codex alimentarius commission

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 **CX/FBT 07/7/4 Add.1**
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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 AT STEP 4

Comments at Step 3 (Section on Use of Antibiotic Resistance Marker Genes), in response to Circular Letter CL 2006/54-FBT, by Brazil and Kenya

BRAZIL

Brazil considers that the recommendations in the current document have covered the main concerns on the use of antibiotic resistance marker genes, not being necessary modify the original text.

Currently, there is no technology that can fully substitute the use of resistance marker genes for positive selection of transgene integration (homologous or not) in the receiving genoma. Avoiding the use of antibiotics with medical relevance, such as vancomicine, is common practice. This antibiotic, as well as others, are used in the treatment of multi-resistance bacteria infections, such as *Streptococcus* and *Staphylococcus aureus*. However, the use of antibiotic resistance genes such as beta-lactamase (ampicillin resistance), is allowed and widely employed in genetically modified microrganisms.

Regarding the use of non-antibiotic resistance markers or reporter genes, such as GFP, toxicity and allergenicity studies must be carried out, as well as with any other transgenic protein whether it has antibiotic effect or not.

Moreover, the use of recombination systems for the removal of the resistance gene, like the Cre/Lox recombinase system, must be well assessed, since it will be necessary to insert an extra transgene (recombinase) and there is the possibility of non intentional recombination events, mainly if the recombinase is over-expressed.

KENYA

We appreciate the recommendations made by the expert group, and in particular the need to insert introns within the marker gene to ensure that the marker does not function in gut microflora that may take up the gene. We propose that:

Paragraph 66A

The bracket is expanded to provide for an additional third statement as follows:

If non antibiotic resistant markers are not available, introns should be inserted within the marker genes to make them non functional in case they are taken up by bacteria.