FAO Platform for Foods Derived from Modern Biotechnology – prepared by the former Chairperson of the Task Force

1. Start of the work on Low level presence of r-DNA Plant Material in Food Resulting from Asynchronous Authorization - Extract from the record of discussion in the 6th session of the Task Force

74. Several delegations were of the opinion that the establishment of **mechanisms for data sharing and information exchange** would be a key to ensuring the food safety in situations of the low-level presence of unauthorized recombinant-DNA plants. The Delegation of New Zealand expressed the view that the Biosafety Clearing-House did not serve this purpose as it had been designed to deal exclusively with living modified organisms. The Delegation of the European Community pointed out that there was less than satisfactory progress in constructing databases and relevant mechanisms to make information available for this purpose and there was the need to share, among regulatory authorities, relevant information including detection methods, molecular characterizations and testing protocols. Other delegations also pointed out that the need for information on detection methods and reference materials.

75. The Representative of FAO indicated that **FAO was prepared to consult with other international bodies such as CBD and OECD, as well as industry consortiums with a view to designing and establishing a data-sharing mechanism** while giving due considerations to the protection of confidential information. Several observers representing developers of recombinant-DNA plants expressed their willingness and commitment to contributing to information sharing mechanisms by providing relevant food safety data and information that has been previously reviewed by the country or countries that have satisfactorily completed their food safety assessment. In this context, reference was also made to the ILSI database.

78. [A physical working group was established.] To develop recommendations to the Task Force on **performing a safety assessment** in situations of **low-level presence in which the recombinant-DNA plant has already been found to be safe and authorized for commercialization for food by one or more countries** through an assessment performed according to the Codex Plant Guideline, **but the importing country has not determined its food safety, and on the requisite data and information sharing systems to facilitate this process.**

The working group will:

-Identify and incorporate into a draft annex the relevant sections of the Plant Guideline essential to the safety assessment in situations of low-level presence; and

-Identify information-sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply, and the data necessary to conduct an assessment of food safety in the importing country. The draft annex would 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.

2. Extract from the Annex Guidelines on LLP

27. In order for Codex Members to use this Annex, it is essential that they have **access to requisite data and information.**

28. Codex Members **should make available to a publicly accessible central database to be maintained by FAO information on recombinant-DNA plants authorized in accordance with the Plant Guideline.** This information should be presented in accordance with the following format: a) name of product applicant; ….

29. This process should **facilitate rapid access by importing Codex Members** to additional information relevant to the assessment of food safety assessment in situations of low level presence of recombinant-DNA plant material in foods in accordance with this Annex.

30. The authorizing Codex Members should make available **complementary information** to other Codex Members on its safety assessment in accordance with the Plant Guideline, in conformity with its regulatory/legal framework.

31. **The product applicant should provide further information and clarification as necessary to allow the assessment** according to this Annex to proceed, as well as a validated protocol for an event-specific or trait-specific detection method suitable for low-level situations and appropriate reference materials (non-viable or, in certain circumstances, viable). This is without prejudice to legitimate concerns to safeguard the confidentiality of commercial and industrial information.

3. Reference: http://www.mhlw.go.jp/english/topics/foodsafety/dna/02-03.html