codex alimentarius commission

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Seventh Session

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PROPOSED DRAFT ANNEX TO THE GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS ON LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL AT STEP 4

Comments at Step 3, in response to Circular Letter CL 2007/17-FBT rev.,
by Costa Rica and European Community

COSTA RICA

Costa Rica welcomes the opportunity to express its comments on the Proposed Draft Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants on Low-level Presence of Recombinant-DNA Plant Materials (CL 2007/17- FBT rev.) and wishes to state the following:

1. Costa Rica also supports the transparent exchange of information for which it proposes that "the low levels that each country determines should be made public for the purpose of transparency of trade" and agrees to the publication of this type of information through the Biosafety Clearing-House (BCH) referred to in paragraph 19 of document CL 2007/17-FBT rev., or though any other mechanism or system of exchange of information endorsed by the Codex, in accordance with Section 3 on data and information sharing of Attachment 2 of that document.
2. Costa Rica considers that the format of Attachment 2 should be adopted, as it expressly states the differences from the plant guideline.

EUROPEAN COMMUNITY

The European Community (EC) welcomes the outcome of the meeting of the working group on low-level presence co-chaired by the United States, Germany, and Thailand. Substantial progresses have been made on the two key aspects of these draft guidelines, namely the guidance on the risk assessment elements to be considered and the establishment of an information sharing mechanism.

The EC would like to recall that these draft guidelines should only apply in specific and exceptional circumstances. In particular, this project should not:

- Address risk management measures; national authorities will determine when a recombinant-DNA plant material is present at a level low enough for this Annex to be appropriate.
- Preclude national authorities from conducting a full risk assessment; countries can decide when and how to use the Annex within the context of their regulatory systems.

- Eliminate the responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet countries' relevant import requirements, including in relation to unapproved recombinant-DNA material.

In this context, the EC would like to underline that ensuring a low-level presence in commodities and other products is difficult to achieve without appropriate measures to be taken by the national authorities of the exporting country requesting the active participation of all the operators involved in the production and distribution chain.

Prior the commercialisation of a recombinant-DNA plant, operators shall consider whether the conditions are met to fulfil the legislative requirements of the countries where the food derived from recombinant-DNA plant or food containing recombinant-DNA plant material, even present at a low level is likely to be commercialised. Recent experience has shown that the commercialisation of a single recombinant-DNA plant in a trading partner of the EC is jeopardising the trade flow of the concerned commodity. This is notwithstanding preventive measures including attempts to channel the concerned recombinant-DNA plant material out of the export channels to the EC and complementary control measures taken by the operators. The EC also notes that the negative consequences of such a situation are usually not borne by the recombinant-DNA plant, producer but by other operators in the food chain in both the country of export and import.

The current draft and the discussion held within the working group indicate that the assessment of food safety considerations arising from the low-level presence of recombinant-DNA plant material in food, even in situation of low-level presence, requires consideration of a substantive body of data. The EC is of the view that this body of data is necessary and should therefore be made readily accessible to the risk assessors of member countries where such a situation is likely to occur and who wish to apply these guidelines.

The implementation of these draft guidelines will be largely conditioned by the effectiveness of the information exchange mechanism, which the EC considers therefore to be an essential complement to the guidelines. The EC appreciates the efforts made by FAO, with the help of the OECD, in view of submitting to the Task force a proposal to establish the information sharing mechanism. It looks forward to consider the proposal to be made by FAO at the next meeting of the Task Force.

With respect to the information to be exchanged, the EC considers that the outcome of the working group is going in the right direction. The task force should nevertheless consider whether this aspect could be elaborated further. In particular, the information to be exchanged could also include immediately include information about detection methods. This is important in relation to the implementation of the guidelines in countries where the recombinant-DNA plant is not yet authorized. Further reflections should also be made on the usefulness to further precise whether more extended information from the authorising countries on its risk assessment performed according to the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (Codex Plant Guideline) could be part of the information exchange mechanisms.

Another aspect that should be considered by the Task force is the possibility to ensure coherence between the information exchange currently under development in Codex and the information exchanged through the Biosafety Clearing House of The Cartagena Protocol. The EC only authorises the placing on the market of food containing or consisting of recombinant-DNA plant material (such as food exchanged as commodities) after having carried out a thorough environmental risk assessment. For this type of food, information on the food safety and on the environmental safety is thus complementary.