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 2 **CX/NFSDU 02/2**
July 2002

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-fourth Session
Berlin, 4 – 8 November 2002

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES

1. MATTERS REFERED BY OTHER CODEX COMMITTEES

1.1 CODEX COMMITTEE ON FOOD LABELLING

Proposed Draft Amendment to the Guidelines on Nutrition Labelling (ALINORM 03/22, Appendix VI)

The Committee on Food Labelling is considering the Proposed Draft Amendment to the Guidelines on Nutrition Labelling. For full details of the consideration see paras 70-81 of the above ALINORM. Web:

ftp://ftp.fao.org/codex/alinorm03/al03_22e.pdf

The Committee advanced the Proposed Draft Amendment of the Guidelines, as revised at the current session, to Step 5 for adoption by the Executive Committee (see Appendix VI).

While considering the above Guidelines at Step 5 at the 50th Session of the Executive Committee (June 2002) the Regional Coordinator for Asia expressed its reservations on the proposed draft amendments to the Guidelines, in particular Sections 3.2.2, 3.2.2.1, 3.2.2.2 and 3.2.2.3. The delegation proposed the deletion of these sections as they required mandatory labelling for five nutrients/components, i.e., sugars, dietary fibre, saturated fatty acids, trans fatty acids and sodium. It was suggested by the Regional Coordinator for Asia that the Codex Committee on Food Labelling reconsider this issue at its next Session because:

- Nutrition labelling was still a relatively new subject with very few countries requiring mandatory labelling of food products and in any case, where mandatory labelling was required, it was normally restricted to energy, fat, carbohydrate and protein. The labelling of additional nutrients might in fact lead to increased consumer confusion;

- Scientific data to support the role of these additional nutrients/components as related to health and diseases are still being gathered and it is therefore not justifiable to require labelling of these nutrients/components at the present time;

- There is already sufficient flexibility in the existing draft for the inclusion of any other nutrients or food components required by national legislation; and,

- The inclusion of the additional 5 nutrients/components to the 4 core nutrients in an international context would not be in the interest of all countries as they may tend to adopt these guidelines in developing their national legislations which might not address the nutritional needs and consumer understanding of nutrition labels.

The Executive Committee adopted the text as proposed and forwarded the above discussion to the Codex Committee on Food Labelling for consideration (ALINORM 03/3A, paras 76-77).

Proposed Draft Guidelines for Use of Health and Nutrition Claims (ALINORM 03/22, Appendix VII)

The Committee on Food Labelling is developing the Proposed Draft Guidelines for Use of Health and Nutrition Claims (Proposed Draft Recommendations for the Use of Health Claims). For full details of the consideration see paras 82-92 of the above ALINORM. Web:

ftp://ftp.fao.org/codex/alinorm03/al03_22e.pdf

While considering the above Guidelines the Committee made several amendments and agreed to advance the Proposed Draft Guidelines to Step 5 for adoption by the Executive Committee (see Appendix VII).

The Committee recalled that the Committee on Nutrition and Foods for Special Dietary Uses (CNFSDU) had initiated work on developing criteria on the scientific basis of health claims. In view of the progress achieved with the definition of health claims, the Committee agreed to request the CCNFSDU to resume its work on the scientific basic of health claims as it would provide additional guidance and clarity concerning the substantiation of health claims.

The 50th Session of the Executive Committee noted the comment that the Scope and method of application of the Guidelines should be extended to cover young children and adopted it Step 5.

1.2 CODEX COMMITTEE ON PESTICIDE RESIDUES (ALINORM 03/24)

Pesticide Provisions in the Proposed Draft Standard for Cereal – Based Foods for Infants and Young Children

The CCPR noted that the 23rd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)[1] had amended the wording of pesticide residue provisions endorsed at the 32nd session of the CCPR[2] by proposing additional wording "These limits shall take into account the specific nature of the products concerned and the specific population group for which they are intended in order to provide additional protection of infants and young children".

