BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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International Trade and Cooperation Team
Korea Food and Drug Administration (KFDA)
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Re: KFDA Notice 2008-193 Dated October 7, 2008 Regarding Labeling Standards for Genetically Modified Foods (Draft)

Dear Sir or Madam:

On behalf of the Biotechnology Industry Organization (BIO), I am writing in response to the above referenced notice regarding the draft revision of the Labeling Standards for Genetically Modified Foods ("Draft Revision"). Based in Washington, DC, BIO represents more than 1,200 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.

BIO supports regulatory programs, policies, and decisions that are based on sound science and that hold biotechnology-derived products to the highest standards of health and environmental safety. We believe national and global regulatory measures should be consistent with the World Trade Organization (WTO) Agreements, and the Association works toward this end in a number of international fora, including the Codex Committee on Food Labeling and other international bodies supporting the development of international food standards.

Korea is a very important trading partner to BIO member companies. At present, Korea is the sixth largest market for U.S. food and agriculture products – with a market of over $1 billion - many of which contain products derived from agricultural biotechnology. BIO is very concerned about the scope of the Draft Revision. It appears to require labeling of all food products approved in Korea for human consumption containing ingredients derived from agricultural biotechnology products. Such requirements will have an unjustified negative impact on trade of these food and agriculture products between the United States and Korea.

BIO does not support mandatory labeling for products of biotechnology, particularly when such requirements are based on the *process* and not on the final product. BIO believes that labeling

requirements should be science-based and must give consumers meaningful information about the foods they buy and eat. For example, U.S. law limits affirmative labeling requirements for food to situations where there is a scientifically valid and constitutionally reasonable rationale for protecting the public, such as making nutrition information available to promote healthy food choices or warning about a common food allergen to protect susceptible populations. Therefore, under current statutes and regulations of the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA), changes to foods require labeling only if the product has been significantly changed nutritionally or if there have been changes in other health-related characteristics of the food (allergenicity, toxicity, or composition). BIO agrees with the U.S. government that mandatory labeling requirements for foods derived from modern biotechnology that are substantially equivalent to conventional food products are not based on science and have the potential to disrupt trade.

BIO further strongly supports the laws and regulations administered by FDA and USDA that require food labeling to be truthful and not misleading. Labeling foods that are indistinguishable from foods produced through traditional methods misleads consumers by falsely implying differences where none exist. It also risks diverting attention from important safety and nutritional information. Food companies have the right to voluntarily place claims on their products and often do so. However, U.S. federal law is very clear that the burden of truthfulness and non-misleading statements of the claim falls on the food company. While the stated purpose for the Draft Revision is to respond to the "consumer's right to know about genetically modified foods", BIO asserts that, in fact, requiring labeling of foods derived from biotechnology will actually have a negative impact on the quality of information provided on food labels and would mislead consumers to think that there is some unique aspect to the food product when in fact there is none.

Notably, a recent study from the Asian Food Information Center (www.afic.org) of more than 1000 adults in China, India, Japan, Philippines and the Republic of Korea demonstrates that, in fact, consumers in Asia do not feel that the presence of biotechnology-derived ingredients should be included on food labels. None of those interviewed in China, India, Philippines and Japan suggested the presence of biotechnology-derived ingredients as an additional item to be included on labels. In Korea, only a very small number of consumers (3% of total respondents) mentioned biotechnology contents as information to be added on labels. Additionally, the survey data from Korea indicated that 74% of Korean respondents feel that current food labels provide sufficient information for their purposes.[1] The AFIC study results support the view that the consumers are much more interested in other food information, not the presence of biotechnology-derived ingredients.

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[1] The full study results are available at: http://www.afic.org/2008/consumerresearch.php?news_id=819&start=0&category_id=25&parent_id=25&arcyear=&arcmonth=

In addition, the Draft Revision raises concerns with respect to Korea's compliance with WTO Agreements. For example, Article 2.2 of the Agreement on Technical Barriers to Trade (TBT Agreement) requires WTO members to ensure that technical regulations do not create unnecessary obstacles to international trade. To this end, it requires technical regulations to "not be more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create." In BIO's view, the Draft Revision does not fulfill a legitimate objective under Article 2.2, as biotechnology-derived foods undergo a safety assessment process that ensures there are no risks to consumer health or the environment. The Draft Revision, therefore, risks violating Article 2.2 of the TBT Agreement by effectively presenting a technical barrier to trade that is more restrictive than necessary.

Korea risks negative impacts on its food supply if the Draft Revision is implemented as it currently stands. Evidence in other countries implementing mandatory, broad-scope labeling requirements for foods derived from modern biotechnology demonstrates that these new labeling requirements effectively ensure food manufacturers will reformulate or identity-preserve their products to exclude any ingredients from products derived from modern biotechnology. Such actions increase the costs of manufacturing food products, thereby increasing the costs of the products to consumers at a time when food prices are already substantial.

To conclude, BIO is concerned that the Draft Revision would have an unjustified negative impact on trade of food and agriculture products while not providing useful information to consumers related to nutrition or safety. Specifically, BIO wishes to reiterate the following with respect to labeling policies for biotech foods:

- Labels should not be required if the food is substantially equivalent to its traditional counterpart.
- Labels should only be required if the food is materially different from its traditional counterpart in nutritional or safety attributes.
- Voluntary claims are acceptable on food labels provided such labels are truthful, do not mislead consumers and are verifiable.

Thank you for this opportunity to provide comments on the Draft Revision.

Sincerely,

Sharon Bomer Lauritsen
Executive Vice President
Food and Agriculture