codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 8 **CX/PR 04/6**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

Thirty-sixth Session
New Delhi, India, 19 – 24 April 2004

DISCUSSION PAPER ON THE RISK ANALYSIS POLICIES USED BY THE CODEX COMMITTEE IN ESATBLISHING MRLs FOR PESTICIDES

(prepared by the Chairperson)

INTRODUCTION

1. The Codex Alimentarius Commission, at the twenty-sixth Session (30 June – 7 July 2003) adopted the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius and the Definitions related to risk analysis.[1]

2. The CAC requested that relevant Codex Committees develop or complete specific guidelines on risk analysis in their respective areas, for inclusion in the Procedural Manual, as recommended in the Action Plan. The Commission noted that these texts would be submitted to the Committee on General Principles in order to ensure coordination of work and consistency with the overarching Working Principles.

3. In the 35th Session of the Codex Committee on Pesticides Residues, it was pointed that a clear CCPR policy framework was necessary, clarifying the relation between risk assessment and risk management.[2]

4. The Committee agreed the chair should prepare a paper on the risk analysis policies used by the Committee in establishing Maximum Residue Limits for Pesticides.

RISK ANALYSIS PRINCIPLES

5. In the past, the Committee discussed and established several risk management options in relation to MRL-setting. There may be a need to prepare a document containing the Risk Management Policies applied by the Codex Committee on Pesticide Residues. Examples of Risk Management Policies are the establishment of MRLs and EMRLs, including the option when an acute RfD is exceeded, MRLs for processed or ready-to-eat foods or feeds.

[1] ALINORM 03/41, Appendix IV
[2] ALINORM 03/24A, 143

6. In the future Risk Analysis Principles and Risk Management Policies may be incorporated in one document.

7. In developing the Proposed Draft Risk Analysis Principles, the same approach and lay-out was used as developed by the Codex Committee on Food Additives and Contaminants.[3] .

8. Member States are invited to consider the Proposed Draft Risk Analysis Principles applied by the Codex Committee on Pesticide Residues (Annex 1) and clarify what further action is necessary on this matter at the Committee.

[3] ALINORM 03/12A, Appendix IV

ANNEX 1

PROPOSED DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES

SCOPE

a) This document addresses the respective applications of risk analysis principles by the Codex Committee on Pesticide Residues (CCPR) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and it is an aid in the uniform application of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius[4].

CCPR AND JMPR

b) CCPR and JMPR recognize that an adequate communication between risk assessors and risk managers is a conditio sine qua non for successfully performing their risk analysis activities.

c) CCPR and JMPR will continue to develop procedures to enhance communication between the two committees.

d) CCPR and JMPR will ensure that their contributions to the risk analysis process are scientifically based, fully transparent, thoroughly documented and available in a timely manner to Member States[5].

e) JMPR, in consultation with CCPR, will continue to explore developing minimum data requirements necessary for JMPR to perform risk assessments. These criteria will a.o. be used by CCPR in preparing its Priority List for JMPR. The JMPR Secretariat will consider whether these minimum quality criteria for data have been met when preparing the provisional agenda for meetings of JMPR.

CCPR

f) CCPR is primarily responsible for recommending risk management proposals for adoption by the Codex Alimentarius Commission (CAC).

g) CCPR will base its risk management recommendations to the CAC on JMPR's risk assessments of pesticides in relation to proposed MRLs..

h) In cases where JMPR has performed a risk assessment and CCPR or the CAC determines that additional scientific guidance is necessary, CCPR or CAC may more specifically request JMPR to provide the scientific guidance necessary for a risk management decision.

i) CCPR's risk management recommendations to the CAC will be based on JMPR's quantitative risk assessments and other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade.

j) CCPR's risk management recommendations to the CAC will take into account the relevant uncertainties and safety factors as described by JMPR.

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[4] ALINORM 03/26/6

[5] Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5-104759-6

k) CCPR will endorse maximum residue levels (MRL's) only for those pesticides for which JMPR has completed a full safety evaluation including a quantitative risk assessment.

l) CCPR will base its recommendations on the 5-12 regional diets used to indentify consumption patterns on a global scale when recommending MRL's in food. The 5-12 regional diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the 97.5th percentiles of consumption as provided by a select number of countries.

m) When establishing its standards, CCPR will clearly state when it applies any non-science-based considerations in addition to JMPR's risk assessment and specify its reasons for doing so.

n) CCPR will consider the following when preparing its priority list of compounds for JMPR evaluation:

- CCPR's Terms of Reference;
- JMPR's Terms of Reference;
- The Codex Alimentarius Commission's Medium-Term Plan of Work;
- The Criteria for Inclusion of Compounds on the Priority List;
- The Criteria for Selecting Food Commodities for which Codex MRL's or EMRL's should be Established;
- The Criteria for Evaluation of New Chemicals;
- The Criteria for Prioritising Chemicals for Periodic – Re-evaluation;
- A commitment to provide the necessary data for the evaluation in time.

o) When referring substances to JMPR, the CCPR will provide background information and clearly specify the reasons for the request when chemicals are nominated for evaluation.

p) When referring substances to JMPR, the CCPR may also refer a range of risk management options, with a view toward obtaining JMPR's guidance on the attendant risks and the likely risk reductions associated with each option.

q) CCPR will request JMPR to review any methods and guidelines being considered by CCPR for assessing maximum limits for pesticides.

JMPR

r) JMPR is primarily responsible for performing the risk assessments upon which CCPR and ultimately the CAC base their risk management decisions.

s) JMPR will select scientific experts on the basis of their competence and independence, taking into account geographical representation where possible.

t) JMPR will strive to provide CCPR with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCPR's risk-management discussions. JMPR will continue to use its risk assessment process for establishing ADIs and Acute Reference Doses where appropriate.

u) JMPR will provide CCPR with information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations and will as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children).

v) Recognizing that primary production in developing countries is largely through small and medium size enterprises, JMPR will strive to base its risk assessments on global data, including that from developing countries. These data may include monitoring data and exposure studies.

w) JMPR is responsible for evaluating exposure to pesticides.

x) When evaluating intake of pesticides during its risk assessment, JMPR will take into account the 5-12 regional diets used to identify consumption patterns on a global scale. The 5-12 regional diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the 97.5^{th} percentile of consumption as provided by a select number of countries.

y) JMPR will communicate to CCPR the magnitude and source of uncertainties in its risk assessments. When communicating this information, JMPR will provide CCPR a description of the methodology and procedures by which JMPR estimated any uncertainty in its risk assessment.

z) JMPR will communicate to CCPR the basis for all assumptions used in its risk assessments.