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 11 **CX/PR 01/17**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

Thirty-third Session
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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

(Prepared by Drafting Group led by Australia)

BACKGROUND

Codex is required to base its standards, guidelines and other recommendations on sound scientific analysis and evidence, and to "have regard, where appropriate, to other legitimate factors relevant for the protection of consumers and for the promotion of fair practices in food trade"[1].

In 1997, the Joint FAO/WHO Expert Consultation on Risk Management and Food Safety recommended to the Commission that it should "should clarify for the guidance of Codex Committees other legitimate factors….". Later in 1997, the CAC agreed to include guidance in the Procedural Manual, including the four principles, one of which makes reference to having regard, "where appropriate, to other legitimate factors….".

The 14th session of the Codex Committee on General Principles (CCGP), meeting in 1999, in referring to its 1998 Session discussion of bovine somatotropin (BST) and the extent to which other legitimate factors are taken into account, agreed to ask relevant Committees to identify and clarify the relevant factors taken into account in their work, in the framework of risk analysis, as this would facilitate general debate in the CCGP. Furthermore, Codex Committees were requested to provide information on the weight given to, or the extent to which these factors were applied, along with examples of their application.

The 15th session of the CCGP, meeting in April 2000, further considered its request to Codex committees for information on the other legitimate factors that are taken into account in the framework of risk analysis. The Committee discussed a draft text on this issue and agreed to further consider this issue at its next

[1] Codex Alimentarius Commission, Procedural Manual, Eleventh Edition, Food and Agricultural Organization, Rome, 2000

session, taking into account the conclusions of the committees involved in risk management, including the CCPR. The CCGP recognised that further clarification may be necessary from these Committees on the integration of other factors in their work.

The 32nd session of the Codex Committee on Pesticide Residues (CCPR), meeting in May 2000, considered the request from the CCGP. In particular, the committee was provided with a draft delegation paper from the United States of America, which included an initial list of OLFs that the committee may have considered during the course of its work. However, given the complexity of the issue, the Committee concluded that it was not in a position to provide information to the CCGP at this time, and agreed that a drafting group led by Australia would prepare a discussion paper for consideration by the Committee, with the intention of reporting to the 16th Session of the CCGP.

ISSUES

This paper attempts to outline the factors that have been applied by the CCPR in its recent decision making, to describe how they were used in risk analysis and to define their relative importance. The factors that are used by the JMPR[2] in undertaking scientific evaluations and risk assessments are not outlined.

It is recognised that some other legitimate factors may be appropriate for use in MRL setting at the national level but have not been considered appropriate for use by the CCPR at the international level.

CONSIDERATION

The Committee is cognisant at all times 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', as set out in the Procedural Manual; and of the importance of ensuring that the work of the Committee is directed towards the protection of consumer health and promotion of fair practices in trade.

The following sets out the approaches adopted by the CCPR in its work.

1. Economic aspects

The CCPR does not take specific account any macroeconomic effects of its decisions (ie upon the overall effect upon the world economy or the economy of individual countries). However, these may be taken into account via consultation in the step process where members are asked to consider the "possible implications of the draft standard for their economic interest." For example, a member government may request modification of a specific proposed MRL to support its export program, and such a request might be considered provided supporting (residue field trial) data were available to the JMPR.

The CCPR does consider other economic effects: for instance, the costs of chemical analysis, where a residue definition may be chosen because of costs; or the cost of generating data, where for 'minor uses' a reduced residue trials data package may be accepted.

2. ALARA (As low as reasonably achievable)

The CCPR utilises implicitly the ALARA principle in the establishment of MRLs. This is done through the recommendation of MRLs that are no higher than are required to allow use of the chemicals in accordance with Good Agricultural Practice (GAP).

3. Consumption patterns

[2] Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues

The CCPR takes consumption patterns into account in their consideration of the WHO regional diets. These regional diets are used by the JMPR and WHO to carry out chronic dietary exposure assessments for the CCPR. Consumption data provided by national governments are used by the JMPR and WHO to carry out acute dietary exposure assessments.

4. Food processing and preparation

Food processing and preparation is taken into account in the derivation of the WHO regional diets and in the consideration of their affects on pesticide residue concentrations. For example, the CCPR have considered in its work the relatively new food processing practice of microwave baking of potatoes and the effect of this process on residue levels.

