

U.S. Biotech Crops Alliance

March 12, 2015

Commissioner Vytenis Andriukaitis
Directorate General Health and Food Safety
European Commission
Rue de la Loi 170
B-1049 Brussels

Dear Commissioner Andriukaitis,

The undersigned organizations, representing a broad section of the U.S. food and agricultural industry, wish to provide you with their comments on the review of the European Union's (EU) regulatory procedure for approving the import of new biotechnology products being conducted by DG SANTE.

Since 1990, the EU has had three different regulations covering imports of biotechnology products. The current (2003) regulation articulated a science-based and workable framework for imports of biotechnology food and feed, including the central role of the European Food Safety Authority (EFSA) in providing independent food safety and environmental risk assessment. Unfortunately, the implementation of the procedure has been slow and suffered from political interference. This has led to large disruptions in the trans-Atlantic trade in raw materials used by EU food and feed producers and increased costs for producers, the agricultural supply chains and EU consumers.

Whereas the time required for EU decisions on new biotech crops has only lengthened in recent years, this process now appears to have come to a complete stop. The last approval dates back to November 2013. Unfortunately, the review of the approval procedure for the import of biotech events has introduced an additional level of uncertainty and risk.

Therefore, our organizations believe that a number of core principles and commitments must result from this review:

- A commitment to uphold and not fragment the EU's single-market for imported biotech crops.
- A commitment for respect of existing law while the review is underway. The review must not be used to further delay decisions on products that have completed all risk assessment and administrative procedures and only await final Commission action.

- A commitment that the result of the review shall not be retroactive and create additional delays for products in the regulatory queue.
- A commitment to ensure regulations are consistent with the EU's obligations under the WTO SPS agreement, and to meet the timeline of 18 months (from submission to approval) of GM import dossiers provided for in the current approval procedure.
- A commitment to maintain the role of the EFSA risk assessment process and to provide sufficient resources for EFSA to complete its task in a timely manner, and a commitment to develop a practical and more efficient science-based risk assessment process for stacked biotechnology events.
- A commitment to complete the review no later than the six-month deadline from installation of the new Commission (30 April 2015).
- A commitment to full transparency during conduct of the review including regular consultation with stakeholders.
- A commitment to providing for EU access to the global supply of proven safe crop products enhanced through the use of biotechnology in the interest of EU agriculture and consumers.
- A commitment to establish a policy covering the low-level presence of biotechnology traits that is commercially feasible and for the Commission to participate formally in the Global Low Level Presence Initiative.

Adherence to these principles would support a number of the recently published Commission goals in the Transatlantic Trade and Investment Partnership (TTIP) negotiations, including:

- Pragmatic and speedy procedures and decisions on regulations related to trade;
- A single approval process for exports from all EU countries, just as there is a single approval process for US exports to the EU;
- Clear and transparent processes and time lines that reflect the fact that we are each other's most important trading partner; and
- Strong mechanisms for resolving trade issues.

U.S. Biotech Crops Alliance
March 12, 2015
Page 3

We urge you to consider these principles as part of the review and that the results of the review do not impede market access for biotechnology products that meet all requirements of existing EU legislation.

Sincerely,

American Farm Bureau Federation

American Seed Trade Association

American Soybean Association

Biotechnology Industry Organization

Corn Refiners Association

National Association of Wheat Growers

National Corn Growers Association

National Grain and Feed Association

National Oilseed Processors Association

North American Millers' Association

U.S. Canola Association

U.S. Grains Council

U.S. Soybean Export Council

cc: President Jean-Claude Juncker
Vice-President Frans Timmermans
Vice-President Jyrki Katainen
Secretary-General Catherine Day
Commissioner Cecilia Malmström
Commissioner Phil Hogan
Commissioner Carlos Moedas
Commissioner Elzbieta Bienkowska
Ambassador David O'Sullivan