Biotechnology Innovation Organization

November 17, 2017

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

Re: *FDA-2017-N-5991: "Agricultural Biotechnology Education and Outreach Initiative; Public Meetings; Request for Comments"*

To whom it may concern:

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to provide comments to the Food and Drug Administration (FDA) on its proposed Agricultural Biotechnology Education and Outreach Initiative (*FDA-2017-N-5991).*

BIO is the world's largest biotechnology trade association, representing small and large companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of agricultural, healthcare, industrial and environmental biotechnology products. BIO represents its members in a number of matters related to the uses of biology-based technologies in agriculture, animal health and human health.

As stated by FDA in its Federal Register notice[1],

> "The Consolidated Appropriations Act, 2017 (Pub. L. 115-31) stipulates the Commissioner of Food and Drugs, in coordination with the Secretary of Agriculture, will use appropriated funds to provide consumer outreach and education regarding agricultural biotechnology and biotechnology-derived food products and animal feed, including through publication and distribution of science-based educational information on the environmental, nutritional, food safety, economic, and humanitarian impacts of such biotechnology."

BIO appreciates the breadth of the charge given to the FDA and the United States Department of Agriculture, (USDA). Modern agricultural biotechnology is a set of technological tools that are typically used in conjunction with each other to improve agricultural products and processes. Each of these technologies has a long history of progressive improvements, based upon scientific advances. Understanding that history helps the public place new biotechnology developments in context and leads to a greater appreciation of the importance of science in providing sufficient, nutritional food sustainably and with less environmental impact. BIO and its members are pleased that Congress understands the fundamental importance of sharing this information with consumers.

[1] Federal Register 82: 197, October 13, 2017p. 47750-47752 https://www.gpo.gov/fdsys/pkg/FR-2017-10-13/pdf/2017-22172.pdf

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Importance of Government Education and Outreach:

BIO, along with 65 food and agricultural organizations, supports this initiative[2] to help the public better understand science- and fact-based information about agricultural biotechnology.

Unfortunately, there is a tremendous amount of misinformation about agricultural biotechnology in the public domain – especially on the internet and in social media posts.

For too long the government voice has not been heard in these discussions, leaving industry experts, scientists, academics, farmers and other stakeholders in the food value chain to defend the thoroughness of the U.S. regulatory system and the safety of the technology.

The debates about food labeling, disclosure and transparency continue to take place in the public arena – and rulemaking is ongoing for the National Bioengineered Food Disclosure Standard[3] – so an accompanying government-led education and outreach program is especially timely. Dedicated educational resources will ensure key federal agencies responsible for ensuring the safety of our nation's food supply – namely the FDA and USDA – are able to better convey science- and fact-based information about the use of biotechnology in farming and food production to the public.

The funding for this initiative has been criticized by some who allege that it will be used for the government to "promote genetically modified organisms";[4] however, we urge FDA and USDA to focus this program on 1) educating the general public about the breadth of agricultural biotechnology, i.e., it is much more than "genetically modified organisms; 2) explaining the science underlying the development of the biotechnologies used in agricultural production and food processing, and 3) informing the public about the rigor of the regulatory system – specifically about how products are evaluated and assessed for safety to human health, agriculture, animal health and the environment.

In short, the government has a role to play in defense of its regulatory evaluation processes as well as in defense of the safety of products reviewed and authorized via that process.

FDA is seeking comments on three questions:

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

In our experience, the most useful messages to convey to consumers are 1) the breadth of agricultural biotechnology, including microbes, plants and animals; 2) the role science has played in improving agriculture production and food safety; and 3) the history of plant and animal breeding and uses of microbial fermentation in food production.

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[2] http://www.biotech-now.org/food-and-agriculture/2016/04/food-ag-groups-urge-support-for-biotech-education-provision

[3] https://www.ams.usda.gov/rules-regulations/gmo

[4] https://www.washingtonpost.com/news/wonk/wp/2017/05/03/the-government-is-going-to-try-to-convince-you-to-like-gmo-foods/?tid=a_inl&utm_term=.d63d6642568f

With respect to specific topics, many BIO members have been involved with improving the genetic makeup of microbes, plants or animals, using various techniques, from breeding and selection to genetic engineering. As such, we have substantial experience in helping the public understand the history and interrelatedness of different genetic modification techniques.

