ＦＡＯ／ＷＨＯ合同食品規格計画（Ｃｏｄｅｘ）
第４回バイオテクノロジー応用食品特別部会（ＣＴＦＢＴ）について

日時：２００３年３月１１日（火）午前１０時から１４日（金）

場所：パシフィコ横浜（神奈川県横浜市西区みなとみらい）

議題：第３回ＣＴＦＢＴ（２００２年３月開催）は、以下の問題を第４回会議の議題とすることとしている。（第３回ＣＴＦＢＴ報告書 *ALINORM 03/34 page15 para. 97*参照）

- 他のコーデックス部会から特別部会に回付された事項
- バイオテクノロジー応用食品の安全性・栄養面の評価に関する他の国際機関の関心事項
- 組換えＤＮＡ微生物利用食品の食品安全性評価の実施に関するガイドライン案の提案
- トレーサビリティについての自由議論

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

ALINORM 03/34

JOINT FAO/WHO FOOD STANDARD PROGRAMME

CODEX ALIMENTARIUS COMMISSION

TWENTY-FIFTH SESSION

ROME, ITALY 30 JUNE - 5 JULY 2003

REPORT OF THE THIRD SESSION OF THE CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

YOKOHAMA, JAPAN 4-8 MARCH 2002

Note: This document incorporates Codex Circular Letter CL 2002/9-FBT

criteria and specificity of methods; to comment on the status of publication of validated methods; to provide opinions on the purpose, appropriate place(s) of a register of a register containing relevant information on methods; to provide opinions on how the access to reference materials could be guaranteed.

93. The Chairperson of the Working Group on Analytical Methods informed the Task Force that the second session of the Working Group on Analytical Methods had been convened on 1 March 2001 and had considered the list of methods elaborated from the information reported by member countries in response to the circular letter and country comment on the registry. It finally agreed on the list of validated methods of analysis that contain the Annex 1 of CX/FBT 02/9 and methods reported later by Japan and United States.

94. The Working Group decided to recommend the Task Force;

- to forward to the CCMAS for its consideration this agreed list submitted to the Task Force as Appendix 1, 2, 3 of CRD12
- to propose to CCMAS to consider further methods of analysis with respect to foods derived biotechnology on the basis of the proposal from member countries
- to propose through Codex Alimentarius Commission (CAC) that FAO, WHO and the FAO/IAEA Joint Division for Nuclear Techniques in Food and Agriculture encourage the development and maintenance of information of methods under development or not yet validated in co-operation with national/regional institutions.

95. The Task Force expressed its gratitude to the delegation of Germany for its work and approved the recommendation by the working Group. In relation to the registry, the Codex Secretariat informed the Task Force that the FAO Biosecurity Portal was under development in cooperation with WHO and other agencies. This will provide an electric information exchange mechanism that will provide a single access point for official national and international information on food quality and safety, plant and animal life and health. It was envisaged that registries of official information, such as methods of analysis would be available through the Portal.

OTHER BUSINESS, FUTURE WORK AND DATE AND PLACE OF NEXT SESSION (AGENDA ITEM 9)

OTHER BUSINESS

96. The Representatives of FAO and WHO announced that they were planning to convene a Joint FAO/WHO Expert Consultation on genetically modified animals, the outcome of which would be reported to the Task Force.

FUTURE WORK

97. The Task Force noted the following matters would be considered at the Fourth Session:

- Matters Referred to the Task Force by other Codex Committee
- Matters of Interest from the Other International Organizations with respect to the Evaluation of the Safety and Nutrition Aspects of Foods Derived from Biotechnology
- Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms
- Open discussion on traceability

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CX 4/80.1

CL 2002/40 -FBT
September 2002

TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Joint FAO/WHO Food Standards Programme
FAO, 00100 Rome, Italy

SUBJECT: **Request for comments on the Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms** ***at Step 6***

DEADLINE: **29 November 2002**

COMMENTS: To:
Mr. Toshiro Nakagaki, Director
Standards Division
Department of Food Safety
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare
1-2-2 Kasumigaseki, Chiyoda-ku
100-8916 Tokyo, Japan
Fax +81 3 3595 2251
codexj@mhlw.go.jp

Copy to:
Secretary
Joint FAO/WHO Food Standards Programme – FAO
Viale delle Terme di Caracalla
00100 Rome, Italy
Fax: +39 (06) 5705 4593
E-mail: codex@fao.org

BACKGROUND

The 3rd Session of the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology discussed the *Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms* and agreed to advance it to the next session of the Codex Executive Committee for its adoption at Step 5 since the Task Force noted that the general approach and outline of the Proposed Draft while it noted there were several proposals to amend the paragraphs in the text (para 88, ALINORM 03/34).

The 50th Session of the Codex Executive Committee adopted it at Step 5 and advanced to Step 6 *Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms*.

Therefore, the text (Appendix V in ALINORM 03/34) attached as Annex to this letter is hereby circulated for comments *at Step 6*. Governments and international organizations wishing to submit comments should do so in writing, preferably by email, to the above addresses **before 29 November 2002**.

Attention is drawn to paragraph 44 of the text which two alternative proposals on the treatment of the Annex on Allergenicity are presented.

