codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 11 **CX/PR 01/17-Add.1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

Thirty-third Session
The Hague, 2-7 April 2001

DISCUSSION PAPER ON OTHER LEGITIMATE FACTORS IN THE FRAMEWORK OF RISK ANALYSIS THAT HAVE BEEN OR ARE CURRENTLY BEING TAKEN INTO ACCOUNT IN THE WORK OF THE COMMITTEE

Note by the Codex Secretariat and the Secretariat of JMPR

Introduction

1. The 14th session of the Codex Committee on General Principles (CCGP), meeting in 1999, while considering Agenda Item 7 "Review of the Statements of Principles on the Role of Science and the Extent to Which Other factors are Taken into Account" agreed to ask the relevant Committees to identify and clarify the relevant factors taken into account in the work, in the framework of risk analysis, as this would facilitate the general debate in the CCGP.

2. The 15th session of the CCGP, meeting in April 2000, further considered the information provided by Codex committees on the other legitimate factors that are taken into account in the framework of risk analysis. Different views were expressed during the discussion. Some delegations pointed out that some of the factors identified by the committees or in the working document should not be considered as "other factors" since they were based on scientific information, especially Good Manufacturing Practice, Good Agriculture Practice, Good Veterinary Practice, and methods of analysis and sampling. Some delegations stressed the need for further clarification from the individual committees on how other factors were integrated into the risk management process, especially on the weight they were given in the decision making process; the replies received so far from the Committees were not precise enough. In this regard the Committee noted that the CCPR had not yet addressed this question. The Committee agreed to further consider this issue at its next session, taking into account the amendments made at the current session. The conclusions of the committees involved in risk management, including the CCPR would also be taken into account, with the understanding that those committees might need to clarify further integration of other legitimate factors in their activities involving risk analysis. The CCGP recognised that further clarification may be necessary from these Committees on the integration of other factors in their work (ALINORM 01/33, para 95).

3. Following a question originating from the Committee on Food Additives and Contaminants, the Executive Committee noted that the question of other legitimate factors was under consideration by the CCGP at the request of the Commission. The CCGP had asked relevant Codex Committees to provide examples of other legitimate factors taken into account in their decision-making processes so as to facilitate the general debate in the CCGP on other legitimate factors. The CCEXEC confirmed that responsibility for a system-wide approach to the consideration of "other legitimate factors" rested with the Committee on General Principles and that no further action in this matter should be taken by the Committee on Food Additives and Contaminants (or any other Committee) at the moment (ALINORM 01/3, para. 56).

4. It is therefore clear from the decision of the CCEXEC that no furher action is required from other committees in relation to the discussion of other factors in the CCGP. It may be noted that as decided at its last session, the CCGP will not discuss further examples but the criteria to be used when considering "other factors" in the framework of risk analysis, as indicated in document CX/GP 01/5. This will be seen in conjuction with the development of Working Principles for Risk Analysis, as there is a reference to other factors in the section on Risk Management.

5. However, other Committees might need to clarify further the integration of other factors when describing the relevant elemtents of risk analysis (as required by the CAC in 1997). This also corresponds to the recommendations of the Joint FAO/WHO Expert Risk Management Consultation on Risk Management and Food Safety.

6. As it is important to ensure consistency throughout Codex, consideration of other factors could be integrated in the recommendations concerning risk analysis in relation to the work of CCPR under elaboration.

Consideration

7. The paper CX/PR 01/17 introduces factors which are part of the scientific evaluation process as specified in the First Statement of the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken Into Account. The Commission has stated that it considers <u>all</u> relevant information in arriving at a scientific basis for its decision-making. This is also reflected in the Proposed Draft Working Principles for Risk Analysis as they indicate that: "Risk assessment should take into account all scientific data and relevant production and handling practices used throughout the food chain.." (point 16).

8. Because the scientific data and evidence taken into account by the CCPR must include the scientific evidence and data taken into account by the JMPR when estimating ADI's and recommending MRL', JMPR reviews a broad data base that includes:

- Acute toxicity
- Short term and long term toxicity
- Genotoxicity
- Reproductive toxicity
- Other pharmacokinetic data including studies on metabolites
- Observations in humans including occupational exposure (EHC 104, p27)
- Special studies, e.g. neurotoxicity, delayed neuropathy, immune responses
- Metabolism studies in plants and animals
- Environmental fate in soil and water
- Methods of residue analysis

- Residues resulting from supervised trials
- Fate of residues in storage and processing
- Consumption patterns.
- GAPs
- (FAO/WHO Specifications to be initiated in 2003)

9. Both Codex and the JMPR Secretariat are of the opinion that the main problem with the paper CX/PR 01/17 is the Section "Consideration". It is not clear whether the list of items in this section is a list of OLFs or not. It is recommended that the list be broken into the following groups; items that are clearly part of the scientific risk assessment (Consumption patterns, Food processing and preparation, environmental fate, GAP, GMP, Good Practice in the Use of Veterinary Drugs, and the treatment of Population sub-groups); items that are risk assessment policy issues (Level of protection, ALARA); items that are risk management issues related to the scientific evaluation (quality and quantity of scientific data, technical feasibility); and items that probably are other legitimate factors that may or may not have been taken into account by CCPR (economic issues). This leaves "Availability of expertise" out of the list altogether, and this is correct since it is not a factor that decides either the MRL or the ADI.

10. As regards feasibility and the practical aspects, the economic feasibility may be taken into account, (as in the case of contaminants EMRL's) and also since this was mentioned in the CCGP and in other committes.

11. The availability of methods of analysis and sampling is an important aspect related to the establishment of maximum levels for contaminants and this would also apply to pesticide MRLs, unless there are specific reasons for not taking it into account.

12. As to the list of other factors not used by CCPR, it is not clear whether the "Impact of the pesticide on the environment" and "Impact of the pesticide on wildlife and the ecosystem" should be considered or be excluded. Since JMPR is supposed to look at environmental effects, it is assumed that these are integrated into the GAP. It should be recognized that the registration of a product at the national level has taken into account the environmental effects and effects on wildlife and non-target organism. Following the registered uses (GAPs) such effects should be reduced or prevented. The FAO Guidelines on Pesticide Registration address these issues. It should be noted that if other factors have not been used by CCPR, or are not currently used - they should not be considered as Other Legitimate Factors in the paper at all.