The Committee noted that the phrase "these limits" in the wording proposed by the CCNFSDU was not technically correct and did not fit into the context of provisions already endorsed, therefore agreed to replace this phrase by "these measures" i.e. :

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1 ALINORM 03/26, para. 114.
2 ALINORM 01/24, para. 74.

> *"These measures shall take into account the specific nature of the products concerned and the specific population group for which they are intended"*

The Committee **restated** that its conclusions reached at the 32nd Session that the current system of establishing MRLs on raw commodities should be protective for all subgroups of the population including infants and young children[3]. The Committee also noted that the 2002 JMPR intended to consider increased vulnerability of infants and children, and **agreed** that any change that would result from this consideration would be taken into account, as appropriate.

1.3 CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Proposed Draft Standard for Infant Formula (ALINORM 03/12, paras 8-9)

The Committee noted the concern expressed at the 23rd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) on the large number of additives and levels of use proposed for infant formula and foods for infants and children in the draft sections of the General Standard for Food Additives (GSFA), and asked the CCFAC to defer finalization of those GSFA additive levels until the CCNFSDU had carried out a thorough review of the additives listed in both the proposed draft Standards for Infant Formula and for Processed Cereal-Based Foods for Infants and Young Children.[4] Switzerland and the representative of the European Community supported the request of the CCNFSDU. The delegation of Switzerland also clarified that there were inconsistencies between both the GSFA and the two aforesaid Standards, particularly in regard to the use of certain colours, sweeteners and thickeners and in this regard, the CCNFSDU had established a Working Group to examine the food additive provisions in these Standards.

The Committee noted that the Procedural Manual specified that in any case, "all provisions in respect of food additives contained in Codex commodity standards should be referred to the CCFAC, preferably after the standards had been advanced to Step 5"[5] and that the aforementioned Standards were at Step 3 of the Codex Step procedure. It was also noted that comments from Codex member countries and international organizations were requested during both the endorsement and/or elaboration of levels within the GSFA and furthermore, the Food Category System (FCS) was being thoroughly revised by the Working Group on the GSFA in order to avoid inconsistencies between the GSFA and individual Codex standards.

2. MATTERS ARISING FROM FAO/WHO

Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food Including Powder Milk with Live Lactic Acid Bacteria, Cordoba, Argentina 1-4 October 2001

The Consultation agreed that the scope of the meeting would include probiotics and prebiotics in food, and exclude reference to the term biotherapeutic agents, and beneficial microorganisms not used in food. The Consultation redefined probiotics for the purpose of the meeting as 'Live microorganisms which when administered in adequate amounts confer a health benefit on the host' but restricted its scope to discussion of 'Live microorganisms which when consumed in adequate amounts as part of food[6] confer a health benefit on the host'. The Consultation agreed that the specific issues related to powder milk could not be discussed without a more general consideration of probiotics in food.

The main topics addressed by the Consultation were:

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3 ALINORM 01/24, paras 67-78.

4 ALINORM 03/26, paras. 63-69

5 Procedural Manual of the Codex Alimentarius Commission, pages 84-85, 12th Edition.

6 Water is included as a food

- Properties of probiotic strains and their assessment
- Probiotic product specifications, quality assurance and regulatory issues
- Safety and beneficial human health effects

In terms of safety of probiotics, the Consultation believed that a set of general principles and practical criteria need to be generated to provide guidelines as to how any given potential probiotic microorganism can be tested and proven to have a low risk of inducing or being associated with the etiology of disease, versus conferring a significant health benefit when administered to humans.

The Consultation recommended that disease reduction claims be permitted for specific probiotics if these have been demonstrated using guidelines outlined in their report.

The new paradigm of risk analysis is making its way into regulatory food safety and focuses on a functional separation of the science-based risk assessment and risk management. However, the issue of communication is now also considered an important integrated part of risk analysis. Communication includes exchange between assessors and managers and two-way interaction with other interested parties. Within this concept, the transparency of the decision making process for food safety regulatory action is emphasized, as well as the importance of providing a vehicle for consumers and others to participate in the development process. Therefore communication efforts relative to the use of probiotics should be considered as an integrated part of the development of regulatory initiatives.

