fruit, Stone Fruit, Berries and other small fruits and Tropical and subtropical fruits with edible and inedible peel) regarding production, consumption, MRLs and characteristics and justification for selection of the representative commodities according to the indicated principles. In all cases, it is assumed that all of the commodities covered by a commodity group MRL utilize the similar use pattern or GAP.~~

~~Addendum II to this document provides more detailed background information regarding residue extrapolations and history and use by JMPR.~~

GUIDANCE AND PROCEDURES

~~As proposals for the revision of the Codex Classification are made and revised commodity groupings are developed and provided to the CCPR for their review, proposals on representative commodities will also be provided in parallel with the respective commodity grouping revisions and will advance through the CCPR step process for adoption by the CAC.~~

~~As comments are addressed on the revisions of the classification and the proposed representative commodities and these are approved by the CCPR and accepted by the CAC, two separate documents will be created and maintained: (1) the revised Codex Classification (without mention of representative commodities) and (2) principles and guidance on the selection of representative commodities.~~

The JMPR may be advised to use the representative commodities adopted by the CAC. However, JMPR may use other representative commodities (including those which may be specifically requested by member nations) on a case-by-case basis. The JMPR will be requested to provide to the CCPR justification for the use of any alternative representative commodities, based on all available data.

Good Agricultural Practices (GAPs)

~~The application of the three principles in the selection of representative commodities is based on the assumption that all of the commodities, covered by the commodity group MRL, utilize the same use pattern or GAP.~~

Alternative Representative Commodities

~~To facilitate the global use of the commodity groups for MRLs, alternative representative commodities may be selected giving flexibility for use of residue research conducted in different countries or regions that may vary due to regional differences in dietary consumption and/or areas of production for certain commodities.~~ Table 1 in this document proposes examples of representative commodities for commodity groups. Depending on country or regional differences, alternative representative commodities may be proposed by a country. For example, leeks may be proposed as an alternative representative commodity for green onions in the green onion subgroup of Bulb Vegetables.

Precedence in Selection of Representative Commodities

In situations where a representative commodity does not meet all three of the above principles, a representative commodity should at least meet the first two principles (likely to contain the highest residues and also major in terms of production and/or consumption).

Definition of Similar Residues

When representative commodities are utilized to extrapolate to other members of a commodity group, it is based on the assumption that the representative commodities will have similar residues. "Similar residues" are difficult to define numerically, because this would require knowing actual residues for all commodities in a group. Rather, the expectation of similar residues is based upon consideration of all of the information provided in Addendum I of this document. This information will be prepared for each commodity group and will form the basis of the proposals for representative commodities.

Use and Combination of Data Sets

When representative commodities are utilized to extrapolate MRLs to other members of the commodity group, MRLs may be calculated as either the highest MRL calculated for any of the individual representative commodities or the residue data may be combined and the MRL calculated from the larger combined data set.

Wider Extrapolations

A representative commodity should meet at least the first two principles described above, i.e. likely to contain the highest residues and also major in terms of production and/or consumption. However, it may not always fit well with the growth habits, or pest problems of morphology within one group or subgroup. In such situations, extrapolations beyond the members of a commodity group may be appropriate. These can be considered on a case-by-case basis when commodities (with similar GAPs) have similar size, shape and surface area. Examples of these possible wider extrapolations include (1) translation of certain stone or pome fruit MRLs to a tropical fruit; (2) where residues are all <LOQ for pre-emergent herbicide uses and (3) seed treatments for non systemic pesticides.