

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

CODEX GUIDANCE ON FOODS DERIVED FROM GM ANIMALS

Issue

This paper provides an update on the Codex Alimentarius Task Force dealing with GM foods and invites Members to identify issues that need to be considered in the elaboration of Codex guidelines for the safety assessment of GM animals.

Background

1. As described in paper ACNFP/73P/1B, Codex Alimentarius has re-formed its *ad hoc* Task Force on Foods derived from Modern Biotechnology, which met for the first time in Japan in September 2005. At that meeting, the Task Force considered several possible topics that might be tackled during the fixed life time of the group. The Task Force agreed to begin work on:
 - Guidelines for the safety assessment of foods derived from GM animals. This would complement current guidelines on the assessment of GM plants and GM microorganisms, which were adopted in 2003. The Project Document describing this new activity is attached at Annex A; and
 - Detailed guidance on the assessment of GM plants modified to produce nutrition or health benefits. This would take the form of an Annex to the existing guidelines on assessment of GM plants. The work is to be led by Canada, who will produce a discussion paper (scoping document) for the next Task Force meeting.
2. Codex guidelines such as these have no legal force, but they are an important point of reference for any discussions or disputes in relation to international trade, for example at the World Trade Organisation, and they are available to be used by countries when developing their national policies. The existing GM guidelines have been taken fully in account by the European Food Safety Authority in developing its approach to the safety evaluation of GM foods.
3. The Task Force meeting discussed various other topics, but decided not to undertake work in these areas:
 - Low-level (adventitious) presence of unauthorized GM plant material;
 - Stacked genes;
 - Comparative compositional analysis; and
 - Plants producing pharmaceutical bioactive substances.
4. The Task Force agreed to consider papers on the following topics at a future session:
 - Comparative food composition analysis of staple foods (prepared by India);
 - Post-market surveillance of GM foods (Mexico); and
 - Safety assessment of foods derived from animals exposed to protection against disease through gene therapy or GM vaccines (Kenya).

Guidelines on GM animals

5. A Working Group consisting of Task Force members is developing a first draft of the GM animal guidelines for discussion at the next meeting of the Task Force (provisionally scheduled for the end of November 2006). The Working Group will meet in February and the Food Standards Agency will represent the UK. The attached document (Annex A) is a working draft prepared by the joint chairs of the Working Group (Australia and Japan) and has been modelled closely on the existing guidelines on GM plants, following the same structure and addressing many common issues, with various additions to take account of issues that are unique to GM animals.
6. The intention is that the main document will provide a general framework for GM animals, and specific annexes will be gradually added to provide more specific guidance on different types / species of animal.
7. The Task Force had a lengthy debate on whether or not ethical and other considerations should explicitly be included in the scope of this work. As a compromise, it was agreed to make a general reference in the Project Document to previously agreed general principles concerning the role of factors other than science in Codex decisions but to focus the guidance on the safety assessment. Representatives of FAO and WHO suggested that, given the likely importance of ethical and other considerations in regard to the international trade of foods derived from GM animals, a separate workshop could be convened to address these issues. The importance of identifying all problems relevant to consumers' concerns was stressed, as part of effective risk communication.
8. Development of the guidelines will follow the general principles previously agreed by Codex in 2003 ("Principles for the Risk Analysis of Foods Derived from Modern Biotechnology") and will draw on an expert consultation on GM animals organised by FAO and WHO in November 2003. It is likely that a second consultation will be held to provide additional expert advice on issues that emerge during the development of the guidelines.

Committee Action Required

9. To help prepare for discussions on this topic, the Committee is invited to consider the attached working draft (Annex B).and to
 - advise on any additional topics that need to be considered; and
 - provide any other comments on this activity and on the document.

**Secretariat
January 2006**

Annexes attached:

Annex A: Project document "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals" (Appendix II to document ALINORM 06/29/34).

Annex B: Working draft of guidelines for the safety assessment of foods derived from recombinant DNA animals (*restricted*).

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Available at <http://www.codexalimentarius.net/>

**Secretariat
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