codex alimentarius commission

E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 5 **CX/FBT 07/7/5 Add.1**
August 2007

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Seventh Session

Chiba, Japan, 24 – 28 September 2007

PROPOSED DRAFT ANNEX TO THE GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS: *FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS MODIFIED FOR NUTRITIONAL OR HEALTH BENEFITS* AT STEP 4

Comments at Step 3, in response to Circular Letter CL 2007/18-FBT,
by Japan and the United States of America

JAPAN

We would like to express our appreciation to the Co-Chairs and the members of the Working Group in developing the Proposed Draft Annex to the Plant Guideline on Food Safety Assessment of Foods Derived form Recombinant-DNA Plants Modified for Nutritional or Health Benefits.

The Government of Japan is pleased to submit the following comments in response to CL2007/18-FBT.

General comments

Japan agrees that the scope of the draft annex should be limited to the food safety assessment of foods derived from plants modified for nutritional or health benefits and that risk management measures are outside this scope

Japan also would like to note that it is very important to avoid duplication between this draft annex and the new work to be taken by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) on the establishment and application of risk analysis principles.

Paragraph 9:

As a result of genetic modification, the quantity and chemical structure of counterionic compounds of an ion such as of iron and zinc may alter due to the changes of the related metabolic enzymes. In addition, chemical modification of organic compounds of nutritional relevance may also occur.

In the former case, the term "chemical forms" can be used to explain changes in ion / compound complex formations (*e.g.*, iron / myo inositol complex, iron / cis-inositol complex) and structural changes in a compound containing a specific element such as selenium. In the latter case, however, the term "chemical forms" do not appropriately describe the changes, but the term "analogues" can specify the modifications in the chemical structure of compounds of nutritional relevance (*e.g.*, multiple analogues of catechin: epicatechin, epigallocatechin [hydroxyl epicatechin], epicatechin gallate, epigallocatechin gallate).

Therefore, Japan would like to suggest retaining the term “analogues”.

Paragraph 12:

Japan is concerned that this paragraph could be misinterpreted and cause unnecessary animal studies. We believe that the animal studies should be considered only when no other studies can replace them and only when there is an assurance that the animal studies give scientifically valid results, therefore we would like to suggest to revise the first sentence as follows (The new sentence is consistent with paragraph 53 of the Plant Guideline),:

~~"If the case animal studies are performed to assess the nutritional value and the bioavailability of the newly expressed substance(s)~~ *If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed animal studies could be requested. In those cases,* the animal species (strain/sex) should be sensitive enough to the nutrient(s), or substance(s) in question."

Paragraph 14:

Japan fully agrees with the idea, which is expressed in this paragraph, that there should be careful consideration for the particular physiological characteristics and metabolic requirements of specific groups of people and geographical and cultural variation in food consumption patterns when the assessment is carried out. However, we would like to propose to delete this paragraph, because we think that this is not the issue which is specific to foods derived from r-DNA plants modified for nutritional or health benefits, and also, the gist of this paragraph has been already covered in paragraph 4, 7 and 16 of the proposed draft annex as well as paragraph 49 and 52 of Plant Guideline.

UNITED STATES OF AMERICA

The United States would like to express its appreciation to the Government of Canada for leading the physical Working Group that developed the draft Annex. The United States would also like to express its appreciation to the Governments of Argentina and New Zealand for co-chairing the physical Working Group. The United States believes that the leadership provided by Canada, Argentina and New Zealand have contributed to generating a high quality document for the Task Force to consider.

General Comments

The United States supports the approach, taken by the Working Group, that the draft Annex should not encompass risk management or the assessment of benefits of foods derived from r-DNA plants modified for nutritional or health benefits, but should focus only on the food safety assessment of such foods. The United States also agrees that the Annex should not repeat or revise the safety assessment approach taken in the Plant Guideline.

