CENTER FOR
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By Electronic Submission
Docket No. FDA-2017-N-5991
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments to Docket No. FDA-2017-N-5991 on Agricultural Biotechnology Education and Outreach Initiative.

The Center for Science in the Public Interest (CSPI)[1] appreciates the opportunity to submit this letter in response to the Food and Drug Administration's (FDA) request for comments on its Agricultural Biotechnology Education and Outreach Initiative. The education initiative should focus on factual and scientifically accurate information about the safety of genetically engineered (GE) crops and animals and how they have been developed. In particular, the FDA should focus its education initiative on (1) the safety of GE crops and animals; (2) how scientists develop them; (3) which GE crops and animals are commercially available; and (4) the types of foods and ingredients made from GE varieties. By focusing on only a few subjects, the FDA can have a greater impact with the limited funds available for the initiative.

I. The FDA's education campaign should provide information about the safety of GE foods and ingredients.

The FDA should focus its education initiative on the safety of GE foods and ingredients because many consumers incorrectly believe those foods and ingredients are not safe to eat. In 2015, the Pew Research Center conducted a poll that found only 37 percent of American adults agreed that it was safe to eat genetically modified (GM) food while 57 percent said that it wasn't.[2] That contrasted with its poll of scientists who were members of the American Association for the Advancement of Science. Eighty-eight

[1] CSPI is a nonprofit education and advocacy organization that focuses on improving the safety and nutritional quality of our food supply. CSPI seeks to promote health through educating the public about nutrition; it represents citizens' interests before legislative, regulatory, and judicial bodies; and it works to ensure advances in science are used for the public good. CSPI is supported by the 600,000 member-subscribers to its *Nutrition Action Healthletter* and by foundation grants. CSPI receives no funding from industry or the federal government.

[2] Funk C and Rainie L. (2015). Public and Scientists' Views on Science and Society. *Pew Research Center*. Available at http://www.pewinternet.org/2015/01/29/public-and-scientists-views-on-science-and-society/.

percent of them said it was safe to eat GM foods.[3] In a 2016 poll by the Annenberg Public Policy Center, only 24 percent of Americans agreed with the statement that scientists have established that "[g]enetically modified foods on the market in the U.S. are as safe as the conventionally grown varieties of the same crop." Another 24 percent thought that statement was false, while 47 percent said they thought that scientists are not sure.[4] Moreover, a 2017 study by the International Food Information Council Foundation found that of the consumers who seek non-GMO labels, 73 percent do so "because they believe these foods are either healthier, safer, or better for the environment."[5]

The viewpoints documented in those polls are not consistent with the worldwide, scientific consensus that foods and ingredients from currently grown GE crops are as safe as the same foods from non-GE crops. The FDA states on its website that "GE plant varieties marketed to date are as safe as comparable, non-GE foods."[6] Additionally, after thoroughly reviewing all of the available evidence on GE crop safety, a National Academy of Sciences report concluded that "no differences have been found that implicate a higher risk to human health and safety from these GE foods than from their non-GE counterparts."[7] That same conclusion has been reached by other respected scientific and regulatory bodies, including the European Commission and the World Health Organization.[8,9]

Given this disconnect between the facts and consumer opinions, the FDA should focus on providing safety information about GE foods and ingredients. Discussing food safety is within the FDA's area of expertise. The FDA can explain the international safety tests that are required and how regulators independently evaluate safety data before GE food products enter the food supply. In addition, the FDA has reviewed safety data from all currently grown GE crops and can speak about that review.[10] The FDA's statements on the

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[3] Rainie L and Funk C. (2015). An elaboration of AAAS scientists' views. *Pew Research Center*. Available at http://www.pewinternet.org/2015/07/23/an-elaboration-of-aaas-scientists-views/.

[4] Annenberg Public Policy Center. (2016). Annenberg science knowledge survey: Zika and GMOs. March 9-13, 2016 (Week 5): Appendix. Available at https://www.annenbergpublicpolicycenter.org/wp-content/uploads/GMOS-WK5-Appendix.pdf.

[5] International Food Information Council Foundation. (2017). 2017 food & health survey: Healthfulness and safety top GMO concerns. Available at http://www.foodinsight.org/sites/default/files/2017%20Food%20and%20Health%20Survey%20-%20Final%20Report.pdf/.

[6] U.S. Food and Drug Administration. (2015). Consumer info about food from genetically engineered plants. Available at https://www.fda.gov/Food/IngredientsPackagingLabeling/GEPlants/ucm461805.htm.

[7] Committee on Genetically Engineered Crops, Board on Agriculture and Natural Resources, and Division on Earth and Life Studies. Genetically engineered crops: Experiences and prospects. Executive summary: Human health effects. Page 18. *National Academies of Sciences, Engineering, and Medicine.* Available at https://www.nap.edu/read/23395/chapter/3#19.

[8] European Commission. (2015). Fact sheet: Questions and answers on EU's policies on GMOs. Available at http://europa.eu/rapid/press-release_MEMO-15-4778_en.htm.

