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Genetically Engineered Feed Products, Regulations Update

Report Categories:

Biotechnology - GE Plants and Animals Grain and Feed Oilseeds and Products

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Report Highlights:

Under Taiwan's Feed Control Act, amended on February 4, 2015, all genetically engineered (GE) products for animal feed use are now required to register with Taiwan's Council of Agriculture (COA) for premarket approvals by February 4, 2017. While the non-food GE event application and approval process has, thus far, proceeded without concern, COA has yet to finalize certain guidelines.

General Information:

Under Taiwan's Feed Control Act, amended on February 4, 2015, all genetically engineered (GE) products for animal feed use are now required to register with Taiwan's Council of Agriculture (COA) for premarket approvals by February 4, 2017, in accordance to Article 11 of the amended Act. This change shifts the regulatory burden from Taiwan's Food and Drug Administration (TFDA), the agency which previously had regulatory oversight over all GE event approvals. TFDA will now focus exclusively on those GE events which may enter general food system (i.e. not destined for animal feed) while COA will oversee GE event approvals in commodities destined for animal feed.

Taiwan's COA notified "Regulations for Certificate Inspections of Genetically Modified Feed and Feed Additives" to the World Trade Organization (WTO) as G/SPS/N/TPKM/373 on September 24, 2015, with a 60-day comment period. To provide sufficient time for regulatory compliance, the notified Regulation is anticipated to be implemented as soon as COA's regulatory system is established, anticipated in January, 2016 at the earliest.

While local life science companies (LSCs) are in communication with COA regarding the GE feed safety assessments to be included in the applications, COA has yet to publish or finalize such guidelines. COA also needs to establish a GE feed safety assessment committee to review the dossiers and conduct feed safety assessments. COA will need time to build its safety assessment capacity on non-food products – such as alfalfa - as TFDA has no experience to share.

"Grandfathered" GE Products Exempt from COA Technical Review

Those GE products/events either previously submitted to TFDA and/or granted TFDA approval are exempt from COA technical review and approval requirements. However, LSCs are required to submit dossiers for these grandfathered GE products to COA. As of reporting date, local LSCs have submitted all GE cotton, canola, and one sugar beet for food use dossier to TFDA, ahead of COA's implementation date for the notified regulations.

TFDA's current approval list comprises of 99 GE products including four canola, twelve cotton, 21 soybean, and 62 corn events. Six cotton and one GE sugar beet applications have been granted approval but are yet to publish. All non-corn and non-soybean GE products in commercial chains for food use are required to register to TFDA by February 5, 2016 in compliance with February 5, 2014 amended Act Governing Food Safety and Sanitation. TFDA extended its GE regulatory scope to all GE products from the existing GE corn and soybeans in accordance to February 5, 2014 amended Act Governing Food Safety and Sanitation.

This list of those GE events currently approved by TFDA, and thus approved by COA, is located **HERE**

Concerns Linger as Anti-GE Rhetoric Spreads

Concerns linger regarding COA's (thus undefined) policy on animal products including meat, eggs, and milk, including potential safety and biosafety assessment. COA is currently drafting a law governing living modified organisms (LMO). There is concern that future premarket approval registration will include additional data on environmental safety. Although it is not clear of the draft act governing

LMOs, this may prolong approval and regulatory process.

Anti-GE rhetoric has become increasingly common in Taiwan's Legislative Yuan (LY) and media reports. Approximately two years ago, Taiwan LY members passed legislation mandating a GE labeling and traceability system specifically modeled after the European Union. Post efforts were eventually successful in limiting the scope of that legislation, but the possibility exists that LY members will seek to expand current GE labeling legislation. Just recently, on November 30, a bi-partisan coalition of Taiwan's Legislative Yuan (LY) members passed the first reading of a proposed amendment which prohibits genetically engineered food in school lunches.