In particular, some of BIO's member companies are also members of the Council for Biotechnology Information (CBI), which launched its *GMO Answers* initiative in July 2013 to answer consumers' questions about genetically modified organisms (GMOs), including genetically engineered, or transgenic, crops in the U.S. food supply.[5] For the purposes of these comments, BIO will be citing as examples some of the resources developed by CBI as part of the *GMO Answers* program. However, it is essential to keep in mind that transgenic crops, commonly referred to as "GMOs" by many members of the public, are but one of many applications of agricultural biotechnology.

In October 2016, as part of its GMO Answers program, CBI conducted a nationwide survey to gather consumers' top ten questions related to GMOs[6] and to further the conversation on biotechnology's role in agriculture. The survey, conducted by Opinion Research Council (ORC), showed that the top questions consumers have about GMOs deal with food safety and health.[7]

Safety:

In 2016, the National Academies of Sciences, Engineering and Medicine released the results of a two-year study assessing all available research studies for persuasive evidence of adverse health effects directly attributable to consumption of foods derived from genetically engineered crops but found none.[8, 9]

Likewise, in 2015 testimony before the Senate Committee on Agriculture, Nutrition and Forestry, Susan Mayne, Ph.D., Director of FDA's Center for Food Safety and Applied Nutrition said:

> "In its 1992 Policy Statement, FDA explained that it found no basis to conclude that foods derived from new plant varieties developed using genetic engineering techniques, as a class, differ from other foods in any meaningful or uniform way or pose any different or greater safety concern than foods developed by traditional plant breeding."[10]

BIO strongly feels – and scientific consensus agrees – that more than three decades of scientific analysis and data and two decades of widespread use and consumption endorse

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[5] https://gmoanswers.com/about
[6] https://www.prnewswire.com/news-releases/gmo-answers-kicks-off-annual-get-to-know-gmos-month-300337757.html
[7] https://gmoanswers.com/top-10-consumer-questions-about-gmos-answered-2016
[8] http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=23395
[9] https://gmoanswers.com/sites/default/files/Are%20GMOs%20Safe%3F_NAS%20Study_p_d_f.pdf
[10] https://www.fda.gov/NewsEvents/Testimony/ucm468833.htm

the benefits and safety of genetically engineered crops and animals.[11] But for the public, concerns about safety remain. A 2015 Pew Research survey found that a majority of adults (57 percent) believe eating "genetically modified" foods is unsafe, with only 37 percent believing it is generally safe.[12]

First and foremost, the government should – in its own voice – provide fact-based and consumer-facing information to assure the public about the safety of foods containing biotech ingredients.

What is a "GMO"?:

While many consumers express concerns about the safety of "GMOs", most cannot explain what they think a GMO is. In what is supposed to be a comedic segment on Jimmy Kimmel Live in 2014, the lack of public understanding about GMOs becomes painfully clear.[13] In the 4-minute video clip, Kimmel's film crew conducts man-on-the-street interviews about GMOs. An excerpt:

Interviewer: "What is a GMO?"

> Respondent: "I don't know. I know it's like some corn. Bad stuff, right? [laughs] …I know it's bad. But to be completely honest with you, I have no idea."

A 2017 Michigan State University Food Literacy and Engagement Poll found that more than one third of Americans think that non-GMO products do not have genes.[14]

The 2017 study, "*GMO Beyond the Science: Perplexing Case of Consumer Confusion About GE Foods*" by Brandon McFadden, Assistant Professor in the Food and Resource Economics Department at the University of Florida, has some important reference insights:[15]

He writes:

> "Research has shown that people are poorly educated about basic science and genetics, which is one of the key reasons why there is so much conflicting results stemming from consumer polls regarding food."

Understanding the history and science underlying modern biotechnology goes a long way toward alleviating fears about safety. It has been our experience that once people are reminded of the genetics lessons taught in high school science class and learn how the fruits

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[11] https://geneticliteracyproject.org/2013/08/27/glp-infographic-international-science-organizations-on-crop-biotechnology-safety/
[12] In this survey, "genetically modified" was used inaccurately as synonymous to "genetically engineered." http://www.pewinternet.org/2015/07/01/chapter-6-public-opinion-about-food/
[13] https://www.youtube.com/watch?v=EzEr23XJwFY
[14] http://food.msu.edu/articles/msu-food-literacy-and-engagement-poll
[15] https://geneticliteracyproject.org/wp-content/uploads/2017/02/McFadden_together_finalA.pdf

and vegetables we enjoy today have evolved through history, the technology is demystified in a way that makes sense to the average consumer, helping to foster acceptance and easing concerns.