The United States also recognizes the complexity of, and gaps in, the knowledge regarding safety assessment of nutrients and related substances as is addressed in the FAO/WHO Report, *A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances, Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment (May 2005).* Thus, we support references to this report, as appropriate, in the Annex.

In addition, the United States notes current work by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to establish risk analysis principles for nutrients and related substances and that this Committee's terms of reference include: "(d) to consider, amend if necessary, and endorse provisions on nutritional aspects proposed for inclusion in Codex (texts)". Thus, we suggest that the Task Force consider referring any technical issues relating to nutrition that it cannot resolve to CCNFSDU.

Specific Comments

Paragraph 6

The United States recommends adding "that" to the first sentence and the following additional sentence:

> "Upper levels of intake for many nutrients **that** have been set out by some national, regional and international bodies may be considered as appropriate. **The basis for their derivation should also be considered in order to assess the public health implications of exceeding these levels.**"

The United States notes that a number of national and regional bodies (e.g. European Community Scientific Committee on Food/ European Food Safety Authority, U.S. Institute of Medicine, and United Kingdom Expert Group on Vitamins and Minerals) have only recently established upper levels of intake for nutrients, and that FAO/WHO only recently held a workshop to discuss an approach to establish international upper levels (2005 nutrient risk assessment workshop). Moreover, national and regional bodies have used different bases for establishing upper levels for a nutrient (e.g., critical adverse effect, specific study used to identify the no-observed-adverse-effect-level or lowest-observed-adverse-effect-level, and uncertainty factor for setting an upper level). The United States further notes significant data gaps (e.g., limited dose-response data and clinical data) in identifying risk associated with nutrient substances at high levels of intake (see Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment, 2-6 May 2005), and that most U.S. upper levels for children and adolescents are derived by extrapolation. Thus, the United States emphasizes the need to consider the basis for deriving these upper levels in risk assessment of nutrient substances.

Paragraph 9

The United States generally agrees with the comments submitted by Australia on this paragraph, in particular that the term "chemical form" is understandable and that "more than one chemical form" is clearer than "multiple chemical forms." The United States also suggests adding the phrase "(e.g., bioavailability)" immediately after "characterized from a nutrition perspective," to help explain what such characterization refers to.

Paragraph 12

The United States questions the need for this paragraph, and is concerned that it implies greater relevance for animal feeding studies than are warranted. In general, animal studies are only useful as preliminary screening tests for nutritional value and bioavailability. In addition, the United States believes that any guidance on the design of bioavailability studies should be left to CCNFSDU. Therefore, the United States does not support keeping this bracketed paragraph.

Paragraph 13

The United States suggests retaining only the first sentence and inserting the following new second sentence so it will read as follows:

> "Guidance on dietary exposure assessment of foods derived from recombinant-DNA plants with nutritional modifications is provided in paragraph 49 of the Codex Plant Guideline. **Additional applicable guidance on dietary exposure assessment of nutrients and related substances is provided in the Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment, 2-6 May 2005.**"

As noted in the last sentence of the current paragraph 13, most if not all aspects of exposure assessment are not unique to recombinant–DNA plants modified for nutritional or health benefits. Thus, rather than attempt to provide specific guidance in this paragraph that may oversimplify or overlook certain aspects of exposure assessment, we recommend instead referencing the two documents above for guidance on exposure assessment.

Paragraph 14

The United States notes that Paragraph 14 refers to the consideration of benefits and risk management measures. The United States believes that, as articulated in Paragraph 1 of the Annex, risk management measures should be excluded from the Annex. Therefore, the United States does not support keeping this bracketed paragraph.

Paragraph 16

The United States recommends that the last two sentences at the end of Paragraph 16 be removed. More detailed guidance on the appropriate use of aggregate data on food consumption is already provided in the report of the FAO/WHO nutrient risk assessment workshop which is referenced in the previous sentence. In particular, the FAO/WHO report states on page 167 that national or regional food-use data such as food balance sheets, regional diets, and sales data provide very limited information for quantitative exposure estimation.