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/FL 02/2-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

Thirtieth Session
Halifax, Canada, 6 - 10 May 2002

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES

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

1-4 October 2001 Cordoba, Argentina

A joint Food and Agriculture Organization of the United Nations/World Health Organization (FAO/WHO) Expert Consultation on Health and Nutritional properties of powder milk with live lactic acid bacteria was held in Amerian Cordoba Park Hotel, Cordoba, Argentina from 1 to 4 October, 2001, at the request of the Government of Argentina, through its Secretaría de Agricultura, Ganadería, Pesca y Alimentación.

The Consultation, which was the first meeting of this group, focused on the evaluation of the scientific evidence available on the properties, functionality, benefits, safety, and nutritional features of probiotic foods. A total of 11 experts from 10 countries participated in the Consultation.

As there are no international consensus on the methodology to assess the efficacy and the safety of these products, at present, it was considered necessary to convene an Expert Consultation to evaluate and suggest general guidelines for such assessments.

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[1] 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:

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

[1] Water is included as a food

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