16June 2003

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 5 **ORIGINAL LANGUAGE ONLY**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-sixth Session, FAO Headquarters, Rome, Italy, 30 June - 7 July 2003

DRAFT STANDARDS AND RELATED TEXTS AT STEP 8 OF THE PROCEDURE
(including those submitted at Step 5 with a recommendation to omit Steps 6 and 7 and those submitted at Step 5 of the Accelerated Procedure)

Comments on Draft Standards and Related Texts Submitted to the Commission for Adoption

AD HOC INTERGOVERNMENTAL TASK FORCE ON ANIMAL FEEDING

Proposed Draft Code of Practice on Animal Feeding

COSTA RICA

Consideraciones Generales de Costa Rica sobre el Anteproyecto de Código de Prácticas en Alimentación Animal, del Grupo de Trabajo Ad-Hoc de CODEX sobre Alimentación Animal (Alinorm 03/38A).

Costa Rica no está de acuerdo en dar un trámite acelerado al Código de Prácticas sobre Alimentación Animal y recomienda que se prolongue el periodo del Grupo de Trabajo Ad-Hoc sobre Alimentación Animal por al menos un año más.

Lo anterior en virtud de que el código establece disposiciones en temas críticos para los países en desarrollo, sobre los que no existe un consenso definitivo en los diversos comités del Codex. Esos son métodos de producción (biotecnología), trazabilidad y etiquetado.

Específicamente, en el tema de etiquetado el Comité del Codex (CCFL) no ha llegado a un consenso para el etiquetado de los alimentos genéticamente modificados para seres humanos, dado que todavía no se tiene un sustento que justifique tal medida. Por eso, sería inconveniente establecer disposiciones en esa materia a través de dicho código.

Por último, Costa Rica considera que el CODEX debe coordinar la elaboración del código con organizaciones especializadas en la sanidad animal, como es la OIE.

ECUADOR

En la cuarta Sesión del Grupo Ad hoc del Codex sobre Alimentación Animal, el Presidente del Grupo ha decidido enviar el borrador del Proyecto del Código de Prácticas para una Buena Alimentación Animal a la Comisión del Codex, de ésta forma se ha dado paso a que el documento sea tratado con el Procedimiento Uniforme Acelerado, decisión que no comparte el Ecuador, por lo tanto expresamente solicita a la Comisión que no se trate el documento bajo éste procedimiento y que se lo someta a los trámites 6 y 7 y se envié al conocimiento de la Comisión del Codex en el trámite 8, con el objeto de que el país tenga la oportunidad de presentar nuestras observaciones para que sean consideradas y se enmienda el proyecto de norma.

JAPAN

Japan supports the proposal from EU in the 4th meeting to complete the definition of the feed additives with the sentence "... or may be intended to improve animal performance."

Rationale:

1. Japan congratulates the fruitful conclusion of the Task Force on animal feeding and thanks the Danish authorities for their diligent working in organizing the Draft Code of Practice on Good Animal Feeding.

2. Japan, while hoping that this Code of Practice will be finally adopted in the 26th Codex Alimentarius Committee, expresses its reservation on the decision taken by the Chairman in the 4th meeting about the definition of the feed additives.

3. The current definition as approved in the Draft Code of Practice does not cover the use of vitamins, trace elements, microorganisms etc. This means that when used they should follow the Code of Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993).

4. It should be noted that there are different regulatory frameworks all over the world and a majority of them consider that those products are feed ingredients.

5. The aim of the Code is to ensure feed safety and this objective is guaranteed with the proposal from EU in the 4th meeting to complete the definition with the sentence "... or may be intended to improve animal performance." Paragraph 19 clearly ensures that feed additives should be assessed for feed safety and used under stated conditions as pre-approved by the competent authorities.

6. If performance enhancers are excluded from feed additives, a majority of countries will need to change their feed legislation just to adapt to the Code without any additional advantage as far as the same level of feed safety apply for veterinary drugs and feed additives.

NEW ZEALAND

While New Zealand is broadly in agreement with the provisions of the Proposed Draft Code of Practice on Good Animal Feeding we have specific concerns regarding paragraph 11.

