

codex alimentarius commission

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FOOD AND AGRICULTURE
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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 4

**CX/FBT 07/7/4
July 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 GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT
OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS**

Comments at Step 3 (Section on Use of Antibiotic Resistance Marker Genes), in response to Circular Letter CL 2006/54-FBT, by Australia, Canada, Japan, New Zealand and the United States of America.

AUSTRALIA

Australia is pleased to provide the following comments in response to Circular Letter 2006/54-FBT.

At its 6th Session the Task Force decided to return the section on “Use of Antibiotic Resistance Marker Genes” (paragraphs 64 – 67) of the proposed draft animal guideline to Step 3 for comments, taking into account the outcome of the proposed FAO/WHO Expert Consultation, which was subsequently held on 26 February – 2 March 2007 in Geneva.

Australia agrees with Canada that no additional considerations in relation to marker and reporter genes were raised in the report of the expert consultation, outside those already addressed in paragraphs 64-67 of the proposed draft animal guideline. Australia, in particular, notes that paragraph 64 of the proposed draft animal guideline, as currently drafted, discourages the use of antibiotic resistance marker genes where safe alternatives are available.

Australia therefore believes that there are no compelling scientific reasons for modifying paragraphs 64-67 of the proposed draft animal guideline.

CANADA

Canada welcomes this opportunity to provide input in response to Circular Letter CL 2006/54-FBT concerning antibiotic resistance marker genes. We are pleased to submit the following comment for consideration.

Based on the information, conclusions and recommendations outlined in the report of the most recent Expert Consultation held in February 2007 on marker genes, no additional considerations, outside those already addressed in paragraphs 64-67 of the Draft *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals* were raised. Therefore, Canada suggests that the current proposed text for these paragraphs, adapted from the previously adopted *Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*, is sufficient in addressing all the relevant aspects of the food safety assessment in regards to antibiotic resistance marker genes and does not warrant any further revisions.

JAPAN

The Government of Japan is pleased to provide the following comments on the section of “Use of Antibiotic Resistance Marker Genes” of the “Proposed Draft Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Animals (Paragraph 64-67, ALINORM 07/30/34, Appendix III)”.

We carefully examined the outcome of the Joint FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Recombinant-DNA Animals (2007). The report states that not many non-antibiotic resistance marker or reporter genes are used for producing r-DNA animals at this moment and only limited number of studies has been performed on the safety of non-antibiotic marker genes in r-DNA food animals. For the reason above, we believe that there are no imminent necessity and sufficient scientific justification to revise the current texts taken from the Plant Guideline (CAC/GL 45), and paragraphs 64-67 can remain as they are now.

NEW ZEALAND

Thank you for the opportunity to comment on *CL 2006/54- FBT: Distribution of the Report of the Sixth Session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology (ALINORM 07/30/34) and Request for Comments on the Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals.*

New Zealand notes the report of the 2006 Joint Expert Consultation on the Safety Assessment of Foods Derived from Recombinant-DNA Animals.

New Zealand continues to believe that the *Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals* should only depart from the wording used in the recombinant-DNA plant guidelines (CAC/GL 45-2003) where the biological differences between plants and animals require a different approach.

There has been much interest in the use of reporter and selectable marker genes. However, in light of the report of the Expert Consultation, New Zealand believes that the existing text in paragraphs 64-67 of the draft recombinant-DNA animals document is sufficient. New Zealand believes that there is not sufficient justification for departing from the text used in the corresponding section of the recombinant-DNA plant guidelines.

New Zealand supports the draft recombinant-DNA animals document in its current form.

UNITED STATES OF AMERICA

The United States appreciates the opportunity to comment on CL 2006/54-FBT, and in particular per ALINORM 07/30/34, paragraph 50, and Appendix III, on paragraphs 64-67 (Use of Antibiotic Resistance Marker Genes) of the Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals, taking into account the report of the February/March 2007 FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Recombinant-DNA Animals.

The United States notes that nothing in the Expert Consultation Report contradicts or calls into question anything in paragraphs 64-67 of the Proposed Draft Guideline. Therefore, the United States believes that the paragraphs, which were adapted from the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, should be left as is, and that these paragraphs should move forward with the rest of the Proposed Draft Guideline for the Consult of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals.