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 9 **CX/NFSDU 03/9-Add. 1**

October 2003

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Twenty-fifth Session

Bonn, Germany, 3- 7 November 2003

Proposed Recommendations on the Scientific Basis of Health Claims

- *Comments at Step 3 of the Procedure* -

Comments from:

Malaysia
New Zealand
IDF - International Dairy Federation

Malaysia

Generally, Malaysia supports the Proposed Draft Recommendations on the Scientific Basis of Health Claims.
Malaysia proposes a minor bolded amendment to this Draft as follows:

2 NATURE OF THE EVIDENCE PROVIDED ON THE CHARACTERISTICS OF THE PRODUCT, ON WHICH THE CLAIM IS BASED:

2.1 Identi**fic**ation and stability of the food, the substance or the ingredient:

Information on the origin, ~~**the**~~ nature, ~~**the**~~ chemical composition, **structure**, ~~**the processing**~~, ~~**the**~~ **other** specifications ~~**of the product**~~ on which the health claim is based, **and the processing method of the constituent or ingredient** shall be provided.

When the claim is about a constituent **or the ingredient** of a food, evidence shall be provided that the constituent **or the ingredient**, with the specific function, is present and bioavailable in a quantity and in a form needed to justify the claim throughout the shelf life of the food stored under the conditions indicated on the label.

Validated analytical methods should be available to check the quantity or the activity of the constituent in the food.

A new evaluation is necessary in case of any change affecting the characteristics of the **end** product in such a way as to put into question the claimed effect.

2.2 Safety of the product:

The food safety is provided for by Codex Standards or existing national legislations. In addition to the usual risk assessment :

- The known interactions between the ~~**product**~~ **constituent or the ingredient**, on which the claim is based, with other ~~**products**~~ **constituents** shall be mentioned.
- The requirement that the expected level of consumption shall ~~**be**~~ not lead ~~**to**~~ the ADI (or, if no ADI has been set, any level known to be safe on the basis of the scientific evidence used during the evaluation of the claim), **to** be exceeded, shall be met.

The nutritional safety shall also be taken into account during the evaluation of health claims. The evaluation shall address the risk from a change in the behaviour of the consumer, triggered by the emphasis on the product. The population, or the sub-population targeted by the product, shall be ~~**indentified**~~ **identified**. The selection of this population shall be consistent with the effects alleged by the claim. Where appropriate, various issues can be considered: for instance, the consumption by populations outside the target group, the excessive consumption, the shift of the nutritional balance by the increased consumption of some foods, replacing others, the short-term adverse effects, allergies, the introduction of new risky behaviours, ….

In both cases, the expected/foreseeable adverse effects on the vulnerable population groups (including infant, young children and pregnant women…) shall be considered.

3 SCIENTIFIC REQUIREMENTS ABOUT THE CLAIM EFFECT:

3.1 GENERAL REQUIREMENTS:

A high level of quality of the scientific justification for the claimed effects is obligatory for using any health claim. It seems evident that the level of scientific justification must be sufficient to support the claimed effect but that the substantiation requirements may differ depending on whether the health claim is for disease risk reduction or enhanced function.

The scientific evidence ~~**includes**~~ **shall be derived from** studies results, either already published **or accepted to be published** in ~~**scientific litterature, or conducted by the applicant**~~ **refereed journal** in order to substantiate the alleged claim. ~~**In both cases, the**~~ **The scientific** studies used shall be consistent with generally accepted scientific procedures and principles.

3.2 NATURE OF THE SCIENTIFIC EVIDENCE ON THE CLAIMED EFFECT:

The claim linking the consumption of the food, the ~~**substance**~~ **constituent** or the ingredient and the enhancement of a function, the maintenance or the improvement of a state related to health or the

reduction of a disease risk shall be supported by scientific evidence along one or several of the **~~folllowing~~ following** approaches:

experimental *in vitro* and/or *in vivo* studies,

epidemiological **studies** **~~or clinical studies on humans; clinical interventional studies should comply with the requirements established by ethical committees and should substantiate the change in a relevant indicator~~**.

clinical studies on humans; clinical interventional studies should comply with the requirements established by ethical committees and should substantiate the change in a relevant indicator.

