Food and Agriculture Organization
of the United Nations

Codex and GM Food Safety Assessment

Hiroshi Yoshikura

DEBATE ON FOODS DERIVED FROM BIOTECHNOLOGY IN CODEX ALIMENTARIUS - A Chairperson's Experience

10 – 13 September 2019

I. History

1994: Flavr Savr tomato – 1st GM food plant

1995: Establishment of WTO

1996: Roundup Ready – herbicide resistance

→ Anti-GM campaign

→ Trade dispute

1997: 22nd CAC proposed work on foods derived from modern biotechnology.

1998: 45th CCEXEC recognized foods derived from modern biotechnology as one of 9 program areas in Midterm plan for 1998-2002.

1999: 23rd CAC: Japan expressed its willingness to host the Task Force

1999 November: Seattle Protests against WTO

2000 March: First session of GM Task Force in Makuhari

Agreed Texts in the 1st round (2000-2003) of CTFBT

- Principles for the **Risk Analysis** of Foods Derived from Modern Biotechnology
- Guideline for the Conduct of Food Safety Assessment of Foods Derived from **Recombinant-DNA Plants**
- Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA **Micro-organisms**
- Annex guidelines on assessment of possible **allergenicity** for plant, microorganism and animal guidelines

Agreed texts in the 2nd round of CTFBT (2005-2007)

- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA **Animals.**
- Annex guidelines for safety assessment of recombinant-DNA plants modified for **nutritional or health benefits**
- Food safety assessment in situations of **low-level presence of recombinant-DNA plant material in food.**

2000 Autumn: StarLink corn Incident

- Genetically modified corn containing glufosinate resistance gene (herbicide resistance)+ Bt protein Cry9C (insecticide)
- Approved for use in animal feed only but not for human consumption
- Over 300 food products were found to contain StarLink corn ⇨ Largescale Recall

Low Level Presence Incident

WTO Dispute after 1st round Task Force (DS291, 292, 293)

Approval and Marketing of Biotech Products

Complaints: USA, Canada, Argentina vs. Respondent: EC

Panel: Establishment 2003 → Adoption 2006

Appellate body indicated

- EC applied a general de facto moratorium; by so doing "EC acted inconsistently with its obligation under "Annex C(1)(a) and Article 8 of SPS Agreement (ensure the fulfilment of SPS measures are undertaken without undue delay and in no less favorable manner to imported products …)".
- As regards safeguard measures, EC acted inconsistently with its obligation under Articles 5.1 (SPS measure is based on an assessment …) and 2.2 (SPS measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles ….)

Annex III

Scope – recommended approach to:-

Low levels of recombinant DNA plant materials,

- which have passed a food safety assessment according to the Codex Plant Guideline in one or more countries
- which are present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined
- as a consequence of asymmetric authorization in different countries

- 6. This Annex does not address risk management measures: **national authorities will determine** when a recombinant-DNA plant materials is present at a level low enough for this annex to be appropriate.

Approach

Combination of

1. Food safety assessment in situations of or for advance preparation for such circumstances (Annex paragraph 2);
2. Data and information sharing mechanisms to facilitate utilization of the guideline and to determine whether it should apply (Annex paragraph 3) In order to use this Annex, it is essential that they have access to requisite data and information (Annex paragraph 27).
3. Only certain elements of the Plant Guideline will be relevant for LLP ⇨ The guiding principles were the same for both the plant and LLP guidelines.

Cf. Annex B: Transparency of Sanitary and Phytosanitary Regulations in SPS Agreement

Diverse views among Members on “Guidance on Data and information sharing” - para 28

f. unique identifier
g. links to the information on the same product in other databases maintained by relevant international organizations, as appropriate; ⇦ *Reference to Biosafety Clearing House of Cartagena Protocol and/or OECD Bio Track Product Not agreed*

h. summary of the safety assessment, which should be consistent with the framework of food safety assessment of the Codex Plant Guideline; ⇦ *Structured following the headings of the Codex Plant Guidelines.*

i. where detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situation may be obtained[37].

[37]This information may be provided by the product applicant or in some cases by Codex Members. ⇦ *“viable material” related to intellectual property right matters.*

Event-specific vs. Trait-specific detection

⇨The product applicant* should provide further information and clarification

- To be reminded: The LLP Guideline is based on the food safety assessment using comparators because it is based on the r-DNA plant guide line.
- Guideline after +10 years and global data sharing in the era of technological innovation, e.g., gene editing.