



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-4389]

Genome Editing in New Plant Varieties Used For Foods; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the establishment of a docket to receive comments on the use of genome editing techniques to produce new plant varieties that are used for human or animal food. We invite comment on specific questions contained in this document related to foods derived from such genome edited plant varieties. FDA is taking this action to help inform our thinking about foods derived from new plant varieties produced using genome editing techniques.

DATES: Submit either electronic or written comments by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be

posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-4389 for "Genome Editing in New Plant Varieties Used For Foods; Request for Comments."

Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public docket, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Regarding human food issues: Jason Dietz, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2282. Regarding animal food issues: Kathleen

Jones, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5938.

SUPPLEMENTARY INFORMATION:

I. Background

Use of Genome Editing Techniques to Produce New Plant Varieties Used For Human or Animal Food

Recently, new technologies have emerged that are intended to alter the genomes of various organisms, including plants. FDA is aware that these technologies make it easier for plant developers to produce new plant varieties with targeted genetic modifications. Using deoxyribonucleic acid (DNA) sequence information from a plant, plant breeders can make targeted changes to a plant's DNA sequence to alter expression of traits in the plant. These new methods include processes using targeted nucleases (clustered regulatory interspersed short palindromic repeat associated nucleases, zinc-finger nucleases, meganucleases, and transcription activator-like effector nucleases or targeted oligonucleotides (oligonucleotide-directed mutagenesis) intended to modify a plant's DNA sequence by insertion, deletion, or substitution of nucleotides at a specific site in a plant's genome. The process of producing these targeted DNA sequence alterations is often referred to as "genome editing."

In the National Strategy for Modernizing the Regulatory System for Biotechnology Products (the Strategy; released by the White House Office of Science and Technology Policy on September 16, 2016)¹, FDA noted its intent to clarify its policy for the regulation of products derived from genome editing techniques, including, as appropriate, identifying and/or updating relevant existing guidance documents. Consistent with this commitment in the Strategy

¹ https://www.whitehouse.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf

document, FDA is opening this docket to inform its thinking on foods derived from plants produced using genome editing techniques. FDA also looks forward to receiving the results from the study being conducted by the National Academies of Sciences, Engineering, and Medicine entitled "Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System" commissioned under the Update to the Coordinated Framework for Regulation of Biotechnology, available at <http://nas-sites.org/biotech/>. As we consider this issue, we intend for our actions to be guided by the principles for the regulation of biotechnology products articulated in the 2017 Update to the Coordinated Framework (https://www.whitehouse.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf) and the goals and objectives of the July 2015 EOP memorandum (https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf).

Producers of foods from plant varieties developed using genome editing techniques, like all food producers, have an obligation under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to ensure that the foods they offer consumers are safe and in compliance with applicable legal requirements (57 FR 22984 at 22985), available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm>. The FD&C Act gives FDA broad authority to initiate legal action against a food that is adulterated or misbranded within the meaning of the statute (id.). In 1992, FDA issued a statement of policy (57 FR 22984) that discussed scientific issues and provided guidance relevant to the safety assessment of foods derived from new plant varieties derived by traditional methods, tissue culture methods, and recombinant DNA methods (57 FR 22984 at 22991). The guidance provided in the 1992 policy has helped to ensure that developers of new

plant varieties make market entry decisions consistent with the FD&C Act. FDA also explained that we have long regarded it to be a prudent practice for producers of foods using new technologies to work cooperatively with us to ensure that the new products are safe and comply with applicable legal requirements (57 FR 22984 at 22991). Over the past 20 years, developers have routinely consulted FDA about the safety and legality of foods from new genetically engineered plant varieties prior to marketing. These consultations have relied on the objective characteristics of foods to consider their safety and legality prior to marketing. This process has worked well and has helped developers ensure that all safety and other legal issues are satisfactorily addressed prior to market entry of foods derived from these new varieties. FDA intends to continue offering consultations for developers of new plant varieties, including those produced using genome editing, in order to help developers ensure that applicable safety and legal questions are resolved prior to market. In addition to the information we anticipate gathering from developers in the course of consultations, we recognize that developers, researchers, and other stakeholders may have valuable factual information and data about foods derived from new plant varieties produced using genome editing, which can help inform FDA's thinking for these specific products. Therefore, we invite comment in this notice.

II. Additional Issues for Consideration and Invitation for Comment: Genome Editing in Plants

To help inform our thinking on foods derived from new plant varieties produced using genome editing, we invite comment on the following questions:

1. In what ways are the food safety risks associated with human and animal foods from genome edited plants the same as or different from those associated with other plant development methods (e.g., hybridization, chemical or radiation-induced mutagenesis and non-targeted

genetic modifications using in vitro recombinant DNA technologies)? Please provide data and/or information to support your view.

- To what extent is the scientific knowledge of and experience with current new plant varieties (such as those developed with in vitro recombinant DNA technologies that have gone through the voluntary consultation process) relevant to the safety assessment and regulatory status of food from new plant varieties produced using genome editing? Is there additional scientific knowledge that would be relevant specifically to the safety assessment and regulatory status of new plant varieties produced using genome editing? Please provide data and/or information to support your view.
2. 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? Similarly, are there categories of genome edited plant varieties for which the regulatory status of the food derived from such plant varieties can be said to be no different from that of traditionally-bred plants? If there are such categories, is there a basis upon which to determine that there would be no reason to include them in any voluntary premarket consultation process? If so, please describe the characteristics of such categories (including, for example, information about the types of phenotypes and modifications (insertions, deletions or substitutions) achieved through genome editing) and provide data and/or information for why plant varieties in these categories are unlikely to present food safety risks or regulatory status questions. Regulatory status questions may include, for example, whether food from the new plant variety contains an unapproved food or color additive such that premarket review and approval is required (see sections 409 and 721 of

the FD&C Act). As another example, if food from the new plant variety has a different nutritional profile from food from traditionally-bred plants, then certain labeling may be required to disclose a material change in the food.

- a. If such categories exist, how do plant developers ensure the safety of foods from new plant varieties in these categories? For example, how are safety assessments of foods from these varieties accomplished, and what data and information are or should be considered in such assessments?
 - b. If certain categories of genome edited plants do not raise questions of safety or regulatory status, should there nevertheless be a mechanism separate from the voluntary premarket consultation process through which plant developers may voluntarily notify FDA about their intent to market a food derived from a genome edited new plant variety that falls within these categories? If so, what process should plant developers use to notify FDA? What kind of information should be included in such a notification to FDA?
 - c. Given that genome editing techniques can give rise to a broad range of plant modifications, from simple gene deletions to totally novel genes, and that some such modifications can be achieved through traditional breeding, please discuss the basis upon which to determine that there would or would not be a reason to include, in any voluntary premarket consultation process, foods from genome edited crops with modifications that could have been achieved through traditional breeding.
3. Are there categories of genome edited plant varieties for which there are scientific bases to conclude that foods from these categories are more likely than traditionally-bred plants to present food safety risks? If so, please describe the characteristics of these categories (including, for example, information about the types of phenotypes and modifications (insertions, deletions or

substitutions) achieved through genome editing) and provide data and/or information to support why plant varieties in these categories are more likely to present food safety risks than traditionally-bred plants.

4. What steps can we take to help small firms, including those who may be considering using genome editing to produce new plant varieties for use in human or animal food, to engage with FDA about any questions related to food safety or the regulatory status of foods from their new plant varieties? Please provide supporting data and other information to support your comments and responses to this question.

Dated: January 11, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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