A relevant indicator is a well-defined biological, physiological, clinical or epidemiological indicator which is modulated by the ingestion of the **~~food~~ constituent** or the food ingredient and for which there exists a general agreement among the qualified international scientific community on the relation between the modulation of this indicator and the state of health of the population in which it is measured. The biochemical and physiological mechanisms explaining the beneficial effect on health are either elucidated or explicable with a sufficient degree of certainty in the current state of knowledge. The magnitude of the variation of this indicator, determined under the effect of ingestion of the **~~product~~ constituent** or ingredient, must present (in addition to the statistical significance) a biological, physiological, clinical or epidemiological significance recognised by the scientific community.

Preferably **~~Generally~~**, the evidence shall be provided by studies on humans, and, if a sub-population is specifically targeted, on this group (including the higher consumers of the product). **~~When the claim is about the enhancement of a function,~~ S**tudies on humans may be limited, if animal experimental models or *in vitro* **studies** are relevant or sufficiently close to human metabolism, **such studies may be used as additional supportive findings**. Experiments on animals or *in vitro* studies shall often be required to explain the mechanisms involved precisely enough.

In addition,

The trials shall include large enough population on a long enough timescale with the relevant dose, in the context of the usual diet of the population under study.

The amount of the **~~substance~~ constituent** or the ingredient added to the food shall be determined according to the following criteria:

- The toxicological evaluation: The added amount shall not expose the consumer to health risks.
- The consumption surveys documenting adverse effects: Cumulative intake risks in a situation where the same substance is present in several foods. Simulations to assess the potential risks of excessive consumption may be conducted by the appropriate methods.
- The amount necessary to produce the alleged effect.

Statistical analysis of the data must be conducted with methods accepted for such studies by the scientific community: controlled studies, reference groups, statistical analysis…

4 EVALUATION OF THE SCIENTIFIC PROOFS, USED TO JUSTIFY A CLAIM

The evidentiary dossier constituted in order to support the claims must be evaluated scientifically by a group of qualified experts **recognized by competent authorities**.

Their evaluation of scientific evidence shall be consistent with the principles of risk analysis and, specifically:

shall take all the available scientific data into account.

shall follow state of art norms of scientific methodology.

5 PERIODIC RE-EVALUATION:

Malaysia would like to seek clarifications on {the bullets in Section 5} that the authorized agencies to do the periodic re-evaluation.

Health claims shall be re-evaluated periodically. With this aim in view:

{Fundamental studies or clinical studies shall be conducted to increase the knowledge on the benefit for health of the food, the substance or the ingredient.

The consumption of the products, bearing a health claim, shall be monitored in order to evaluate the real levels of consumption and ensure that the pattern of consumption, as it is documented, is appropriate to provide the expected benefit, specifically for the population group targeted by the claim.
The expected effects and, if appropriate, the adverse effects which may appear after a long-term consumption of the food shall be investigated.}

New Zealand

New Zealand supports the development of recommendations for the scientific basis of health claims.
New Zealand supports a process that is evidence based and follows a sound risk management approach.
Specific comments include:

2.1 Identification and stability of food, the substance or ingredient (final bullet point)

It is important that it is identified that a new evaluation would be necessary only if there is scientifically based justification. There may be some changes made that would not alter the claim, in such a case extensive evaluation would not be of any benefit.

2.2 Safety of the product (final bullet point)

The requirement that the expected level of consumption shall not lead to the ADI (or if no ADI has been set, any level known to be safe on the basis of the scientific evidence of the claim), be exceeded, shall be met.
New Zealand recommends rewording this section to clarify the intent. It is recommended that reference be made to any internationally recognised level of safe intake rather than specifically referring to ADI, which is more relevant to additives than some other constituents of food. Avoiding excessive intakes should refer to any component in the food that the claim is being made for and not just the specific constituent of the food that is the subject of the health claim.

