BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

January 3, 2011

Ministerio de la Protección Social
Dirección General de Salud Pública
Grupo de Promoción y Prevención
Carrera 13 No. 32 - 76
Bogotá, D.C., Colombia
E-mail: bolarte@minproteccionsocial.gov.co
Website: http://www.minproteccionsocial.gov.co/

Dear Sirs/Madams,

The Biotechnology Industry Organization respectfully submits the following comments in response to the proposed Draft Resolution of the Ministry of Social Welfare "Adopting the technical regulation on requirements for the labelling of food and the identification of raw materials for human consumption which contain genetically modified organisms, and adopting other provisions."

The Biotechnology Industry Organization BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

Specifically we would like to call your attention to the following comments to the proposed regulation, which we would recommend to both clarify the focus of the regulation as well as ensure conformance with international guidance.

Article 3 – Definitions:

- Conventional homologue: We recommend the removing of the term "microorganisms" and suggest the following alternative definition to be consistent with the Codex Alimentarius Commission: "A related plant variety, its components and or/products for which there is experience of establishing safety based on common use as food."

- Product derived from GMO: We recommend the following alternative definition: "material(s) produced whole or in part from genetically modified organisms (GMOs)."

Article 4 – Labeling characteristics and requirements:

We recommend that the text of the document be clarified to ensure that the focus is food *intended for human consumption.*

Therefore the text would read:

1. The food, ***intended for human consumption that contains GMOs***, or that used raw materials that are GMOs, is not substantially equivalent to the values of the existing nutritional information, compared to the conventional homologue or the food product being traded.

2. The manner of storing, preparing or cooking the food, ***intended for human consumption that contained GMOs***, or the use of raw materials that are GMOs, differs due to the GMO, as compared to the conventional homologue or the equivalent food product in the marketplace.

3. A food ***intended for human consumption that contained GMOs***, or that uses raw materials that are GMO, where an allergen that consumers do not expect was introduced as a result of the genetic modification. The presence of an ingredient containing the allergen must be stated on the label, as mentioned in the paragraph of Section 5, item 5.2.2 of Resolution 5109 of December 29, 2005.

4. A food ***intended for human consumption*** that has been improved in its physical, chemical or functional characteristics and these differ with those of its conventional counterpart.

Article 5 – Additional information on food or raw materials that are GMOs or that may contain GMOs.

We recommend that Article 5 be aligned with Article 18.2 (a) of the Cartagena Protocol on Biosafety which addresses documentation for Handling, Transport, Packaging and Identification of Living Modified Organisms. We recommend that Article 5 of the proposed regulation apply to **Living Modified Organisms and not Genetically Modified Organisms**.

Article 18.2 (a) states:
2. Each Party shall take measures to require that documentation accompanying:
a) Living modified organisms intended for direct use as food or feed or for processing, clearly identifies that they "may contain" LMOs and are not intended for intentional introduction into the environment as well as a contact point for further information. The Conference of the Parties, as the meeting of the Parties to this Protocol shall take a decision on detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of this Protocol.

And as elaborated in Decision BS-III/10:

> 4. *Requests* Parties to the Protocol and urges other Governments to take measures ensuring that documentation accompanying living modified organisms intended for direct use as food or feed, or for processing, in commercial production and authorized in accordance with domestic regulatory frameworks, is in compliance with the requirements of the country of import, and clearly states:
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> (a) In cases where the identity of the living modified organisms is known through means such as identity preservation systems, that the shipment contains living modified organisms that are intended for direct use as food or feed, or for processing;
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> (b) In cases where the identity of the living modified organisms is not known through means such as identity preservation systems, that the shipment may contain one or more living modified organisms that are intended for direct use as food or feed, or for processing;
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> (c) That the living modified organisms are not intended for intentional introduction into the environment; (d) The common, scientific and, where available, commercial names of the living modified organisms; (e) The transformation event code of the living modified organisms or, where available, as a key to accessing information in the Biosafety Clearing-House, its unique identifier code;

Parties are already implementing its requirements as outlined in decision BS-III/10 in a way that is of minimal cost and not disruptive to trade. Although further decision on BS-III/10 has been postponed for until MOP-7, we recommend adopting language consistent with BS-III/10 paragraph 4(b). As the proposed language in Article 5 of this draft regulation will have a negative effect on trade and will be overly burdensome to implement.

Thank you for the opportunity to comment.

Sincerely,

Matthew O'Mara
Director, International Affairs