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**Re: CX/MAS 10/31/3 CCMAS “Proposed 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”**

Dear Madam:

On behalf of the Biotechnology Industry Organization (BIO), we welcome the opportunity to provide comments on the document “Proposed 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” that is under development in Codex Committee on Methods of Analysis and Sampling (CCMAS).

BIO is a recognized NGO before the Codex Alimentarius Commission and represents more than a 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in 31 countries. BIO members are involved in the research and development of healthcare, agriculture, industrial and environmental biotechnology products.

BIO applauds the work of the Chairman of the electronic working group (e-WG) to invite collaborative input in order to attempt to achieve consensus on the scope and objective of the document. The e-WG made significant progress in agreeing the scientific rationale to broaden the scope of the document to include protein and/or DNA detection for all foods – and not specifically to foods derived from modern biotechnology – as indicated by the Codex Commission at their 2008 CAC meeting.

Broadening the scope of the document is appropriate for a number of reasons:

1. Criteria for methods of detection work in the Codex Procedural Manual do not include areas relevant to protein and/or DNA detection generally;
2. A method of detection guidance document focused on foods derived via a process, such as biotechnology, inappropriately characterizes the product as unique in composition, nutritional quality or end use. Foods and food ingredients derived from modern biotechnology are not different from their conventional counterparts in composition, nutritional quality and/or end use. Therefore, there is

- no scientifically-based justification for specific guidance related to detection of DNA/protein from use of r-DNA technology;
3. Broader guidance would be of greater use for foods produced for the entire food and feed trade than guidance directed to the more narrow use of foods derived from modern biotechnology; and,
  4. The 2002 FAO/WHO Evaluation of Codex, a major recommendation was that Codex devote resources to standards more horizontal in nature. Thus, guidance with a broader scope is more in line with the report's recommendation to Codex and more useful for member governments.

Given the rationale provided, BIO therefore, recommends the use of Alternative Title 1 and the Alternative Scope Paragraph 6 currently listed as bracketed text options. The alternative title and scope are consistent with a more scientifically-based approach, with resulting guidance likely to be more useful for detection of DNA/protein generally.

Again, BIO appreciates the opportunity to participate in the work of the e-WG and all the efforts in developing the document to date. We also appreciate the opportunity to provide these comments and look forward to the continuing work of the Committee.

Sincerely,

Michael J. Phillips, Ph.D.,  
Head, BIO Delegation

Cc: Secretary, Codex Alimentarius Commission, Joint FAO/WHO Standards  
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