

## **BIOTECH AND FOOD REGULATIONS BACKGROUNDER**

### **July 2014**

#### **ASA Position**

- Support and seek co-sponsorship of legislation (H.R. 4432 in House, not yet introduced in Senate) to establish Federal labeling standards for foods containing biotech ingredients to prevent a patchwork of state requirements.
- Modify FDA's proposal to withdraw GRAS status for partially hydrogenated vegetable oils.
- Lead efforts to accelerate USDA and EPA approvals for biotech traits and pesticide labels.

#### **Background**

##### **Biotech Labeling Standards**

Various states have held referendums or are considering state laws to mandate labeling of food products that contain biotech ingredients. Vermont has enacted the first legislation that requires biotech labeling. While this and future state actions may be challenged in future referenda or the courts, the prospect of having differing requirements in different states would make it extremely difficult and costly for food companies selling their products on a nationwide basis. At the same time, food and biotech companies through their trade associations, the Grocery Manufacturers of America and BIO, have indicated that they don't want to continue the expensive political and legal challenges required to fend off state labeling policies.

At the urging of ASA and other members of the Coalition for Safe Affordable Food, Reps. Pompeo (R-KS) and Butterfield (D-NC) introduced legislation (H.R. 4432) in April which would require the Food and Drug Administration to establish standards for labeling biotech foods. Mandatory labels would be required only if a biotech-containing food exhibited a characteristic different from a non-biotech food (e.g., allergenicity). Otherwise, standards would be set for the voluntary labeling of foods which either contain or do not contain biotech ingredients. The legislation would provide that these policies supercede state labeling laws, and would further require FDA to review all biotech applications, replacing current policy which provides for review only at the request of the applicant company.

##### **FDA Rulemaking to Remove GRAS Status for Partially Hydrogenated Oils**

On November 7, 2013, the Food and Drug Administration opened a comment period to measure support for the removal of GRAS status for partially hydrogenated oils (PHOs), because they contain trans fats. The withdrawal of GRAS (generally recognized as safe) status for a process rather than an ingredient is unprecedented. If this determination goes forward, PHOs would effectively be banned from the food supply.

The soybean industry has made remarkable strides in helping to remove trans fats from the U.S. diet; at its height in 2003, the edible oil industry produced over 8.8 billion pounds of products containing trans fats. By the end of 2012, the industry had removed over 6 billion pounds, a reduction of 68%. These reductions were supported by changes throughout the soybean industry, particularly the adoption of low-linolenic acid soybeans. Still, about four billion pounds of U.S. soybean oil was replaced in the food supply during that transition, largely replaced by imported palm oil.

As FDA weighs additional scientific evidence, ASA is encouraging the agency to consider alternative methods to continue to reduce trans fats in the food supply, including successful efforts in Denmark and Canada that set an upper limit on trans fats in foods. As a result, Denmark has concluded that industrially-produced trans fat is no longer a significant source of trans fat in that country.

The adoption of high oleic soybean varieties may be able to replace partially hydrogenated oils in many products. Projections by QUALISOY indicate that by 2016, approximately 900 million pounds of high oleic soybean oil will be available. We are confident that high oleic soybean oil can replace a substantial portion of the roughly 2.2 billion pounds of PHOs still in the market, given adequate time to bring these oils into production.

### **U.S. Approvals of Biotech Traits and Pesticide Labels**

Decisions on petitions for approval of new biotech traits at APHIS/USDA have taken an average of 31 months in recent years, and there has been a backlog of 13 petitions since September 2013. These delays are despite the announcement by Secretary Vilsack in September 2011 that the process would be streamlined and decisions completed in 13-15 months. There have been similar delays at EPA, where decisions are complicated by the need to take the Endangered Species Act into consideration when approving a pesticide product for use on a biotech crop engineered to resist it. In combination, these delays are risking the competitive advantage U.S. farmers have had over producers in other exporting countries.

ASA has taken the lead among grower organizations in addressing the biotech approvals issue. We have organized meetings between farm groups, BIO and APHIS as well as between farm groups and EPA. Responding to ASA's concerns, APHIS has committed to a timetable under which decisions on 12 of the 13 petitions pending as of last September will be made by the end of 2014. APHIS and EPA have indicated that they will coordinate their respective decision processes so that one agency will not wait for the other to approve a trait before it begins consideration.

At the same time, BIO has documented the approval delays and length of time current petitions have been waiting for decisions in a White Paper. ASA is willing to give APHIS time to see if it is able to meet its timetable for expected decisions, five of which are due in July 2014. If this timetable is not met, ASA will consider supporting efforts to put greater pressure on USDA to meet Secretary Vilsack's commitment to an accelerated process.