We think explaining the science underlying modern biotechnology, along with a brief history of plant and animal breeding, is an important component of agricultural biotechnology education. *GMO Answers* offers this "What is a GMO" infographic,[16] "How Are GMOs Created?" chalkboard video[17] and "History of Genetic Modification in Crops"[18] infographic as examples.

Regulatory Scrutiny:

A third element of a government-led education and outreach program should be to familiarize the public with the U.S. regulatory process. A common misconception about agricultural biotechnology, is that regulations are not strict enough and do not adequately assess for safety. In fact, agricultural biotechnology products are more stringently regulated than other agricultural products, and the length of time it takes for a product to get to market often spans more than a decade.[19, 20, 21]

Explaining the thoroughness of the Coordinated Framework – clarifying the independent roles of the USDA, FDA and EPA and how each is responsible for assuring safety and efficacy – can give the public confidence in the government regulatory process.

Environmental Safety:

Just as the public has concerns about agricultural biotechnology and food safety, there are concerns and a great deal of confusion about environmental impacts. Agricultural biotechnology has been a key part of the modern farming evolution that has allowed farmers and growers to operate more sustainably in the following ways:[22]

- Insect resistant (IR) transgenic crop technology has reduced insecticide applications.
- New herbicide tolerant (HT) crops, developed with genetic engineering, have allowed farmers to switch to more benign forms of less toxic herbicides.
- Agricultural biotechnology has facilitated the use of reduced tillage, and no-till framing practices have significantly reduced agriculture's greenhouse gas emissions by decreasing the burning of fossil fuels and retaining more carbon in the soil.
- Biotech crops increase productivity on existing agricultural land and protect biodiversity by sparing lands not intensively cultivated.
- Through the use of agricultural biotechnology, we can enhance the health and welfare of livestock while lessening their impact on the environment.

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[16] https://gmoanswers.com/sites/default/files/What_Is_GMO_Infographic_Oct2015_cover_0.pdf
[17] https://www.youtube.com/watch?v=2G-yUuiqIZ0&feature=youtu.be
[18] https://gmoanswers.com/find?hidden-field=call-search&a=history+of+plant+breeding&type=&topic=All+Topics&sortby=Relevance
[19] https://croplife.org/plant-biotechnology/regulatory-2/cost-of-bringing-a-biotech-crop-to-market/
[20] https://gmoanswers.com/how-are-gmos-regulated
[21] https://gmoanswers.com/think-gmos-arent-regulated-think-again
[22] http://www.pgeconomics.co.uk/page/43/

We think the public would benefit from learning how agricultural biotechnology has actually contributed to environmental sustainability.

Role of Technology in a Modern Ag System:

From GPS-guided self-driving tractors to drones monitoring crop health, today's modern farms use an array of innovative technologies to produce healthier crops and animals while utilizing resources more efficiently than ever before.

An increasing majority of the food-consuming public is unfamiliar with farming. A national survey conducted by the U.S. Farmers & Ranchers Alliance (USFRA) found that 72 percent of consumers know nothing or very little about farming or ranching.[23] To improve our agricultural literacy in the United States, the public would benefit greatly from some basic education about the workings and successes of America's modern farms.

Biotech Food with Consumer Traits:

A new wave of biotech food is hitting store shelves that contains positive consumer traits. This is vastly different from 20 years of farmer-input traits such as insect resistant corn, which the consumer did not directly correlate to a benefit. Now, consumers can access products that might reduce their risk of cancer, lessen food waste, benefit health, or provide more convenience. Examples include a non-browning and low acrylamide potato, a non-browning apple, high-oleic soybean oil and a high lycopene pink pineapple. New technologies, derived from genomics, are bringing significant shifts in time to market, enabling a new wave of these projects in future years.

Familiarizing the public with new consumer-facing traits will raise awareness about the technology's broad applications.

Biotech Food Labeling and Disclosure:

Following a thorough debate on whether or not foods containing GMOs should be labeled or disclosed in the marketplace – and how that information can be conveyed to minimize consumer confusion – the National Bioengineered Food Disclosure Standard Act was signed into law and the rulemaking process is ongoing. Once the rule is finalized, we urge the FDA and USDA to supplement its educational content to include clarification to consumers about how to interpret labels and other disclosure mechanisms to get more information about their food.

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[23] https://www.prnewswire.com/news-releases/nationwide-surveys-reveal-disconnect-between-americans-and-their-food-130336143.html

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

According to the International Food Information Council (IFIC), "About three-quarters of consumers say they rely on friends and family at least a little for both nutrition and food safety information. But only 29 percent actually have high trust in family or friends as information sources."[24]

Increasingly, consumers get information from social media in the form of headlines, infographics and short tweets. This makes communicating about a complicated history, science and regulatory system a challenge.