The labelling provision in paragraph 11 does not clearly spell out the purpose for labelling and could lead to widely divergent application of labelling provisions. While the current draft contains reference to “risk management measures”, it does not link risk management to a risk assessment from a food safety/health protection perspective. The approach being taken in this paragraph is, therefore, inconsistent with the approach being adopted in other areas of Codex and should be modified accordingly.

Clearly and as noted in paragraph 59 of the report of the 4th Session of the Task Force on Animal Feed there was no consensus for adopting paragraph 11. For this reason, New Zealand seeks the deletion of paragraph 11. We can, however, support the adoption of the rest of the Proposed Draft Code.

CROPLIFE INTERNATIONAL

In response to the request for comments on the Proposed Draft Code of Practice on Good Animal Feeding (CL 2003/14-AF), CropLife International does not support adoption of the document at Step 5/8 (with the omission

of Steps 6 and 7). We believe the document requires more thorough consideration and drafting with input form a greater number of member countries to increase its value to Codex and also ensure consistency with existing Codex texts.

Consistency of Work and Work Flow within Codex

We note that the issue of labelling products derived from modern biotechnology is ongoing in the Codex Committee on Food labelling; consensus has yet to be reached in that Committee either on definitions or requirements for labelling. CCFL is the General Subject Committee tasked with issues of labelling within Codex. We believe the appropriate forum for discussion for labelling is in CCFL. Other Committees with concerns in the area of labelling for products derived from modern biotechnology should await the results of the CCFL discussions before forwarding labelling provisions for adoption.

Similarly, Paragraphs 12 and 13 of the Proposed Draft Code contain provisions regarding "traceability"/product tracing. No definition of the term "traceability"/product tracing exists in Codex. The Codex Committee on General Principles (CCGP) has agreed (April 2003) to initiate work on a definition of "traceability"/product tracing for use within the framework of Codex.

Further, the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) has convened a working group to develop guidelines for application of "traceability"/product tracing. Until the work in CCGP and CCFICS has been completed or at least progressed substantially, it is inappropriate for a Codex document to be adopted containing provisions on "Traceability."

Economic Implications of Codex Work

We believe there are provisions in the Proposed Draft Code that will have significant economic implications, especially for developing countries. Step 5 of the *Uniform Procedure for the Elaboration of Codex Standards and Related Texts* requires that "in taking a decision at this step the Commission or the Executive Committee will give due consideration to any comments that may have been submitted by any of its members regarding the implications which the proposed draft standard or any provisions thereof may have on their economic interests" [(page 20), Procedural Manual, 12th Edition]. Because the Proposed Draft was moved from Step 3 to Step 5/8 for adoption, neither the Executive Committee nor the Commission has had an opportunity to consider comments regarding economic implications.

The extremely detailed requirements in paragraphs 12 and 13 would, if adopted, have significant economic implications.

12. *Traceability/product tracing of feed and feed ingredients, including additives, should be enabled by proper labelling and record keeping at all stages of production and distribution. This should facilitate the prompt trace-back or trace-forward of materials and products if any actual or potential health risks are identified, and prompt and complete withdrawal or recall of products where necessary. Records should be maintained and readily available regarding the production, distribution and use of feed and feed ingredients for as long as appropriate to enable trace-back should a safety problem emerge, and representative samples of feed and feed ingredients should be kept where applicable for a suitable period of time.*

13. Feed manufacturers should keep records containing full details of the supplier and date of receipt of feed ingredients, of the manufacturing process and the destination of all feed. These records could include:

inventory records (including labels and invoices on received goods), actual formulae, mixing sheets, daily production logs, files of complaints, files on manufacturing errors and corrective actions taken, analytical results and investigations of out-of-tolerance sample results, records respecting the disposition of returned and recalled feeds and feed ingredients, records of the disposition of flushed or recovered material, records of mixer validation and scale/metering device verification, etc.

We also believe these provisions should be examined to determine if such detail is required to achieve consumers; health protection or if this goal could be achieved with less burdensome requirements. Until this type of analysis and consideration is accomplished, this document should not be adopted at Step 5/8.

Science Basis for Codex Work

The Strategic Vision for Codex as adopted at the 24th Session of the Codex Alimentarius Commission (CAC) mandates a scientific basis for work produced by Codex in order to best meet its objectives. CropLife International believes that portions of the Draft Code are inconsistent with this priority.

