



24 November 2016

(16-6446)

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Committee on Sanitary and Phytosanitary Measures

Original: English

## NOTIFICATION

### Addendum

The following communication, received on 23 November 2016, is being circulated at the request of the Delegation of the United States of America.

#### Indirect Food Additives: Paper and Paperboard Components; Final Rule

The Food and Drug Administration is amending the food additive regulations to no longer provide for the use of two specific perfluoroalkyl containing substances as oil and water repellents for paper and paperboard for use in contact with aqueous and fatty foods because these uses have been abandoned. This action is in response to a petition filed by Keller and Heckman LLP on behalf of 3M Corporation.

This rule is effective 22 November 2016.

<https://www.gpo.gov/fdsys/pkg/FR-2016-11-22/pdf/2016-28116.pdf>

[http://members.wto.org/crnattachments/2016/SPS/USA/16\\_4851\\_00\\_e.pdf](http://members.wto.org/crnattachments/2016/SPS/USA/16_4851_00_e.pdf)

#### **This addendum concerns a:**

- ☐ Modification of final date for comments
- ☒ Notification of adoption, publication or entry into force of regulation
- ☐ Modification of content and/or scope of previously notified draft regulation
- ☐ Withdrawal of proposed regulation
- ☐ Change in proposed date of adoption, publication or date of entry into force
- ☐ Other:

**Comment period: (If the addendum extends the scope of the previously notified measure in terms of products and/or potentially affected Members, a new deadline for receipt of comments should be provided, normally of at least 60 calendar days. Under other circumstances, such as extension of originally announced final date for comments, the comment period provided in the addendum may vary.)**

- ☐ Sixty days from the date of circulation of the addendum to the notification and/or (dd/mm/yy): Submit either electronic or written objections and requests for a hearing by 22 December 2016.

**Agency or authority designated to handle comments:** ☐ National Notification Authority, ☐ National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

You may submit objections and requests for a hearing as follows.

#### Electronic Submissions

Submit electronic objections in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to

<http://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection 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 objection, that information will be posted on <http://www.regulations.gov>.

If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection 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 objections submitted to the Division of Dockets Management, FDA will post your objection, 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-F-1153 for "Indirect Food Additives: Paper and Paperboard Components". Received objections will be placed in the docket and, except for those submitted as "Confidential Submissions", publicly viewable at <http://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 an objection with confidential information that you do not wish to be made publicly available, submit your objections 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". The Agency will review this copy, including the claimed confidential information, in its 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 <http://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, 18 September 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

#### **Text(s) available from: ☒ National Notification Authority, ☐ National Enquiry Point. Address, fax number and e-mail address (if available) of other body:**

United States SPS National Notification Authority, USDA Foreign Agricultural Service, International Regulations and Standards Division (IRSD), Stop 1014, Washington D.C. 20250; Tel: +(1 202) 720 1301; Fax: +(1 202) 720 0433; E-mail: [us.spsenquiry@fas.usda.gov](mailto:us.spsenquiry@fas.usda.gov)

Text can also be found in the Federal Register, Vol. 81, No. 225, page 83672 or on the internet at: <https://www.gpo.gov/fdsys/pkg/FR-2016-11-22/pdf/2016-28116.pdf>.

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