National Milk Producers Federation

2107 Wilson Blvd., Suite 600, Arlington, VA 22201 | (703) 243-6111 | www.nmpf.org

November 17, 2017

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration (FDA)
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. FDA–2017–N–5991 Agricultural Biotechnology Education and Outreach Initiative; Public Meetings; Request for Comments

Dear Sir/Madam:

The National Milk Producers Federation (NMPF), based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies. Visit www.nmpf.org for more information.

NMPF submits these comments in response to FDA's request for stakeholder input regarding the FDA Agricultural Biotechnology Education Outreach Initiative. We completely support the work you are doing and commend for your efforts. In the Federal Register notice about this initiative, you raised three questions, we will address each in turn below.

1. What are the specific topics, questions, or other information that consumers would find most useful, and why?

Consumers need to know that bioengineered foods are safe. This docket is full of vicious, hostile and highly inaccurate statements that attempt to show otherwise. Below is a sampling that shows how some consumers perceive bioengineered foods.

> I have a very sensitive gut & learned quickly that processed GMOs are the worst of the worst for me.
>
> Our country is overwhelmed with diseases, many of which have been contributed to by the usage of GMO products.
>
> Do not use taxpayer dollars to promote GMO's. These are known carcinogens. How dare my government use my hard-earned money to promote poison to my family.
>
> We do not want your GMO's. We do not want them don't you know. We do not want them on our plate. This poison food our bodies hate.

There is much science that shows deleterious effects from GMO's

Many people have negative physical reactions to modified foods.

Stop killing us softly with GMO's.

I do not want my tax dollars go to promote something that's harmful to me and me fellow citizens. I'm suffering from epilepsy. GMO products have been proven harmful to humans and animals.

As part of its educational effort, FDA should review each comment filed in the docket and create a Question and Answer (Q&A) document that addresses the misperceptions raised about bioengineered foods. It is important that consumers have accurate information coming from an authoritative source they can trust for answers to the allegations that have been raised about this technology. This resource should be maintained on FDA's and USDA's websites as a downloadable document that can used by stakeholders in their educational outreach efforts as well.

2. Currently, how and from where do consumers most often receive information on this subject?

Clearly most consumers are not getting their information from medical experts, scientific journals or literature; instead they are getting their information from Internet sources not based on fact, amplified through social media and exacerbated by fear-based marketing efforts by unscrupulous food companies.

3. How can FDA (in coordination with USDA) best reach consumers with science-based educational information on this subject?

FDA, in coordination with USDA, should develop materials that explain the benefits of using bioengineering including using less pesticides, creating foods and feed with better traits and improved agricultural sustainability. To date, the benefits of bioengineering have not been properly conveyed.

FDA should develop additional informational materials that explain why eating a bioengineered food does not make a person a "GMO" themselves. Most people probably recognize that, but for some reason many people shun meat and milk derived from animals that have been fed bioengineered grain. FDA needs to dispel any fears created by the misperception that the meat or milk is somehow different – it isn't.

As noted above, FDA should create a Q&A document to debunk the massive misinformation that is everywhere. Both USDA and FDA should have that Q&A on their websites.

FDA should also educate consumers using its existing authority in the FD&C Act as described below.

FDA in its guidance[1] on labeling bioengineered foods states:

> The FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that is misbranded. 21 U.S.C. § 331(a). Under section 403(a)(1) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular. 21 U.S.C. § 343(a)(1). Section 201(n) of the FD&C Act (21 U.S.C. 321(n)) provides that labeling is misleading if, among other things, it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual. 21 U.S.C. § 321(n). In a 1992 "Statement of Policy: Foods Derived from New Plant Varieties" (1992 Policy) (Ref. 5) FDA explained its interpretation of the FD&C Act with respect to foods derived from new plant varieties, including varieties developed using bioengineering. **In the 1992 Policy, FDA stated that it was not aware of any information showing that bioengineered foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding (Ref. 5) [emphasis added].** Further, FDA concluded that the method of development of a new plant variety (including the use of new techniques such as rDNA technology) is generally not material information within the meaning of section 201(n) of the FD&C Act, and would not usually be required to be disclosed in the labeling for the food. This determination was reviewed and upheld by the court in Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 178–79 (D.D.C. 2000) (finding that FDA's determination that genetic engineering, alone, is not a material fact that warrants food labeling was entitled to deference) (Ref. 10). Labeling provided by manufacturers on a wholly voluntary basis regarding whether a food was or was not bioengineered as described in this guidance is acceptable to FDA, provided that such labeling is truthful and not misleading. Some consumers are interested in the information provided in such labeling.

[1] Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants

In that same guidance, FDA cautions the reader against making false and misleading statements with respect to bioengineering.

> Further, **a statement may be false or misleading if, when considered in the context of the entire label or labeling it suggests or implies that a food product or ingredient is safer, more nutritious, or otherwise has different attributes than other comparable foods because the food was not genetically engineered [emphasis added].** For example, the labeling of a bag of specific type of frozen vegetables that states that they were "not produced through modern biotechnology" could be misleading if, in addition to this statement, the labeling contains statements or vignettes that suggest or imply that, as a result of not being produced through modern biotechnology, such vegetables are safer, more nutritious, or have different attributes than other foods solely because the food was not produced using modern biotechnology.

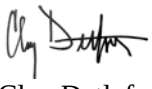
NMPF opines that the pervasive anti-bioengineered rhetoric that is ubiquitous, including in this docket, not only implies that bioengineered foods are not safe, it screams it. And, due to the constant rhetoric, any disclosure that a product is "not bioengineered" is an assertion that that product is safer. NMPF asks how can we overcome the fearmongering and educate consumers about the safety of bioengineered products and the benefits that they convey? At a minimum, FDA should require a qualifying statement, like the one below, to be used whenever any disclosure is made regarding the presence or absence of a bioengineered ingredient that has been deemed substantially equivalent to its conventional counterpart:

"*No material difference has been shown between ingredients created using bioengineering and ingredients created without bioengineering.*"

We believe that such a statement as above will go a long way in educating consumers and is consistent with the Bioengineered Food Disclosure statute which requires that bioengineered food disclosures shall not assert or imply that a bioengineered food is safer than, or not as safe as a non-bioengineered counterpart. We have a serious problem on our hands; consumers are constantly being misled and we must stand up for science.

We thank you for this opportunity to provide our views.

Sincerely,



Clay Detlefsen
Senior Vice President, Environmental and Regulatory Affairs & Staff Counsel