A number of industry and stakeholder groups are engaged in efforts to educate consumers about food, farming and technology. For reference, some of these are:

- The Council for Biotechnology/GMO Answers
- Crop Life International – A Seed Story: Plant Biotechnology in Focus and Plant Biotechnology Benefits webpage
- The International Food Information Council – including "A Useful Guide to Understanding GMOs" and "*Food Biotechnology: A Communicator's Guide to Improving Understanding*"
- U.S. Farmers & Ranchers Alliance Food Dialogues
- Center for Food Integrity Best Food Facts
- Peel Back the Label coordinated by America's Dairy Farmers
- A Fresh Look
- The International Service for the Acquisition of Agri-biotech Applications (ISAAA)

In contrast, the Non-GMO Project Verified program (identified by the non-GMO butterfly label) communicates to consumers at the retail level, as well as via website, Facebook, Twitter, Instagram and Pinterest about the alleged virtue of purchasing non-GMO products. According to its website, the non-GMO Project represents $22.3 billion in annual sales and more than 43,000 verified products for over 3,000 brands.[25] It claims that it is committed to "providing consumers transparent choice in the marketplace."[26] However, the Non-GMO project also states "There is no scientific consensus on the safety of GMOs" and defines GMO crops or foods containing organisms that are known to be genetically modified as "high risk."[27]

Since this runs counter to FDA's 1992 policy statement,[28, 29] and the prevailing scientific consensus, it raises the question of whether the Non-GMO Project verified label is "truthful

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[24] http://www.foodinsight.org/press-releases/survey-nutrition-information-abounds-many-doubt-food-choice

[25] https://www.nongmoproject.org/product-verification/verification-faqs/

[26] https://www.nongmoproject.org/about/

[27] https://www.nongmoproject.org/gmo-facts/high-risk/

[28] https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm

and not misleading." While that question is not at issue in these comments, it is representative of the types of divergent information that exist in the public domain on this topic and illustrates the challenge of engaging in a communications initiative on a non-level playing field.

Fueled by the growth of the Non-GMO Project, many companies are turning to what some could argue is deceptive food labeling to distinguish their products and to play upon food safety fears and misconceptions. An increasing number of "non-GMO" products are appearing in stores that don't have a GMO counterpart and therefore should not be labeled. Examples include, GMO-free tomatoes, salt, water and orange juice. This creates significant confusion in the marketplace.

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

Tone:

Our experience has shown that consumers respond favorably to discussions about food when their concerns and skepticism are embraced and their choices are respected. *GMO Answers* has worked to change the tone of these discussions by humanizing the dialogue and enabling independent experts to answer consumer questions speaking from their personal expertise and experience.[30] For this effort, a government expert should present relatable, credible content in the government's voice.

Messengers:

Polling shows that messages about science and safety resonate with consumers when they come from trusted sources with expertise or first-hand knowledge. According to IFIC's Food Technology Survey, the following sources are the most trusted for information of food biotechnology:[31]

1. Health organization (e.g. American Medical Association, American Heart Association, etc.)
2. Health professional (e.g. doctor, nurse, pharmacist, dietitian, etc.)
3. Government agency (e.g. U.S. Department of Agriculture [USDA], U.S. Food & Drug Administration [FDA], Centers for Disease Control & Prevention [CDC], etc.)
4. Farmer
5. Scientist

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[29] https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm

[30] https://gmoanswers.com/about

[31] http://www.foodinsight.org/sites/default/files/ctools/IFIC%202014%20Food%20Technology%20Survey_Topline%20Summary_FINAL.pdf

Components of an Effective Public-Facing Communications Plan:

- **Online Resources:** In our modern information age, online communications are imperative. The Pew Internet Project states that seven out of ten people use social media[32] for information, so in addition to a stand-alone web page, cross-posting information and providing links to online resources on Facebook and Twitter is crucial. Equally important will be the use of Search Engine Optimization to ensure that online information is easy to find.

  As referenced above, stakeholder organizations are already communicating in this space on this topic, so BIO encourages the FDA and USDA to follow this model, while not duplicating efforts.

