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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 10

**CX/NFSDU 01/10
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Twenty-third Session

Berlin, Germany, 26-30 November 2001

DISCUSSION PAPER ON THE APPLICATION OF METHODOLOGY OF RISK ASSESSMENT FOR NUTRITION ISSUES: THE INCORPORATION OF NUTRIENT INTAKE ASSESSMENT IN A RISK-BASED APPROACH TO ASSIST DECISION MAKING PROCESSES OF CCNFSDU *(Paper prepared by Australia)*

BACKGROUND

A paper on the incorporation of nutrient intake risk assessment in CCNFSDU decision-making processes was prepared by Australia and presented at the 22nd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in June 2000. It was agreed at this meeting that a circular letter (CL 2000/22-NFSDU) be sent to invite governments to provide information on their experience with risk assessment for nutrition issues at the national level, including methodology and principles (ALINORM 01/26 para 131).

Conference room documents available at the 22nd Session of CCNFSDU indicated support from Thailand, the United States of America and Uruguay for continuing to explore the potential for CCNFSDU to apply a risk-based approach to nutrients.

In response to the circular letter, four countries (Cuba, Germany, New Zealand and the United States of America,) submitted comments for consideration that recognised the complexity of nutrient risk assessment work undertaken at national level, but offered general support for the Committee to further consider the matter. In particular, comments focused on the importance of establishing internationally applicable reference tolerable upper nutrient intake levels (ULs).

A detailed analysis of the potential application of a risk-based approach to nutrients to assist decision making processes of CCNFSDU was described in Australia's paper presented to the 22nd Session of CCNFSDU (CX/NFSDU 00/13) and will not be reproduced in detail here.

PROPOSAL

It is proposed that, as a necessary first step the CCNFSDU is invited to adopt a formal approach to nutrition-related risk assessment, the Committee should focus on the first of the recommendations proposed at the 22nd Session to explore the potential for establishing international reference standards for ULs based on toxicological data.

USE OF A RISK ASSESSMENT APPROACH TO NUTRIENT INTAKE ASSESSMENTS AT INTERNATIONAL AND NATIONAL LEVELS

1. From time to time, the work of CCNFSDU may require a risk-based approach when setting standards to assess the risk of intakes exceeding ULs for vitamins and minerals. For example, such an approach may be required when setting maximum nutrient levels in vitamin and mineral supplements or in specific foods such as infant formula, infant cereals or foods for special medical purposes. In such cases, a formal risk analysis could be undertaken using the internationally agreed FAO/WHO principles of risk analysis (FAO/WHO 1995, 1997a, 1997b, 1998).
2. In the absence of a risk-based approach to setting maximum limits for nutrients in standards, the alternative is to multiply existing recommended nutrient intakes (RNIs) by one or more established factors, such as two or three times the RNI. Although this approach requires fewer resources than a risk-based approach, its considerable disadvantage is that it does not discriminate well between nutrients with large safety margins, and those with narrower margins of safety.
3. A risk-based approach to assessing potential nutrient intakes would require the use of internationally agreed ULs for vitamins and minerals to ensure the proposed maximum levels of nutrients for dietary supplements or foods in Codex food standards do not cause a potential risk for populations in Member countries. There is increasing interest in Member countries and other jurisdictions in using a risk-based approach to nutrient intake assessments and support for progressing this particular area of work was the focus of comments submitted by Member countries.
4. There are established procedures for setting recommended nutrient intakes (RNIs) based on the known risks of deficiency of nutrients (FAO/WHO 2000), but there are no similar internationally agreed procedures for establishing ULs, although upper safe levels were established for vitamin A, folates, vitamin B₁₂, and iron by FAO/WHO in 1988 (FAO, 1988). The FAO Nutrition Program recently advised an Australian enquiry that consideration of the development of ULs could and should be part of the FAO/WHO ongoing work to establish reference nutrient intakes.
5. Recently, the European Commission (EC) Scientific Committee on Food and the US Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences have independently undertaken considerable work in this area.
6. The principles of applying risk assessment to nutrients are clearly set out in the recent Guidelines of the EC Scientific Committee on Food for the development of tolerable upper intake levels for vitamins and minerals (EC SCF 2000). This paper defines terms used in risk assessment and outlines the special considerations for nutrients in the risk assessment process compared to other food chemicals:
 - nutrients are essential for human well-being within a certain range of intakes;
 - there is a long history of consumption of nutrients at levels found in balanced human diets;
 - there may be experience of chronic consumption (eg from dietary supplements) at levels significantly above those obtained from endogenous nutrients in food without reported adverse effects;
 - (unlike other chemicals) data on adverse effects are often available from studies in humans; and
 - many nutrients are subject to homeostatic regulation of body content through adaptation of absorptive, excretory or metabolic processes and this provides a measure of protection against exposures above usual intakes from balanced diets.
7. The US National Academy of Sciences has established ULs for some vitamins and minerals (NAS 1998, FNB 1997, 1998, 2000). The US Food and Drug Administration has shown that a scientific risk assessment approach can be applied successfully to nutrients by using ULs in nutrient safety evaluations, for example, in assessing the risk of excessive folic acid intakes as a result of a national folic acid fortification program (Lewis et al 1999).
8. Comments from Germany emphasise the complex nature of nutrient risk assessments. The starting point for setting recommendations for nutrients is an assessment in healthy individuals of the physiological requirements for a nutrient, plus margins of variability, uncertainty and bioavailability such as due to the

chemical form of the nutrient, nutrient interactions and synergistic effects. Despite the difficulties in establishing ULs for nutrients, Germany suggests that, with increased use of dietary supplements and fortified foods, it becomes essential that such ULs be set as a measure of risk prevention. However, it is noted that ULs adopted by individual countries may need to deviate from those established elsewhere in special circumstances.

9. Germany also comments '*international recognition and political acceptance of governments on changing perspectives on nutrition, health and the economic consequences of poor diets on health care costs provide a strong incentive for enhancing the nutrition content of Codex standards and guidelines*'. Some governments have responded by introducing nutrition labelling and nutrition recommendations for consumer use.

10. A risk assessment approach to setting standards for nutrients may be of increasing importance as all governments and Codex address controversial topics such as the use of non-nutritive ingredients (fat, oil and sugar replacements) and different dietary fibres in foods, increased use of novel foods or ingredients, foods derived by biotechnology, dietary supplements and food fortification. An associated issue is the assessment and scientific validation of nutrition and health claims.

CONCLUSION

11. A risk-based approach to setting food standards is recognised in several jurisdictions as being critical to the assessment of potentially high nutrient intakes from all sources (food, water, nutrient supplements and medicines). There is support for CCNFSDU to adopt a similar risk-based approach to setting food standards and in particular, support for establishing internationally recognised ULs for vitamins and minerals for use in such risk assessments. This is particularly so, given that tolerable upper levels have been established by the United States of America for some vitamins and minerals, and the EC also recently established guidelines for the development of tolerable upper intake levels for vitamins and minerals.

RECOMENDATIONS

12. As a first step toward adopting a risk-based approach to nutrient intake assessments, it is recommended that CCNFSDU requests FAO/WHO to consider extending their current work on developing RNIs to include the development of internationally accepted ULs for vitamins and minerals.

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