# codex alimentarius commission



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS WORLD HEALTH ORGANIZATION



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Agenda Item 10

CX/PR 10/42/12-Add. 1 March 2010

# JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES Forty-Second Session Xi'an, China, 19 - 24 April 2010

# Comments on the REVISION OF THE RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES, submitted by Brazil, Canada, New Zealand, Argentina, Cuba, Guatemala

#### Brazil

Brazil would like to emphasize its agreement with the proposal that MRLs not be withdrawn unless there are new scientific data, following risk analysis which indicates that active compound use may compromise human health.

# Canada

Canada supports the ongoing work of the electronic working group, led by Argentina, to ensure consistency between the documents under consideration for pesticide residues and other risk analysis documents such as the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

The proposed revisions are in line with Canada's current risk assessment methodology.

#### New Zealand

It is noted that the Codex Committee on General Principles in its paper (CL 2010/1-GP) will be considering a number of changes (suggested by the Codex Secretariat) to the Risk Analysis Policies of various committees including CCPR. While their comments on CCPR's Risk Analysis Policy relate to the current version, we assume the EWG will take these comments into consideration for future revisions of this paper.

The document using the term 'must' (eg Sections 3 and 4) and we would like to suggest whether the term 'should' may be more appropriate in a number of instances.

Under 5.2, the second sentence in the first paragraph is incomplete.

Under 6.1.1:

• It is unclear on the practicability of the proposals to include compounds, which are not yet registered/commercialised for JMPR consideration. Factors such as delays in registration at the national level, or changes in GAP may adversely impact on the workload of the JMPR evaluation.

• We are unsure of the benefits of assessing compounds where there are no detectable residues in the traded RAC or animal feed. Trade should not be interrupted where there are no detectable residues in the traded commodity irrespective of whether a Codex MRL (at the LOQ) exists or not. There, we would suggest this should be deleted or the compounds given a low priority.

Under 6.2, the terminology appears to be confusing. The title refers to Criteria and Procedures yet the text in a number instances refer to priorities.

Under 6.2.3.7, it would be helpfully to clarify the process for this, and how it will be managed from a priority perspective.

Under 7.1 and 8.5, there may be some advantage to better define the terms 'adequate scientific data' and 'insufficient data'. While appreciating this may difficult, it would be useful to describe the scope of these terms.

Under 8.2.1.2, in considering the principle that MRLs should only be set where there are significant residues in the traded commodity, the rationale is unclear on why MRLs should be set for livestock at LOQ.

Under 8.2.2.2, we would seek clarification on whether the second part of the sentence is correct as it appears to conflict with the first part of the sentence.

Under 8.4 MRLs for fat soluble pesticides, it may be beneficial to include text on measuring residues in milk products.

Under 8.3 Establishment of EMRLs:

- It is assumed that the toxicological end points are acceptable before undertaking the assessment. While inferred, they may wish to be stated more explicitly.
- We believe 8.3.5 could be deleted as this can be better managed under the priorities process.

### Argentina

### **General Comments**

Argentina would like to thank GTE chair for their work with the draft of the document of Applied Principles of Risk Analysis by CCPR, in the effort of integrating the texts of: Applied Principles of Risk Analysis by the Codex Committee on Pesticide Residues, Criteria for the Procedure of Priorities Setting on Composites for JMPR Assessment, LMR Periodical Examination Procedure, and the Form to Express Concerns with the necessary clarifications. Argentina also thanks for the harmonization of the text and the document of Principles of Practical Application for Risk Analysis Applicable within the frame of the Codex Alimentarius and the Principles Declarations Regarding the Role of Science in the Process of Decision Making of Codex and the measure in which other factors are considered, all of which is within the frame of the orders eventually received, besides taking into account the debates of the last CCPR meetings and the comments and proposals of the GTE members.

Furthermore, Argentina highlights the valuable exchange with the other members that resulted in some of the initial viewpoints becoming more flexible.

### **Specific Comments**

Additionally, Argentina highlights that, during the performance of GTE activities, it proposed the addition of an index, aiming at making it easy to read and understand the contents of the document.

Regarding the formal aspects and the organization of the document, such as annexes, re-numbering of the items, titles, etc., we support the last criteria adopted.