One example of particular concern is Paragraph 11 of the Proposed Draft Code:

11. *Competent authorities may decide that feed and feed ingredients consisting, containing or produced from GMOs should be labelled with references to the genetic modification as a risk management measure.*

This provision fails to make clear that labelling for health and safety purposes must be based on an appropriate risk assessment. The provision, as worded, implies that feed or feed ingredients derived through modern biotechnology are, in and of themselves, hazards that result in a risk to consumers and therefore require labeling. There is no scientific rationale to support that contention.

Given the issues of concern with the Draft Code, CropLife International does not support the adoption of the Proposed Draft Code of Practice on Good Animal Feeding at Step 5/8 (with the omission of Steps 6 and 7). We strongly believe that a more thorough and complete review and consideration of all text in the document must occur before the draft Code could be made acceptable.

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Revised Codex General Standard for Irradiated Foods

GERMANY

During its last session the Codex Committee on Food Additives and Contaminants forwarded the draft Revised Codex General Standard for Irradiated Foods to the Commission for final adoption at Step 8. The delegations of Germany and Austria reserved their positions on this decision, in particular with regard to the provisions concerning the absorbed dose in Section 2.2 and 5.3.

With respect to the 26th session of the Commission the position of the German delegation is confirmed. The absorbed dose should continue to be limited to 10 kGy on the basis of the lack of or weak evidence of technological need, current non-use of doses above 10 kGy, consumer perceptions and the need for more complementary studies on cyclobutanones, found in irradiated fat containing foods.

CODEX COMMITTEE ON FOOD LABELLING

Draft Guidelines for Use of Nutrition and Health Claims

DENMARK

We expect that the title mentioned in Annex IV - Draft Guidelines for Use of Health and Nutrition Claims - be due to a mistake, as it was agreed at the 31st session of CCFL in Ottawa to amend the title in conformity with the rest of the text. The correct title is: Draft Guidelines for the Use of Nutrition and Health Claims.

SOUTH AFRICA

At the 31st Session of the Codex Committee on Food Labelling (CCFL) it was agreed to advance the Draft Guidelines for Use of Nutrition and Health Claims to Step 8 of the Procedure.

In 7.1.1 (1) "Information on the physiological role of the nutrient or on an accepted diet-health relationship;" reference is made to nutrient only whereas it should have read "nutrient or food constituent" in order to be in line with the text under 2.2.2, Other function Claims: "These claims concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health."

The recommended wording of 7.1.1 (1) should then read as follows: "Information on the physiological role of the nutrient or food constituent or on an accepted diet-health relationship;"

Motivation: Health claims are not allowed for nutrients only but for other substances as well.

South Africa recognized this omission during the report back session on Friday (2 May 2003) of the CCFL meeting, by which time it was too late to amend the text. Since this document on Health Claims is now at Step 8 and may therefore be adopted as a standard by the Commission, we propose that the amendment receives attention before the document is adopted as a final standard.

UNITED STATES

The United States is pleased to comment on CL 2003/18-FL, Part A: #3, the Draft Guidelines for Use of Nutrition and Health Claims.

The United States opposes the adoption of the Draft Guidelines for the Use of Nutrition and Health Claims. The addition of advertising fundamentally changes and significantly broadens the scope of the Codex text on nutrition claims.

No new work was approved to amend the Guidelines for Use of Nutrition Claims. The inclusion of "and advertising" in 1.1 of the Scope of the document introduces a substantial amendment to the scope of the Guidelines for the Use of Nutrition Claims. The *Guidelines for Use of Nutrition Claims* (CAC/GL 23-1997) were adopted in 1997 and amended in 2001. No new work has been approved to amend the guidelines since that time. At a previous session, the Codex Committee on Food Labelling (CCFL) had agreed to incorporate the Guidelines for Use of Health Claims into the Guidelines for Use of Nutrition Claims and change the title of the Guidelines; however, at no time was there a request for new work to change the scope of the Nutrition Claims guidelines. Accordingly, from a procedural standpoint, this new wording cannot be included in the scope.

Advertising was a new concept added during the CCFL meeting. Therefore, member countries and organizations that were not present did not have the opportunity to comment on this major change before it was included in the Step 8 document. The document should be returned for circulation and continued for discussion at the next CCFL meeting.