Annex

DRAFT GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS PRODUCED USING RECOMBINANT-DNA MICROORGANISMS

(At Step 6 of the Procedure)

SECTION 1 – SCOPE

1. This Guideline supports the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and addresses safety aspects of foods produced through the actions of recombinant-DNA microorganisms.[1] The recombinant-DNA microorganisms that are used to produce these foods are typically derived using the techniques of modern biotechnology from strains that have a history of safe, purposeful use in food production. However, in instances where the recipient strains do not have a history of safe use their safety will have to be established.[2] Such food and food ingredients contain viable or non-viable recombinant-DNA microorganisms or may be produced by fermentation using recombinant-DNA microorganisms from which the recombinant-DNA microorganisms may have been removed.

2. Recognizing that the following issues may have to be addressed by other bodies or other instruments, this document does not address:
   - safety of microorganisms used in agriculture (for plant protection, biofertilizers, in animal feed or food derived from animals fed the feed etc.);
   - risks related to environmental releases of recombinant-DNA microorganisms used in food production;
   - safety of substances produced by microorganisms that are used as additives or processing aids, including enzymes for use in food production;[3]
   - specific purported health benefits or probiotic effects that may be attributed to the use of microorganisms in food; or
   - issues relating to the safety of food production workers handling recombinant-DNA microorganisms.

3. A variety of microorganisms used in food production have a long history of safe use that predates scientific assessment. Few microorganisms have been assessed scientifically in a manner that would fully characterize all potential risks associated with the food they are used to produce, including, in some instances, the consumption of viable microorganisms. Microorganisms are amenable to modification using recombinant-DNA technology and new strains can be rapidly developed due to their rapid growth rates. Furthermore, the Codex principles of risk analysis, particularly those for risk assessment, are primarily intended to apply to discrete chemical entities such as food additives and pesticide residues, or

[1] The microorganisms included in these applications are bacteria, yeasts, and filamentous fungi. (Such uses include, but are not limited to, production of yogurt, cheese, fermented sausages, natto, kimchi, bread, beer, and wine.)

[2] The criterion for establishing the safety of microorganisms used in the production of foods where there is no history of safe use is beyond the scope of the current document.

[3] The Working Group noted that the Joint FAO/WHO Committee on Food Additives (JECFA) is revising guidelines for General Specifications and Considerations for Enzyme Preparations used in food processing. These guidelines have been used to evaluate enzyme preparations derived from genetically modified microorganisms.

specific chemical or microbial contaminants that have identifiable hazards and risks; they were not originally intended to apply to intentional uses of microorganisms in food processing or in the foods transformed by microbial fermentations. The safety assessments that have been conducted have focused primarily on the absence of properties associated with pathogenicity in these organisms and the absence of reports of adverse events attributed to ingestion of these organisms, rather than evaluating the results of prescribed studies. Further, many foods contain substances that would be considered harmful if subjected to conventional approaches to safety testing . Thus, an alternative approach is required where the safety of a whole food is being considered.

4. Information considered in developing this approach includes:

   A)uses of living microorganisms in food production;

   B)consideration of the types of genetic modifications likely to have been made in these organisms;

   C)the types of methodologies available for performing a safety assessment;

   D)issues specific to microorganisms used in food production, including their genetic stability, gene transfer, colonization of the intestinal tract and persistence therein and, interactions with the recombinant-DNA microorganism, the gastrointestinal flora and the mammalian host, and impacts on the immune system.

5. This approach is based on the principle that the safety of foods produced using recombinant-DNA microorganisms is assessed relative to the conventional counterparts that have a history of safe use, not only for the food produced using a recombinant-DNA microorganism, but also for the microorganism itself. This approach takes both intended and unintended effects into account. Rather than trying to identify every hazard associated with a particular food or the microorganism, the intention is to identify new or altered hazards relative to the conventional counterpart.

6. This safety assessment approach falls within the risk assessment framework as discussed in Section 3 of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. If a new or altered hazard, nutritional or other food safety concern is identified by the safety assessment, the risk associated with it would first be assessed to determine its relevance to human health. Following the safety assessment and, if necessary, further risk assessment, the food or component of food, such as a microorganism used in production, would be subjected to risk management considerations in accordance with the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology before it is considered for commercial distribution.

7. The Guideline describes approaches recommended for making safety assessments of foods produced using recombinant-DNA microorganisms, using comparison to a conventional counterpart. the safety assessment will focus on the safety of the recombinant-DNA microorganisms used in food production, [or] and, where appropriate,]on metabolites produced by the action of recombinant-DNA microorganisms on food. The Guideline identifies the data and information that are generally applicable to making such assessments. While this Guideline is designed for foods produced using recombinant-DNA microorganisms or their components, the approach described could, in general, be applied to foods produced using microorganisms that have been altered by other techniques. [On the condition that the microorganism is considered to be safe when compared with the conventional counterpart taking into account its interactions with the food matrix or the microflora, that any newly expressed protein(s) encoded by the modified DNA is considered to be safe, and that any secondary metabolic products present as a consequence of the genetic modifications are deemed to be safe, it is unlikely that the food produced by the microorganism would be harmful to human health.]