The Codex

"PROPOSED GUIDELINES ON CRITERIA FOR METHODS FOR DETECTION, IDENTIFICATION AND QUANTIFICATION OF SPECIFIC DNA SEQUENCES AND SPECIFIC PROTEINS, IN PARTICULAR IN FOODS DERIVED FROM MODERN BIOTECHNOLOGY"

Update on the draft status and future perspectives.

International Workshop on
Harmonisation of GMO Detection and Analysis for Central and South America

Codex Alimentarius

- ***Codex Alimentarius* is a collection of internationally adopted food standards to protect consumers' health and ensure fair practices in food trade.**

- Program established in 1962 by the World Health Organization and the Food and Agriculture Organization of the UN

- Elaborated through consensus building and a scientific basis

Codex Alimentarius legal status

- Traditional role as an optional technical reference for national regulatory frameworks.

- **New role as a reference for justified measures of sanitary protection, recognized by the SPS* agreement of WTO.**

*and, arguably, TBT.

Codex Works related to foods derived from Modern Biotechnology

- Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology
- *Codex* Committee on Food Labeling
- *Codex* Committee on Methods of Analysis and Sampling

Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology

- Elaborates guidelines for risk analysis and food safety assessment of Foods derived Modern Biotechnology
- It has incorporated 4 guidelines and 3 annexes to the *Codex Alimentarius*.

Codex Committee on Food Labeling

- Draws labelling provisions. One of its purposes is to examine those problems related with food advertisement, especially when connected with claims of benefits and misleading descriptions.

- Working from 1991 in *"provide guidance on how the fact that a food derived from 'modern biotechnologies' can be made known to the consumers".*

Codex Committee on Methods of Analysis and Sampling

- Defines criteria for Codex methods of analysis and sampling, and coordinates the work of Codex with other international groups working in methods of analysis and sampling and quality assurance systems for laboratories.

- CCMAS is currently working on *"Draft guidelines on criteria for methods for detection, identification and quantification of specific DNA sequences and specific proteins, in particular in foods derived from modern biotechnology"*

Specific provisions regarding GMO Analysis Methods in Codex Alimentarius

- Explicit:
  - Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (risk management tool)
  - Annex on situations of low level presence to the Guideline for the Safety Assessment of Foods derived from rDNA Plants.
- Implicit?:
  - CODEX standard for organic products.
  - General Standard for the Labeling of Prepackaged Foods (only in case a known allergen is transferred)

History of the draft guideline

- 2001: drafting process initiated after exchanges between CCMAS, the Task Force and the Labeling Committee - Originally intended only for GM foods. Work led by Germany and UK
- 2009: scope expanded to specific DNA and Proteins of interest, in particular as biomarkers for biotech foods.

Current Status

- Draft has been just revised by a electronic WG, co-chaired by Argentina, UK and Germany.
- Countries and organizations can now submit comments in writing to the CCMAS Secretariat.
- Guideline will be considered again by CCMAS at step 4/8 of the Codex Process.

Current scope of the Guideline

- *These guidelines provide information for the validation of methods for the detection, identification, and quantification of specific DNA sequences and specific proteins in foods derived from modern biotechnology. These Guidelines may also provide information on the validation of methods for other specific DNA sequences and proteins of interest in other foods.*

Current Structure

- **Main Text:**
  - **Introduction, Definitions, Method Validation, Specific Considerations, Quality Control Requirements**
- **Annexes:**
  - **Required Information**
  - **Definitions**
  - **Validation of a Quantitative PCR Method**
  - **Validation of a Qualitative PCR Method**
  - **Validation of a Protein-Based Method**

Perspectives

- Open issues:
  - Scope language
- Potential room for improvement in:
  - Guideline structure.
  - Guidance gaps (primer design criteria, use of uracyl-n-glycosylase, “practicability” criteria, suitability for developing countries, others?).
  - (Codex) Style: notes, “recommendations”, references.

Getting involved

- The report of the electronic Working Group is already available.
- The report and detailed eWG debates can be found in ("login as guest"): www.agrobiotecnologia.gov.ar/ccmas
- Written comments can be submitted through Codex Focal Points to the CCMAS

Thank you for your time and interest!

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