

13 February 2008

Mr. Sung-Woong Nah  
Director, Trade Cooperation Team  
Ministry of Health and Welfare  
Joongang-dong, Gwacheon-si, Gyeonggi-do 427-721  
Republic of Korea

Re: Act on Transboundary Movements of Living Modified Organisms, etc., Law  
Number 6448

Dear Mr. Nah:

Further to the recent entry into force of the Act on Transboundary Movements of Living Modified Organisms (LMO Act), the Biotechnology Industry Organization<sup>1</sup> submits the following comments on a number of its provisions that are of concern to our member companies.

Korea imports millions of tons of corn and soybeans from the United States each year. The United States is the largest biotechnology crop producing country in the world, with 73 per cent of corn and 91 per cent of soybeans grown in biotech varieties. From October 2006 through September 2007, the United States supplied Korea with 3.88 million metric tons of corn worth \$693 million, a substantial amount of which was likely derived from products of agricultural biotechnology. During that same time period, Korea imported 514 thousand metric tons of soybeans worth \$145 million from the United States, again most of which was likely derived from agricultural biotechnology varieties.

It is within this context that we write to you regarding the Risk Review Consultation requirements in the LMO Act. Prior to the entry into force of the LMO Act, the agricultural biotechnology companies followed the risk assessment procedures outlined in the applicable regulations for biotech crops by making the appropriate applications to both the Korean Food and Drug Administration (KFDA) and Ministry of Agriculture and Forestry's Rural Development Administration (RDA). This process has been demonstrated to be efficient and addressed all appropriate safety assessment needs for these products sufficiently.

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<sup>1</sup> BIO represents more than 1,150 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the annual BIO International Convention, the global event for biotechnology. [www.bio.org](http://www.bio.org).

However, the LMO Act includes globally unprecedented regulatory requirements that are both duplicative and burdensome. Primary among these are the new Risk Review Consultation provisions. Following entry into force of the LMO Act, Article 13 of the LMO Act provides that three additional government agencies, including Korea Center for Disease Control & Prevention (KCDC), National Fisheries Research & Development Institute (NFRDI), and National Institute of Environmental Research (NIER) are now required to conduct Risk Review Consultations on biotech crops. As a result, as many as five agencies are going to assess each crop, in many cases for the very same purpose.

For example, for human health risk assessment purposes, KFDA has followed the *Codex Alimentarius* Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (Codex Guideline). Such reviews are very similar around the world for every country that follows the Codex Guideline. According to provisions of the LMO Act, KCDC is now required to conduct an additional human health risk assessment on the very same biotech crops that KFDA also assesses. The results of these assessments should effectively be identical. Clearly, such a requirement is not scientifically justified, will simply duplicate efforts and will have the likely effect of causing significant delays in the approval process. In addition, there are no examples of other Codex member countries that require such redundant human health risk assessments by more than one government agency for the same biotech crop.

Another example can be found in the NFRDI Risk Review Consultation mandated by the LMO Act which requires an assessment of impact on marine ecosystems. There are no known cases indicating that biotech crops can impact marine ecosystems, nor are there any other examples of countries requiring such a review as part of the risk assessment process.

Similarly, the LMO Act requires NIER to have a new role in the Risk Review Consultation for possible impacts on natural ecosystems, duplicating the environmental risk assessment already conducted by RDA. Such processes are both redundant and likely to cause unnecessary confusion and burdens to both government agencies and applicants alike.

Lastly, the LMO Act effectively requires LMOs intended for food, feed and processing only (LMO-FFPs) to be subject to the same environmental risk assessment requirements as LMOs that are intended for environmental release. It is recognized by the provisions of the Cartagena Protocol on Biosafety, the very Protocol that the LMO Act implements in Korea, as well by numerous Parties to the Protocol, that a full environmental risk assessment is not appropriate for LMO-FFPs.

No evidence exists of negative impacts to the environment or human health caused by biotech crops. In fact, studies show that there are numerous environmental and socio-economic benefits that accrue from their use. This history of safe and beneficial use, combined with the large amounts of biotech crops imported into Korea over the years, demonstrates that the risk assessment systems followed by KFDA and RDA to date have been successful in protecting the environment and consumer health in Korea. BIO contends that the new Risk Review Consultation provisions of the LMO Act are excessive, and are not based on science or global consensus of the safety of biotech crops. Therefore, BIO respectfully submits the following recommendations:

1. The risk assessment process for biotech crops should be science based and not duplicative. Where particular products are to be assessed by RDA and/or KFDA, those products should not be subject to duplicate Risk Review Consultations by KCDC, NFRDI, and NIER.
2. The LMO Act should not apply to the products that have already been approved by the Korean authorities before the LMO Act entered into force.
3. As it is recognized by the provisions of the Cartagena Protocol on Biosafety, different safety assessment processes should be put in place for products that are intended for environmental release versus those products that are food, feed and processing. Any environmental risk assessment for LMO-FFPs under the LMO Act should be limited to assessing the environmental risk of unintended release.

Thank you for your kind consideration of the points raised in this letter. We have a number of additional concerns about the LMO Act that we would also be happy to outline as well. Should you wish to discuss these, or the contents of this letter, further, please do not hesitate to contact me directly.

Sincerely,



Sharon Bomer Lauritsen  
Executive Vice President  
Food and Agriculture