5. Good Agricultural Practice (GAP)

The MRLs considered by the CCPR are based on the highest residue that is likely to result from the application of the pesticide in accordance with GAP. The GAP information for each country is summarised in the JMPR monographs. This JMPR summary includes information such as the application rate the pesticide is applied and the pre-harvest interval.

The CCPR does not aim to make a judgement, either favourable or unfavourable, on individual countries GAPs. However, the GAP information is used to assess the comparability of residue trials data to country practices and is frequently referenced by the CCPR in its discussions on individual MRLs.

6. Good Manufacturing Practice (GMP)

In relation to food processing issues, the CCPR has taken GMP into account in its deliberations. Information on processing practices and GMP in member countries has been sought by the CCPR.

7. Good Veterinary Practice (GVP)

The CCPR considers not only agricultural practices, but has also recommended MRLs for topical treatments to farm animals (eg. diazinon) despite these being considered by some national governments to be veterinary uses. To the extent that these uses could be considered to be based on GVP, the CCPR has considered GVP.

8. Technical feasibility

The CPPR considers the technical feasibility of the widespread adoption of methods of analysis and sampling procedures by governments in making its recommendations. The feasibility of the development of specific methods of analysis by sponsors to certain pesticides has also been considered eg. for certain dithiocarbamate pesticides for which currently only the carbon disulphide method is available. In addition, technical feasibility is also taken into account by the committee when deciding on the appropriate ‘residue definition for compliance with the MRL’ for individual pesticides.

9. Environmental fate of the pesticide

The CCPR in making recommendations for individual MRLs takes data on environmental fate into account. These data are considered to be “critical supporting studies” by the JMPR in making recommendations to the CCPR. The data on environmental fate are used to help determine both the nature and magnitude of certain MRL proposals eg. MRLs for residues in succeeding crops and extraneous residue limits (ERLs). An example of the latter is DDT, where the CCRP has set ERLs for DDT in meat (fat) resulting from soil contamination. The CCPR monitors the levels in certain meat commodities through data supplied by member governments.

10. Availability of expertise

The Committee relies heavily on JMPR to advise it on scientific matters associated with MRLs. The resources available to the JMPR have recently been stretched with an increasing workload. This limitation

on the resolution of scientific issues, has been taken into account by the CCPR in its considerations eg. in deciding on the process by which technical reservations, raised by governments at the CCPR, are reconsidered. The Committee also makes extensive use of expert consultations, for example, the Geneva Consultation of 1997[3] on acute dietary intake. Such consultations are usually arranged through FAO/ WHO.

11. Level of protection

In making its decisions, the CCPR aims to provide at all times a satisfactory level of protection to consumers. In practical terms, this is achieved by comparing the estimated dietary exposure to pesticide residues to the acceptable daily intake (ADI), or where relevant, the acute reference dose (ARfD).

12. Population sub-groups

In cases where concerns are raised about the dietary exposure of a pesticide, the CCPR, in considering risk management options, considers population sub-groups for which the pesticide may pose a greater risk, eg., chemicals with teratogenic toxicology for pregnant women.

13. Quality and Quantity of supporting data

In considering risk management options, the CCPR qualitatively takes into account both the quality and size of the database that were available for evaluation by the JMPR.

Other factors <u>not</u> used by the CCPR

The CCPR has not considered in its work, among others, the following factors:

- Cultural aspects
- Animal health and welfare
- Impact of the pesticide on the environment (other than environmental fate considered above)
- The labelling of food products
- Worker exposure
- The impact of the pesticide on wildlife and the ecosystem
- Consumer preferences
- Ethical and Religious considerations
- Food Security

In developing GAPs at the national level, some of the above factors, eg. worker exposure and environmental impact, are taken into account by the relevant national authorities. Given that the CCPR accepts national GAPs as the basis for their MRLs, these factors may therefore indirectly influence Codex MRLs.

RECOMMENDATION

That the foregoing information be provided to the next session of the Codex Committee on General Principle to assist it in its deliberations.

DEFINITIONS

Good Agricultural Practice (CAC, 1995)

Good Agricultural Practice in the use of Pesticides (GAP) includes the nationally authorised safe use of pesticides under the actual conditions necessary for effective pest control. In encompasses a range of levels

[3] FAO/WHO Joint Consultation on Food Consumption and Risk Assessment of Chemicals, February 1997, Geneva

of pesticide applications up to the highest authorised use, applied in a manner which leaves a residue which is the smallest amount practicable.

Risk analysis (CAC, 2000)

A process consisting of three components: risk assessment, risk management and risk communication.