The following specific conclusions and recommendations were agreed by the Consultation:

Conclusions

1. The experts agreed that adequate scientific evidence exists to indicate that there is potential for the derivation of health benefits from consuming food containing probiotics. However, it was felt that additional research data are needed to confirm a number of these health benefits in humans, applying a systematic approach and following the guidelines for the assessment of probiotics suggested in this report.

2. There is good evidence that specific strains of probiotics are safe for human use and able to confer some health benefits on the host, but such benefits cannot be extrapolated to other strains without experimentation.

3. The health benefits for which probiotics can be applied include conditions such as gastrointestinal infections, certain bowel disorders, allergy, and urogenital infections, which afflict a large portion of the world's population. The application of probiotics to prevent and treat these disorders should be more widely considered by the medical community.

4. In addition, there is emerging evidence to indicate that probiotics can be taken by otherwise healthy people as a means to prevent certain diseases and modulate host immunity.

5. The regulatory status of probiotics as a component in food is currently not established on an international basis. In only a few countries, regulatory procedures are in place or sufficiently developed to enable probiotic products to be allowed to describe specific health benefits.

Recommendations

1. Potential probiotic strains must be identified by methods including internationally accepted molecular techniques and named according to the International Code of Nomenclature, and strains should preferably be deposited in a reputable internationally recognized culture collection.

2. In order to be termed a probiotic, the probiotic microorganism must be able to confer defined health benefits on the host, as outlined in Section 5 of this Report, in the actual product vehicle that will be made available to humans.

3. There is a need for refinement of *in vitro* and *in vivo* tests to better predict the ability of probiotic microorganisms to function in humans.

4. There is a need for more statistically significant efficacy data in humans.

5. Good manufacturing practices must be applied with quality assurance, and shelf-life conditions established, and labelling made clear to include minimum dosage and verifiable health claims.

6. The regulatory status of probiotics as a component in food has to be established on an international level.

7. The Consultation recommends that a regulatory framework be established to better address issues related to probiotics including efficacy, safety, labelling, fraud and claims.

8. Probiotic products shown to confer defined health benefits on the host should be permitted to describe these specific health benefits.

9. Surveillance systems, including trace-back and post marketing surveillance, should be put in place to record and analyze any adverse events associated with probiotics in food. Such systems could also be used to monitor the long-term health benefits of probiotic strains.

10. Efforts should be made to make probiotic products more widely available, especially for relief work and populations at high risk of morbidity and mortality.

11. Further work is needed to address criteria and methodologies for probiotics.

The complete report of the Consultation is available on the FAO website as follows:

http://www.fao.org/es/ESN/Probio/probio.htm

Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases, WHO Headquaters, Geneva, Switzerland, 28 January – 1 February 2002

A Joint WHO/FAO *Expert Consultation on Diet, nutrition and the prevention of chronic diseases* reviewed the relationships between diet and nutrition as determinants of chronic non-communicable diseases (NCDs) and made recommendations with regard to reducing the burden of the epidemic of NCDs in both the developed and developing countries and in promoting healthy diets and physical activity. The draft Report of this expert consultation were then made available to a wide range of stake-holders for their comments. The draft report will be reviewed along with the feedback received so as to enable early release of this Report.

WHO/FAO/UNU Expert Consultation on Protein and amino acids in human nutrition, WHO Headquaters, Geneva, Switzerland, 9-16 April

The FAO/WHO/UNU *Expert Consultation on Protein and amino acids in human nutrition* was held at the WHO headquarters in Geneva from 9 to 16th April. This Consultation reviewed the latest evidence on requirements of protein and amino acids. The main features of this Consultation was the emerging new data based studies using stable isotopic labelled amino acids which influenced quite considerably the recommended requirements of several important amino acids such as lysine and leucine. Discussions also centred around approaches by which the numbers of individuals likely to be a risk of poor intakes of amino acids or proteins could be determined. Issues related to protein quality and labelling were also discussed by the Experts and recommendations made. It is expected that the report of this consultation will be available shortly.