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS' ASSOCIATIONS (ICGMA)

The International Council of Grocery Manufacturers Associations (ICGMA), a recognized NGO before the Codex Alimentarius Commission, represents the interests of national and regional associations who collaborate with all sectors of the consumer packaged goods industry. ICGMA promotes the harmonization of scientific standards and policies concerned with health, safety, packaging, and labelling, of foods, beverages and other consumer packaged goods. ICGMA also works to facilitate international trade in the sector by eliminating or preventing artificial barriers to trade.

The International Council of Grocery Manufacturers Associations (ICGMA) appreciates the opportunity to provide input on the *Draft Guidelines for Use of Nutrition and Health Claims at Step 8* (ALINORM 03/22A, Appendix IV).

ICGMA, a recognized INGO before the Codex Alimentarius Commission, represents the interests of national and regional associations who collaborate with all sectors of the consumer packaged goods industry. ICGMA promotes the harmonization of scientific standards and policies concerned with health, safety, packaging, and labelling of foods, beverages, and other consumer packaged goods. ICGMA also works to facilitate international trade in these sectors by elimination or preventing artificial barriers to trade.

ICGMA strongly opposes the adoption of these Guidelines. References to "advertising" and the requirement to include "other dietary sources" on the label when making a health claim were added during the last session (31st Session) of the CCFL. These requirements introduce a substantial extension to the scope and purpose of the Guidelines, whereas the Committee was to resolve only certain identified text and not to substantively change the document or introduce language outside the identified text. IGCMA opposes the adoption for the following reasons:

No new work was approved to amend the Guidelines for Use of Nutrition Claims.

The inclusion of "and advertising" in 1.1 of the Scope of the document introduces a substantial amendment to the scope of the Guidelines for the Use of Nutrition Claims. The *Guidelines for Use of Nutrition Claims*

(CAC/GL 23-1997) were adopted in 1997 and amended in 2001. No new work has been approved to amend the guidelines since that time. At a previous session, CCFL had agreed to incorporate the Guidelines for Use of Health Claims into the Guidelines for Use of Nutrition Claims and change the title of the Guidelines; however, at no time was there a request for new work to change the scope of the Nutrition Claims guidelines. Accordingly, from a procedural standpoint, this new wording cannot be included in the scope. Further, we do not believe that the CAC should discuss placing a reference for advertising in another section of the document; if this discussion takes place, it should be at the Committee level, and not utilize the CAC's valuable meeting time.

The requirement to include information on other dietary sources on the label with a health claim is not appropriate.

ICGMA supports labelling that provides consumers with clear, useful, and relevant information to make an informed choice when purchasing a product; therefore, we support including appropriate information on the label with a health claim. However, the purpose of the label is to inform consumers about the product in that particular package, and any required information for the label should be limited to the specific labeled product. In addition, label space is very valuable to manufacturers, is often very limited, and in many countries, the information must be presented in several languages. Thus, ICGMA believes that the requirement in Section 7.5.3 to include information on other dietary sources when making a health claim is inappropriate.

"Advertising" and "other dietary sources" were new concepts added during the CCFL meeting.

Member Countries and organizations that were not present did not have the opportunity to comment on these issues before they were included in the Step 8 document. The document should therefore be returned for circulation and comments on these issues.

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)

Draft Guidelines for the Use of Nutrition and Health Claims should not be adopted by the Commission but returned to Step 6 for further consideration by CCFL.

Section 1.4 is redundant and should be deleted from the Guidelines.

ISDI opposes the adoption of the Draft Guidelines for Use of Health and Nutrition Claims (ALINORM 03/22 A Appendix IV) because a major change to the Scope of the document has been made at a very late stage. ISDI believes that the implications of this change for the overall document have not been sufficiently considered.

ISDI believes section 1.4 (reading: "*Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation*") is redundant with section 1.2[1] and should therefore be deleted.

Given the time necessary to advance any revision of Standard texts dealing with foods for infants and young children, we believe that if section 1.4 is not deleted, its implementation should be delayed until after specific provisions have been introduced in the following standards and related texts:

- Infant formula (CODEX STAN 72-1981
- Canned baby foods (CODEX STAN 73-1981)
- Processed cereal-based foods for infants and children (CODE STAN 74-1981)
- Follow-up formula (CODEX STAN 156-1987)
- Formulated supplementary foods for older infants (CAC/GL 08-1991)
- Labelling of and claims for foods for special medical purposes (CODEX STAN 180-1991)

[1] Section 1.2 reads: "These guidelines apply to all foods for which nutrition and health claims are made without prejudice to specific provisions under Codex standards or Guidelines relating to Foods for Special Dietary Uses".