3.2 Nature of the scientific evidence on the claimed effect (general agreement among the qualified international community)

The level of evidence required should be relative to the strength or risk of the claim being proposed. The risk of the claim would refer to the risk to the consumer of the claim not resulting in the claimed benefit. While it is appropriate to expect expert acceptance, and high levels of substantiation, for claims relating to disease risk reduction, lesser claims should be permitted on the basis of a lower level of substantiation. The amount of the substance added to the food must consider the amount necessary to produce the alleged effect to ensure that there is an adequate amount of the substance but also that the necessary amounts are in reasonable for usual consumption.

4 EVALUATION OF THE SCIENTIFIC PROOFS, USED TO JUSTIFY THE CLAIMS

The meaning of "group of qualified experts" needs to be defined for the purposes of the recommendations.

IDF - International Dairy Federation

The IDF welcomes the efforts of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) designed to lay the scientific foundations for nutrition and health claims for foods and to make recommendations for requirements to be met in research work. It is only on the basis of scientific evidence that duly substantiated statements can be made which provide consumers with useful information for making a reasonable choice of food.

However, irrespective of the need for recommendations, it should be noted that not all food producers will equally be able to carry out expensive animal and human studies. There is a risk that small and medium-sized enterprises will not be able to compete with the large, often multinational, groups, because the expense of thorough testing would be beyond the possibilities of many enterprises. Thus, health claims would possibly be reserved to the biggest producers which would consequently be able to strengthen their market position. The IDF therefore suggests to contemplate possibilities that allow all market operators to draw up sufficiently substantiated dossiers to support such claims. As an example, the

examinations of claims already carried out by the US Food and Drug Administration could be taken as a reference in order to save time and money.

Furthermore, the IDF considers the vague formulation in Appendix 1, point 3.2, page 5 somewhat risky (*"The trials shall include large enough population on a long enough timescale .. ."*). It should be taken into account that this formulation appears to leave much room for interpretation, and it has to be made clear in advance how the studies will have to be designed in order to obtain a statistically significant result.

In Appendix 3, point 2.2.3, page 6 reference is made to the *"Reduction of disease risk claims"*. The risk reduction is attributed to the significant alteration of risk factors for certain diseases or health-related conditions. However, the IDF points out that there are more recent studies showing a direct relation to the reduction of diseases and do not only refer to the alteration of risk factors, such as lack of exercise, high blood pressure, overweight, obesity, smoking, diabetes or lipid metabolism disorders. Two publications by KALLIOMÄKI ET AL. (2001 and 2003) show the protective effect of Lactobacillus GG in infants and young children from atopic families. In these studies mothers took probiotics before and after delivery or administered them to their infants via infant formulae. The researchers found out that in the group of infants fed with probiotics the risk of developing an allergy has been significantly reduced compared with the placebo group, an effect that, moreover, persisted until four years after administration. Consequently, what has been reduced, is not the risk of a risk factor, but the risk of developing the very disease. Without wishing to anticipate the final confirmation that is still pending, it should be noted that these studies indicate that a direct reduction of disease risk is possible. Hence, it should be considered not to restrict the endpoints to the sole reduction of risk factors.

In the same paragraph reference is made to the presentation of claims, in order to make sure that these claims are not interpreted as prevention claims. Unfortunately, there is no definition of the term "prevention claims". Here, the IDF suggests that a clear distinction be made between the terms used.

References

KALLIOMÄKI M, SALMINEN S, ARVILOMMI H, KERO P, KOSKINEN P, ISOLAURI E: Probiotics in primary prevention of atopic disease: a randomised placebo-controlled trial. Lancet, 357 (9262), 1076-1079, 2001.

KALLIOMÄKI M, SALMINEN S, POUSSA T, ARVILOMMI H, ISOLAURI E: Probiotics and prevention of atopic disease: 4-year follow-up of a randomised placebo-controlled trial. Lancet, 361 (9372), 1869-1871, 2003.