  Some online government resources currently exist but could benefit from updating and Search Engine Optimization:

  - FDA Education Resource Library: https://www.fda.gov/Food/ResourcesForYou/Consumers/ucm239035.htm
  - FDA Food Facts for Consumers: https://www.fda.gov/Food/ResourcesForYou/Consumers/ucm077286.htm
  - FDA Education Resource Library: https://www.fda.gov/Food/ResourcesForYou/Consumers/ucm239035.htm
  - USDA Biotechnology FAQs: https://www.usda.gov/topics/biotechnology/biotechnology-frequently-asked-questions-faqs
  - Roles of USDA Agencies in Biotechnology: https://www.usda.gov/topics/biotechnology/roles-usda-agencies-biotechnology
  - USDA - Regulation of Biotech Plants: https://www.usda.gov/topics/biotechnology/how-federal-government-regulates-biotech-plants
  - USDA – Agricultural Biotechnology Glossary: https://www.usda.gov/topics/biotechnology/biotechnology-glossary

- **Media Truth Squad:** The USDA and FDA could refute false claims in major articles by proactively writing op-eds, requesting corrections or engaging in comments on online sites before the stories have a chance to gain traction.

- **Traditional Media:** In the 1990's and early 2000s, the Biotechnology Coordinator for FDA's Center for Food Safety and Applied Nutrition, Dr. James Maryanski, did a number of media interviews such as this one with PBS: http://www.pbs.org/wgbh/harvest/interviews/maryanski.html.

  Using this model, a trusted FDA expert spokesperson could do a media tour with

[32] http://www.pewinternet.org/fact-sheet/social-media/

targeted food reporters and editorial boards. Interviews could be audio or video-taped and edited into short-form videos and pod-casts for use online or turned into video and audio news releases.

- **Town Halls:** In a similar effort, a trusted FDA spokesperson could embark on a tour of town hall visits to targeted locations that could be broadcast and archived online. FDA staff conducted a number of town hall meetings in the 1990s-2000s to explain FDAs regulatory system for all new plant varieties, including those developed with agricultural biotechnology, to the general public.
- **Advertising:** FDA and USDA should also explore with the Ad Council opportunities for free or discounted advertising and public service announcements.

- **Curriculum Materials:** The American Farm Bureau Foundation – in partnership with the International Food Information Council Foundation – developed "Bringing Biotech to Life," an Educational Resource Guide for Grades 7-10.[33] USDA and FDA could look at adapting an existing program within USDA's National Agricultural Library[34] to focus more directly on delivering fact-based information on agricultural biotechnology to teachers and students.

Microorganisms and the need for public education:

Consumers are not aware of the essential role that microorganisms play in food production, processing and safety. Understanding the value of microbes will become even more important as the public learns about the "microbiome" associated with human, animal, plant and environmental health.

BIO associates itself with and fully supports the comments submitted to this docket by the Enzyme Technical Association, which, like BIO, represents the enzyme products industry in the United States. Modern biotechnology is a safe and valuable tool when applied to microorganisms used to produce enzymes and other products of fermentation. Biotechnology enables the enzyme industry to produce microorganisms that generate high quality enzyme products at a reasonable cost, products that otherwise could not be produced commercially. There is value in FDA and USDA providing more information to consumers about the benefits of these kinds of applications of biotechnology in food and animal feed.

Conclusion:

The United States is a world leader in agricultural productivity and our food and agriculture industry sectors are healthy and prosperous, in large part due to our use of modern agricultural and industrial bioscience innovations and responsible use of technology. Public outreach and science education – especially aimed at fostering consumer acceptance – is an important part in ensuring American agriculture and global leadership remains strong.

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[33] https://www.agfoundation.org/bringing-biotech-to-life/
[34] https://www.nal.usda.gov/afsic/classroom-and-curricula

BIO believes that farmers and growers must have access to modern agricultural tools to meet current and future food production challenges. Biotech crops, as the fastest adopted crop technology in the world,[35] have a proven track record of safety as well as benefits to farmers, consumers and the environment. And new consumer-facing traits, products derived from new breeding techniques such as gene editing and the potential benefits of animal biotechnology, demonstrate the promises of new innovation when technology is embraced.

We strongly support efforts by FDA and USDA to 1) help the public better understand agricultural biotechnology applications and the science underlying its development; 2) alleviate any concerns about the safety of agricultural biotechnology products on the market; and 3) provide public confidence in the U.S. regulatory system.

BIO appreciates the opportunity to respond to the specific questions posed by FDA. We look forward to continuing to work with FDA and USDA in the future to ensure that the Agricultural Biotechnology Education and Outreach Initiative provides the appropriate types of information and resources to the U.S. public.

Sincerely,

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[35] http://www.isaaa.org/resources/publications/briefs/52/executivesummary/default.asp