In relation to the topics being analyzed, the following shall be highlighted:

- Regarding the item of substances that do not leave detectable residues, Argentine Republic had proposed the following text:

"IV. It generates residues in the surface or in the interior of feed or fodder which are circulating in the international market and whose presence is (or may be) grounds for health concern and that cause (or may be able to cause) problems in the international market, taking into account that there are also innocuous residues and non detectable residues (at the time of the drafting of this legislation) with the aim to consider them for future legislation based on scientific developments that may occur."

However, up to this date, our country agrees with the text of the document CX/PR 10/42/12.

- For Item 8.2.2.2 Argentina proposed the following:

I) CCPR agreed to establish and recommend LMR for important manufactured feed and fodder only when the residues from the RAC to the processed product experience a significant increase (FP >1.3). And/or if the calculated LMR of the processed product is inferior to the recommended LMR of the correspondent RAC, to recommend, also, LMR for processed products when due to the nature of the residues resulting from the specific procedure itself, there appear or increase other pertinent metabolites in significant amounts, and to continue the current practice of JMPR of assessing all studies of the processed provided and to include in each Assessment/Examination a summary chart of all the process factors validated.

In spite of this, it supports the proposal of the chair.

- In relation to the topic of liposoluble pesticides, Argentina proposed:

For liposoluble pesticides, it is recommended that in all cases, for reasons of supervision and legislation, whole milk shall be analyzed and the obtained result shall be compared with the LMR for whole milk, that is why Argentina supports the final text.

- With regard to the Form to Express Concerns, Argentina shares the opinion of the GTE majority.

- In the matters linked to the Periodic Examination Procedure as well as LMR Supervision, considering what is established in:

- Principles of the practical application for Risk Analysis applicable within the frame of the Codex Alimentarius, Items 4 - 9 - 10 - 20 - 34 to 36, Procedural Manual seventeenth edition, (Pages 126, 127, 129, 131 and 132).

- Declarations of principles regarding the role of science in the process of decision making of Codex and the measure in which other factors are taken into account, Item 1, and Criteria for taking into account the other factors mentioned in the 2nd. Declaration of Principles, 1st. and 3rd. Item, Procedural Manual seventeenth edition, (Pages 216 and 217).

- Declarations of principles regarding the role of Risk Assessment as regards the innocuousness of food, item 2, Manual seventeenth edition, (Page 218), which is at the same time supported by the Sanitary and Phytosanitary Measures Agreement of the Uruguayan Round of the WTO.

#### Section 2: Basic Rights and Duties

2. The members shall ensure that all Sanitary or Phytosanitary measures shall only be applied whenever necessary to protect the health and the life of people and animals or to preserve plants, and that such measures shall be based on scientific grounds and that they shall be maintained with enough scientific statements, with reserve of what is provided for in paragraph 7 of section 5.

Section 5: Risk Assessment and determination of the adequate level of sanitary and phytosanitary protection.

#### CX/PR 10/42/12-Add.1

1. The members shall ensure that their Sanitary or Phytosanitary measures shall be based on an evaluation, suitable to the circumstances, of the existing risks for the life and the health of people and animals or for the preservation of plants, taking into account the assessment techniques created by the competent international organizations.

7. Whenever the scientific statements shall not be enough, a member shall be able to adopt, in a provisory way, Sanitary or Phytosanitary measures based on the pertinent information available, including information from competent international organizations and that from the Sanitary or Phytosanitary measures applied by other contracting parties.

In such circumstances, the members shall try to obtain the necessary additional information for a more objective assessment of the risk and shall consequently revise the Sanitary or Phytosanitary measure within a reasonable term.

Argentina understands that the Maximum Residue Limits shall be maintained up to the moment in which the scientific information is presented and demonstrates that it affects people's health.

# Cuba

Cuba approves this document.

### Guatemala

Because Guatemala is a developing country which is predominantly agricultural, several traditional products are used, which after more than forty years of use in our country, are still being used today in the absence of scientific question marks affecting producers and/or users of these products. Furthermore, the after patent introduction of products has made it possible for our agriculture to be more competitive; in conclusion we support the following change:

- Toxicological data that indicate a change in the Acceptable Daily Intake
- Scientific data supporting a change in MRLs