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BIOTECH AND FOOD REGULATIONS BACKGROUNDER
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ASA Position

ASA opposes a patchwork of state labeling requirements for foods containing biotech products and supports Public Law 114-216, the National Bioengineered Food Disclosure Standard, which sets a uniform national standard that preempts individual state laws requiring labeling of GMOs. We are supportive of the definition of "bioengineering" found in Section 291, which excludes modifications that could have been obtained through conventional breeding or found in nature, and we believe that any rules or regulations promulgated by USDA to implement the law should adhere to the statute.

ASA supports efforts to update the regulatory process or Coordinated Framework for biotech traits provided any changes do not disrupt foreign markets and approval procedures by their governments. We oppose broadening the definition of "products of biotechnology" to include traits derived through plant breeding innovations, such as gene editing, which would require them to undergo pre-market approval and prevent their widespread adoption in the market.

Background

Biotech Food Labeling Standards

In previous years, anti-biotech activists pushed state governments to create mandatory biotech labeling laws which would have resulted in a patchwork of standards that was both burdensome to the food companies and costly to the consumer. In addition, imposing conflicting food labeling requirements in different states would have meant a GMO disclosure label could mean different things across the country.

ASA and other biotech supporters in the Coalition for Safe Affordable Food (CFSAF) launched a major grassroots effort and worked with Congress to set a uniform national standard that would preempt state laws and give more information to the consumer on biotech ingredients. Public Law 114-216, the National Bioengineered Food Disclosure Standard, was passed by Congress with bipartisan support and signed into law on July 29, 2016. The Senate passed the bill by a vote of 63-30 and the House subsequently passed the bill by a vote of 306-117. By creating a uniform national standard, the law ensures that the information on biotech ingredients in food is reliable and means the same thing regardless of the state in which it's purchased.

The National Bioengineered Food Disclosure Standard requires mandatory disclosure of bioengineered food in accordance with regulations that are to be promulgated by USDA and finalized by July 2018. Disclosure options for labeling include the use of text, symbols, or electronic/digital links with other allowances for small food manufacturers. The law defines bioengineering as:

> SEC. 291. DEFINITIONS. ‘‘In this subtitle: ‘‘(1) BIOENGINEERING.—The term ‘bioengineering’, and any similar term, as determined by the Secretary, with respect to a food, refers to a food— ‘‘(A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and ‘‘(B) for which the modification could not otherwise be obtained through conventional breeding or found in nature.)

USDA is expected to issue an Advanced Notice of Proposed Rulemaking (ANPR) soon, giving ASA and other stakeholders the opportunity to engage USDA in a variety of issues involved in the rulemaking process. USDA has indicated they intend to propose a rule by fall of 2017. We will continue to work with USDA and other stakeholders throughout the rulemaking and implementation.

Reform of Biotech Regulations

New biotech traits are regulated and approved under the Coordinated Framework developed in the 1980’s by USDA/APHIS, EPA and FDA. Each agency is responsible for reviewing new traits under different pre-existing laws. Some 30 years later, on January 19, 2017 APHIS proposed a new rule to reform Part 340 of the Plant Protection Act to with the intent of expediting reviews of traits that have already been approved for other crops. On the same day, FDA published a Request for Information (RFI) on the regulation of gene-edited plants which asks questions of the public about risks from gene edited plants and plant breeding innovations. FDA’s Center for Veterinary Medicine (CVM) published another proposal that expands their scope to include regulation of gene-edited animals, which is inconsistent with the scope of Part 340 Proposed Rule for plants. The comment period for all three proposals ended on June 19th, 2017.

ASA is working with other farm and industry organizations to ensure that any changes in the U.S. regulatory system for biotechnology do not send the wrong signals to governments in countries that import our crops, which we have been urging to adopt our current approval process as a model.

ASA provided comments on USDA./APHIS’s Part 340 which included praising the rule’s positive signals to exclude certain gene-editing techniques and urged USDA to encourage other countries to adopt similar regulatory systems. However, the rest of the rule is problematic and would expand the regulatory scope to include noxious weed authority. ASA is concerned that the rule as written will stifle innovation and increase the regulatory burden on producers and the agriculture industry.

ASA also provided comments on FDA’s Request for Information on gene-edited plants, arguing that applications of gene-editing techniques should not be required to receive pre-market regulatory approval because they are low-risk and similar to plants found in nature or developed through older breeding techniques.