Indeed, until such provisions are introduced, nutrition or health claims, even if scientifically substantiated, appropriate, truthful and not misleading, will not be allowed in the above mentioned products.

Draft Amendment to the Guidelines on Nutrition Labelling

DENMARK

Regarding 3.2.6.2:

The principle regarding declaration of vitamins and minerals – based on a presence in a significant amount- is now deleted from the original text. Denmark is of the opinion that this is not in harmony with the main purpose of nutrition labelling of micronutrients. A focus on the content of micronutrients in a product should be based on a nutritional relevance, which also includes a "significant amount" in the product. The information is not nutritionally relevant and the consumer can easily be misled if long lists of micronutrients are presented on the label.

Denmark agrees that CCNFSDU should clarify what is meant by significant amount, cf. para 39, but we are concerned that the amended text does not mention the basic principle.

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS' ASSOCIATIONS (ICGMA)

ICGMA Supports the adoption of the amendment to these Guidelines.

Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (Class Names)

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS' ASSOCIATIONS (ICGMA)

ICGMA Supports the adoption of the amendment to this Standard

AD HOC INTERGOVERNMENTAL TASK FORCE ON FRUIT AND VEGETABLE JUICES

Proposed Draft Codex General Standard for Fruit Juices and Nectars at Step 5/8.

NEW ZEALAND

New Zealand made comments in September 2002 in response to CL 2002/14-FJ seeking, amongst other things, the inclusion of potassium and sodium caseinates as clarifying agents in the list of specific processing aids. This request does not seem to have been considered by the Committee.

We continue to seek the inclusion of sodium and potassium caseinates in the processing aids section of the Proposed Draft Standard. These caseinates are used in both the fruit juice and wine industries, because they are gentler fining agents in terms of flavour and are much easier to remove from the final product than substances such as gelatin.

We note also that:

- Casein is listed as a clarifying agent/filtration aid in Appendix A of the Codex Inventory of Processing Aids.
- Casein and caseinates are foods covered by Codex Stan A-18-1995

Any concerns regarding allergenicity can be covered by ingredient labelling as required by the Codex General Standard for the Labelling of Prepackaged Foods.

CODEX COMMITTEE ON MEAT AND POULTRY HYGIENE

Proposed Draft General Principle of Meat Hygiene

THAILAND

We are of the opinion that the newly numbered Principle 10 should be clarified in the scope of the systems to trace and withdraw meat from the food chain that it should cover only safety.

The Principle should be rewritten by adding the term ”when a risk to human health has been identified “. The amendment of the principle should read.

“The Competent Authority should verify that the establishment operator has adequate systems in place to trace and meat should be withdrawn from the food chain when a risk to human health has been identified. Communication with consumers and interested parties should be considered and undertaken when appropriate”

CODEX COMMITTEE ON MILK AND MILK PRODUCTS

Draft Revised Standard for Cream and Prepared Creams

GERMANY

- Under 7. Labelling: correction of the number of the General Standard for the Use of Dairy Terms into CODEX STAN **206**-1999.
- Under 7.2 Declaration of Milk Fat Content: addition of “or”; the sentence should read as follows: “as (i) a percentage of mass or volume, **or** (ii) in grams per serving (...).”

Draft Revised Standard for Whey Powder

GERMANY

Under 3.3. Composition, in the second table “Acid whey powder” the English version does not correspond to the French and Spanish versions. In these versions the mathematical sign for “more than“ is added in the last line (pH maximum content: > 5.1), whereas there is just the sign “≥” in the English version.

However, the mathematical sign for “more than”in the French and Spanish versions seems to be incorrect. The relevant colums is titled with “maximum content”, thus the pH content should not exceed the upper limit of 5.1.

Under 3.3. Composition, last paragraph: addition of “by”, the sentence should read as follows: “(...) to meet the desired end-product composition, for instance, **by** neutralization or demineralization.”