

U.S. Biotech Crops Alliance

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Elizabeth Jones
Senior Trade Advisor, China and Japan
New Technologies & Production Methods
Office of Agreements and Scientific Affairs
Foreign Agricultural Service
U.S. Department of Agriculture

Dear Ms. Jones:

Thank you for requesting comments from the U.S. Biotech Crops Alliance (USBCA) regarding China's Ministry of Agriculture (MOA) amendment of the GMO Safety Assessment Measures (Decree No. 8). Our comments focus on revisions to Article 16 because of their potential negative impacts on technology innovation and international trade due to the lack of predictability, transparency and timeliness of the Chinese agricultural biotechnology approvals system.

The revisions to Article 16 make two significant changes to the approvals system that are of concern to the USBCA. First, the revisions remove references to specific timelines for submission of applications and for MOA to respond to those applications. It allows MOA to adjust the submission and approval process at any time which creates an unpredictable process. It also will allow MOA to make further changes that could provide a basis for MOA to formalize and implement the rumored "one year/one approval" practice. According to CropLife China, such a change, coupled with current requirements from China on local studies and exporting country approval prior to submission that create two-to-three year delays on approvals, will lead to an additional one-to-two year delay on approvals and commercialization.

The elimination of specific timelines for the technical review and approval also raises concern that applications would experience "undue delay" that is prohibited under Article 8 and Annex C(1)(a) of the SPS Agreement. In addition, the absence of specific timelines raises concerns that discrimination against imported or foreign-origin ag biotech products could occur if MOA applies the Measures in a manner that is inconsistent with Article 2.2 of the SPS Agreement and Article III:4 of the GATT.

USBCA recommends that language be restored to the Measures that provide for clearly-defined approval procedures and timelines. USBCA urges that China be encouraged to develop an approval system that mirrors the general international practices followed by Argentina, Brazil, Japan and South Korea. Those approval systems 1) accept and review applications year-round with no time window restrictions, 2) allow the process to continue after receiving each

application and response to technical questions, instead of restarting the process, and 3) after the technical review is completed, issue the approval within a reasonable timeframe, such as 20 working days. At a minimum, the Measures should be restored from previous years that provided for three submission and three decision windows per calendar year.

Finally, Article 16 includes reference to "scientific, economic and social factors" that would be considered by MOA in the approval process. The inclusion of economic and social factors would provide the basis for political and social views into decision-making that, in turn, would add more unpredictability to the regulatory process and delay in commercialization.

By allowing economic and social factors in addition to scientific factors to be considered in the decision process, Article 16 appears to be inconsistent with the requirement that SPS measures be based on scientific principles, potentially violating China's WTO obligations.

We would recommend that the inclusion of "scientific, economic and social factors" in the decision-making process for biotech submissions be removed from the revision. USBCA supports science-based safety assessments and decision-making for biotech applications.

For there to be continued innovation in crop biotechnology and for the industry to have access to technologies that will support a stable, sustainable food supply for China and the rest of the world, USBCA supports science-based regulatory systems that are transparent, timely, and predictable.

Sincerely,

American Farm Bureau Federation

National Grain and Feed Association

American Seed Trade Association

National Oilseed Processors Association

American Soybean Association

North American Millers' Association

Biotechnology Industry Organization

U.S. Canola Association

Corn Refiners Association

U.S. Grains Council

National Corn Growers Association

U.S. Soybean Export Council

cc: Sharon Bomer Lauritsen, USTR

Julia Doherty, USTR

Joan Hurst, USTR

Katherine Nishiura, USDA

Wade Sheppard, USDA