

June 14, 2017

Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Via <https://www.regulations.gov>.

This letter provides comments to Docket No. FDA 2016-N-4389 on “Genome Editing in New Plant Varieties Used for Foods.”

FDA’s Proposals for Gene Edited Plants are Ill-considered and Counterproductive

FDA’s proposal asks the question: “Are there categories of genome edited plant varieties for which there are scientific bases to conclude that foods from such categories are unlikely to present food safety risks different from or greater than those for traditional plant breeding?”¹

This framing turns the principles underlying the Coordinated Framework on their head. For three decades, US policy has been predicated on the finding, robustly corroborated by a mass of accumulated data and experience, that the hazards associated with crops and foods improved through biotechnology are not different from those with which we are familiar from other products of domestication and agriculture. This finding has been ratified by no less than eleven separate studies by the US National Academy of sciences, most recently in June of 2016, which is incorporated here by reference.² The NAS studies themselves built on many years of study by dedicated groups of global experts under the aegis of the Organization for Economic

¹ U.S. Food and Drug Administration, Genome Editing in New Plant Federal Register / Vol. 82, No. 12 / Thursday, January 19, 2017 / Notices <https://www.federalregister.gov/documents/2017/01/19/2017-00840/genome-editing-in-new-plant-varieties-used-for-foods-request-for-comments>.

² U.S. National Academy of Sciences, *Genetically Engineered Crops: Experiences and Prospects* (2016), <https://www.nap.edu/catalog/23395/genetically-engineered-crops-experiences-and-prospects>; L. Val Giddings, “U.S. National Academy of Science Reaffirms Safety of GMOs for 11th Time, But Confuses the Story on Yields,” *Innovation Files*, June 3, 2016, <http://www.innovationfiles.org/u-s-national-academy-of-science-reaffirms-safety-of-gmos-for-11th-time-but-confuses-the-story-on-yields>.

Cooperation and Development, published in five studies also incorporated here by reference.³ For FDA to frame the question on the unsupported and abundantly contradicted assertion that such hazards exist, and justify such a significant departure from longstanding policy, demands a demonstration of hazard they have not provided. The rest of their proposal for gene edited plants is similarly unfounded and at odds with long standing policy, and specifically the mandate from OSTP, and subject to the same kinds of defects and illogic underlying their proposal with regard to gene edited animals.

It is ironic that FDA should publish such draconian proposals for premarket review of gene edited plants and animals even as the National Academy of Sciences was concluding a study highlighting the value of gene editing technologies and their potential to improve human welfare through medical applications, including germline applications.⁴ An interesting contrast to the FDA's proposal is seen in the European Union, which has postponed yet again their review of the topic in an effort to avoid coming to a hasty, but ill-considered conclusion.⁵

FDA should withdraw the present proposal. FDA should develop a new proposal to lay out their authority to regulate, and invite comment on their intention to exercise discretion for the products of modern genome modification techniques in plants until and unless categories of hazardous examples are demonstrated that might post unreasonable risks sufficient to justify regulation under the longstanding policies laid down in the Coordinated Framework. FDA should develop and publish a proposal to invite comments to help define such

³ Organization for Economic Cooperation and Development, "Recombinant DNA Safety Considerations" (Paris: OECD, 1986), ISBN 92-64-12857-3; OECD, "Safety Considerations for Biotechnology" (Paris: OECD, 1992), ISBN 92-64-13641-X; OECD, "Biotechnology, Agriculture and Food" (Paris: OECD, 1992), ISBN 92-64-13725-4; OECD, "Traditional Crop Breeding Practices: An Historical Review to Serve as a Baseline for Assessing the Role of Modern Biotechnology" (Paris: OECD, 1993), ISBN 92-64-14047-6; OECD, "Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles" (Paris: OECD, 1993) ISBN 92-64-13859-5.

⁴ U.S. National Academy of Sciences, Human Genome Editing: Science, Ethics, and Governance (2017), ISBN 978-0-309-45288-5, <https://www.nap.edu/catalog/24623/human-genome-editing-science-ethics-and-governance>.

⁵ Jackie Bird, EU admits more delay on rules for new plant breeding techniques - Any decision on whether new plant breeding techniques will be regulated under EU laws on genetic modification will wait until after new scientific advice and a public debate, both expected later this year, Agrow, 9 February, 2017, <https://www.agra-net.com/agra/agrow/markets-regulatory/europe/eu-admits-more-delay-on-rules-for-new-plant-breeding-techniques--1.htm>; Nature Editorial, Gene editing in legal limbo in Europe; The European Union is dragging its feet on gene-editing rules and scientists should push the issue, Nature 542, 392 (23 February 2017) doi:10.1038/542392a, <http://www.nature.com/news/gene-editing-in-legal-limbo-in-europe-1.21515>.

phenotypic categories of novel plants that represent potentially elevated hazard to human health or animal welfare which may be appropriate subject of regulatory oversight, based on data and experience.

Thank you for the opportunity to provide comments on this matter.

Sincerely,

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