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March 7, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Docket No. FDA-2013-N-1317
Tentative Determination Regarding Partially Hydrogenated Oils**

Dear Sir or Madam:

I am writing on behalf of the American Soybean Association (ASA) regarding FDA's request for comment on its proposal to terminate GRAS status for partially hydrogenated oils (PHOs). ASA represents all U.S. soybean farmers on domestic and international issues of importance to the soybean industry. ASA's advocacy efforts are made possible through the voluntary membership in ASA by over 22,500 farmers in 31 states where soybeans are grown.

Removal of GRAS Status Would Result in Significant Costs to Soybean Farmers

ASA's own estimates, as well as more detailed econometric modeling completed by the soybean industry's QUALISOY board, confirm that the FDA's proposal, unless revised, would have very significant negative impacts on soybean farmers and others in the soybean industry. It is estimated that approximately 2.0 to 2.5 billion pounds of soybean oil are currently partially hydrogenated. The FDA's proposal to withdraw GRAS status for PHOs would result in the substantial substitution of imported and higher saturated fat palm oil for PHOs, and decrease U.S. soybean farmer incomes by approximately \$1.6 billion per year.

Dramatic Reduction of Trans Fat Consumption Already Has Been Achieved

There has been a dramatic reduction in U.S. consumption of trans fat over the last decade. At its height in 2003, the edible oil industry produced over 8.8 billion pounds of products that contained trans fat. By the end of 2012, the industry had removed over 6 billion pounds, a reduction of 68%. This change was reflected by an equivalent reduction in average daily per capita intake of trans fat, from 4.0 to 1.3 grams per day. Further, the FDA's label survey data suggests a continued downward trend in trans fat intake since 2010.

We applaud these strides in removing trans fat from the diet and note that these reductions were supported by changes throughout the food industry. Yet, as four billion pounds of soybean oil were removed from domestic food products during this transition, this sizeable market was largely taken over by imported palm oil as well as imported canola oil.

Soybean Industry is Developing Alternatives, But Needs More Time

The soybean industry has turned its focus to developing high oleic soybean varieties, which may be able to replace partially hydrogenated oils in many applications. Projections by QUALISOY indicate that approximately 1.3 billion pounds of high oleic soybean oil will be extracted from the 2016 crop of high oleic soybeans (harvested in the fall of 2016) and available for use by the food industry in 2017. Increasing quantities of high oleic soybean oil are projected to be available in subsequent years as our industry ramps up the production of high oleic soybean varieties. We are confident that high oleic soybean oil can replace a substantial portion of the roughly 2 to 2.5 billion pounds of partially hydrogenated oils that are still in the market. But that cannot happen without FDA's recognition of the importance of ensuring a sustainable, domestically-produced food supply.

Our grave concern is that the FDA proposal to remove GRAS status for PHOs will result in the substitution of higher saturated fat palm oil for PHOs. While we are confident that our industry will be able to ramp up high oleic soybean production over time to meet the needs of food manufacturers, vegetable oil processor and food manufacturer sources have shared with us that if the FDA's proposal to remove GRAS status for partially hydrogenated oils is finalized, food manufacturers are expected to move as quickly as possible to replace partially hydrogenated oils in their products – regardless of any extended FDA implementation date or transition time. This would replace our domestically-grown, sustainably-produced soybean oil with palm oil. The saturated fat profile of palm oil is 6.7 grams of saturated fat per tablespoon, compared to 2.0 grams for soybean oil. The result of this trade-off would be a “lose-lose” for both the government and American consumers.

FDA Action to Ban A Process is Unprecedented and Would Impair Technology Advancements

An additional concern is that this proposal would ban a process, rather than a substance. We strongly encourage FDA to keep all doors open to progress and new technologies. Some soybean oil is already fully hydrogenated through the process of interesterification, which results in virtually no trans fat. We believe this technology, combined with high oleic soybean production, can replace partially hydrogenated oil use in the medium term. We believe that the FDA's proposal is so sweeping in its application that it would stymie technological advances in oil processing that aren't even envisioned today. As there is no definition of “partially hydrogenated,” and as we know that the term encompasses a whole spectrum of oils, we are concerned that new technologies would be a casualty of the FDA's proposal.

Better Alternatives that FDA Should Pursue to Further Reduce Trans Fat Consumption

In answer to questions posed in the Federal Register notice, we note the examples of both Denmark and Canada in setting a limit on trans fats in food. Denmark has reduced its per capita intake of trans fat to 1.0 gram per day, a level at which it has concluded that industrially-produced trans fat is no longer a significant source of trans fat intake in that country and which compares to the current 1.3 grams in the U.S. This approach seems a more common-sense way to approach the goal of further reducing trans fats consumption in the U.S. diet than the FDA's current proposal, which we see as likely to lead to increased saturated fat consumption, increased reliance on imported oils in the U.S. food supply, diminished ability for food manufacturers to adopt innovative technologies, and costly in terms of U.S. production and jobs.

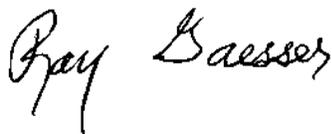
Summary

In summary and for the reasons noted above, we urge FDA to:

- Revise its proposal and not withdraw GRAS status for partially hydrogenated oils;
- Pursue alternative strategies that already have proven effective in greatly reducing trans fat consumption such as education, revisions to the nutrition fact panel, and limits on the amount of trans fats that food products can contain to be labeled free of trans fats; and
- Implement the aforementioned alternative strategies in a timeframe that is cognizant of the time needed to ramp-up domestic high oleic soybean oil production and for food manufacturers to reformulate their products with high oleic soybean oil and interesterified oils.

Thank you for the opportunity to share our views.

Sincerely,

A handwritten signature in black ink that reads "Ray Gaesser". The signature is written in a cursive style with a large, stylized "R" and "G".

Ray Gaesser
ASA President