



4164-01-P

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; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for a docket to receive information and comments on the use of genome editing techniques to produce new plant varieties that are used for human or animal food. We established the docket through a notice that appeared in the Federal Register of January 19, 2017. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: We are extending the comment period on the notice that published January 19, 2017 (82 FR 6564). Submit either electronic or written comments by June 19, 2017. Late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of June 19, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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." Received comments, those filed in a timely manner (see DATES), 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 dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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: In the Federal Register of January 19, 2017, we published a notice 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 requested these comments because we recognize that developers of new plant varieties, 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. The notice also discussed the history of FDA's thinking regarding these products, our long history of consultations with developers, researchers, and other stakeholders, and specific questions and issues for which we invited comments. We provided a 90-day comment period that was scheduled to end on April 19, 2017.

We have received requests for a 60-day extension of the comment period. The requests conveyed concern that the current 90-day comment period does not allow sufficient time to

develop a meaningful or thoughtful comments to the questions and issues we presented in the notice.

We have considered the requests and are extending the comment period for 60 days, until June 19, 2017. A 60-day extension allows more time for interested persons to submit comments to the docket on this issue.

Dated: April 7, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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