[9] World Health Organization. (2014). Frequently asked questions on genetically modified foods. Available at http://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/.

[10] U.S. Food and Drug Administration. (2017). Biotechnology consultations on food from GE plant varieties. Available at https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon.

safety of GE foods would be more authoritative, however, if the FDA had a mandatory pre-market approval process instead of its current voluntary consultation process.

II. The FDA's education initiative should provide materials that explain the science behind genetic engineering, which crops have been engineered, and how those GE crops enter the food supply.

The second area that the FDA's initiative should focus on is explaining the science behind genetic engineering, which crops have been engineered, and how those GE crops end up in our food. In a 2016 poll by the Annenberg Public Policy Center, nearly two-thirds of Americans rated their understanding of GMOs as poor or fair.[11] Similarly, a 2013 poll by Rutgers University found that 54 percent of respondents characterized their knowledge about GMOs as "very little" or "nothing at all."[12] How can one expect consumers to eat GE foods and ingredients if they have little or no information about the science of genetic engineering?

Consumers also lack knowledge about the differences between various breeding techniques employed to create the different varieties of crops grown by farmers. In a 2015 survey of a representative sample of over 1,000 Americans, a significant portion of respondents thought selective breeding did not alter any genes, while they associated GM with genetic alteration.[13] This is not accurate, as both genetic engineering and selective breeding change a crop or animal variety through alternation of their genome.

Consumers also are not aware of which GE crops are available commercially. A recent poll by Michigan State University (MSU) found that when consumers were asked about how often they consume GMOs, 19 percent said every day, 25 percent said at least once a week, 10 percent said at least once a month, and 26 percent said they weren't sure.[14] In fact, researchers found that only fifty percent of Americans correctly believed GM corn was on the market, followed by 34 percent for soybeans, 19 percent for cotton, 18 percent for sugar beets, and 14 percent for papaya. However, roughly 15 percent incorrectly believed that all crops provided as options in the survey question, including onions and carrots, were GM.[15] Many consumers purchase non-GMO labeled products, such as non-GMO orange juice, despite there being no commercially-available GE oranges. All orange juices are "non-GMO," provided that the only ingredient is oranges. If consumers had information about which crops have been engineered, then consumers could identify foods with GE ingredients while also being able to better judge the merits of non-GMO label

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[11] Annenberg Public Policy Center, 2016, op cit.
[12] Hallman WK, Cuite CL, and Morin XK. (2013). Public perceptions of labeling genetically modified foods: Working paper 2013-01. *Rutgers University, School of Environmental and Biological Sciences*. Available at http://humeco.rutgers.edu/documents_PDF/news/GMlabelingperceptions.pdf.
[13] McFadden BR and Lusk JL. (2017). What consumers don't know about genetically modified food, and how that affects beliefs. *FASEB J,* 30(9): 3091–3096. Available at http://www.fasebj.org/content/30/9/3091.full.pdf.
[14] Kirshenbaum S. (2017). MSU food literacy and engagement poll. *Michigan State University.* Available at http://food.msu.edu/articles/msu-food-literacy-and-engagement-poll.
[15] McFadden BR, et al., 2017, op cit.

claims. Therefore, considering the limited information known by consumers, the FDA should design educational materials about GE, the crops that are engineered, and how those varieties compare to crop varieties produced through conventional methods.

III. Information about scientific terms such as "DNA" and "genes" should also be included in the FDA's initiative.

There is evidence that suggests that American consumers know little about genetics and terms such as "DNA" and "genes." A MSU poll also found that 37 percent of Americans believed the following statement to be true: "[g]enetically modified foods have genes and non-genetically modified foods do not."[16] That statement is false because all foods that were living have genes, which are composed of sequences of DNA. In addition, several polls have found overwhelming support for mandatory labeling of foods that contain DNA, which is found in every living organism, including fruits, vegetables, and animals.[17,18] Therefore, the FDA needs to include information about these important terms in its education initiative.

IV. The FDA's education initiative should target key stakeholder groups.

While CSPI commends the FDA's efforts to "provide consumer outreach and education through publication and distribution of science-based educational information on the environmental, nutritional, food safety, economic, and humanitarian impacts of agricultural biotechnology," it is unreasonable to believe that $3 million is adequate to educate American consumers. For the FDA's education initiative to have the greatest impact on society, it should concentrate its outreach efforts on educating key influential groups, including journalists, nutritionists, doctors, academics, and opinion leaders. Those influencers can then greatly multiply the effects of the FDA's initiative by spreading the information to consumers.

CSPI appreciates the opportunity to provide this comment to the FDA. CSPI would be happy to meet with the FDA staff working on this initiative to discuss the comments provided in this letter in more detail.

Sincerely,

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[16] Kirshenbaum S, 2017, op cit.
[17] McFadden BR, et al., 2017, op cit.
[18] Lusk J and Murrary S. (2015). Food demand survey. *Oklahoma State University, Department of Agricultural Economics*, 2(9). Available at http://agecon.okstate.edu/faculty/publications/4975.pdf.