codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 7 **CX/MAS 09/30/8-Add.2**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING
Thirtieth Session
Balatonalmádi, Hungary, 9 - 13 March 2009

PROPOSED DRAFT GUIDELINES ON CRITERIA FOR METHODS FOR THE DETECTION AND IDENTIFICATION OF FOODS DERIVED FROM BIOTECHNOLOGY

GOVERNMENT COMMENTS AT STEP 3

ARGENTINA

Argentina would like to reiterate its appreciation for the document prepared by Germany and England, which we consider very valuable in its technical aspects.

However, it is important to note that the Argentine position during the 29th session of the CODEX Committee on Methods of Analysis and Sampling (CCMAS) is maintained, in particular the proposal on how to tackle this job.

a) <u>On the organization of the guidance:</u>

Given the wide applicability of PCR and immunological (ELISA and lateral flow) detection methods to a wide range of significant toxins and pathogens of actual food safety relevance, the availability of CCMAS guidelines for enabling the general and harmonic use of these methodologies is very necessary.

In addition to these general guidelines, annexes containing specific considerations for special classes of analytes could be easily developed if regarded necessary by the CODEX Committee or Commission.

Consequently, we propose to reorganize the current text of CX/MAS 08/29/8 on two documents:

One of them could be entitled "*Guideline for the validation and quality control of a PCR method*"; it would begin with general considerations for PCR methods, and then provide additional considerations for qualitative and quantitative methods.

In addition to this general guideline, an annex on supplementary considerations for the analysis of foods derived from biotechnology using PCR could be developed.

In this way, guidance would be readily available and/or could be easily complemented with further annexes (if necessary) for other analytes, e.g. on the determination of enterotoxigenic *E. coli* in foods.

In parallel, the other document could be entitled "*Guideline for the validation and quality control of immunological methods*", and it would begin with general considerations equally applicable for ELISA or lateral flow methods, and then provide additional considerations for qualitative and quantitative methods.

In addition, it would have an annex on supplementary considerations for protein-based methods for the analysis of foods derived from biotechnology.

In this way, guidance would be readily available and/or could be easily complemented with further annexes (if necessary) for other analytes, e.g. on the determination of mycotoxins in foods.

This proposal only requires a simple reorganization of the paragraphs already present in the document. Argentina would be willing to collaborate with such editing work, if necessary.

Argentina understands that it will be more positive if the forthcoming CCMAS document is elaborated in this fashion. The final guideline would cover a much broader spectrum of relevant issues in food quality/safety with little extra work, since most of the concepts in the current draft are of general application.

b) <u>On the scope of the methods for foods derived from biotechnology</u>

Argentina considers that the work on "Analysis Methods for Biotechnology food products" must be organized and guided according to the background of CODEX documents in this matter, in order to avoid situations that not have been covered by the relevant CODEX bodies.

After analyzing the CODEX corpus, we have identified only two potential situations calling for the elaboration of guidance regarding methods of analysis of foods derived from modern biotechnology:

1-Organic products:

In the CODEX standard for organic products (GL32-99), it is stated that all the materials and products derived from genetically modified organisms (GMO) are incompatible with organic production. Feeds derived from GMO are not even admissible in emergency situations (art. 15). It can be noted that, in addition to the derivatives of GM crops, the additives and processing aids derived from GM microorganisms neither are admissible (art. 19).

Therefore, in case of organic food it might be considered relevant to verify the absence of ingredients derived from recombinant-DNA organisms. Nevertheless, considering the purposes of such determination in the context of GL32-99, it would be irrelevant to know the quantity or even the identity of the involved transgenic events. It would only be relevant to certify the complete absence of any event, since no presence is tolerated. Therefore, in this area it will only be necessary to employ qualitative methods, and it would be desirable that such methods are capable of detecting as much events as possible, even when this implies not being able to identify or discriminate the specific event(s) involved; for instance by performing PCR on the 35s promoter sequence, present in most current genetic constructs.

2 - Low presence of GM plant material:

The "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" has been approved in the last meeting of the CODEX Commission. This document contains only one mention to detection methods, which are included in the relevant information that should be provided to an *ad hoc* database, currently being developed by the FAO.

Although this food safety assessment guideline does not mention the need or usefulness of detection methods for foods derived from recombinant-DNA plants, we can make two inferences from its scope. In the first place, as the safety assessment of food derived from r-DNA organisms is performed on a case by case basis (which means event by event), it is essential to identify the event for the cases covered by this guideline. Moreover, since the use of the document depends on the level of presence of the ingredient derived from recombinant-DNA plants, quantification is a must. Therefore, in this area, it will be a need to have strictly specific and quantitative methods for each event.

Therefore, Argentina proposes that specific guidance for foods derived from modern biotechnology should focus in two situations, namely:

a) Qualitative methods (protein methods or nucleic acids methods based on proteins or genetic elements frequently used), for the certification of organic products. Guidance to validate these methods should include and be equally suitable for products derived from GM crops and GM microorganisms.

b) Quantitative and event-specific methods (nucleic acids methods based both on the sequences of the genetic construct and the insertion site), to be used in situations of low level presence of recombinant-DNA plant material requiring a food safety assessment.

c) <u>On the biotech-specific terminology:</u>

For the sake of clarity and coherence, it would be advisable to utilize the specific terminology and definitions incorporated by the *Ad Hoc Task Force on Foods derived from Biotechnology* in several CODEX guidelines and, for instance, refer to "foods derived from recombinant-DNA organisms" in the main text of the guideline.

d) Considerations on Annex II of document CX/MAS/09/30/08. CODEX definition applicable to analysis of foods derived from biotechnology methods

Since the CODEX Manual of Procedure includes a chapter for definitions, it is considered that those definition of general applicability proposed in the draft guidelines should, if the committee agreed should be placed in the mentioned section of the Procedural Manual instead of the draft, in order to avoid future duplication of work or incongruence among CODEX documents.