



6 January 2016

(16-0123)

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Committee on Sanitary and Phytosanitary Measures

Original: English

**NOTIFICATION**

<b>1. Notifying Member:</b> <u>UNITED STATES OF AMERICA</u> <b>If applicable, name of local government involved:</b>
<b>2. Agency responsible:</b> Food and Drug Administration
<b>3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):</b> HS Code(s): 29; ICS Code(s): 67 Synthetic flavoring food additives
<b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
<b>5. Title of the notified document:</b> Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, Consumers Union, Improving Kids' Environment, Center for Environmental Health, Environmental Working Group, Environmental Defense Fund, and James Huff; Filing of Food Additive Petition; Notice of Petition <b>Language(s):</b> English <b>Number of pages:</b> 3 <a href="https://www.gpo.gov/fdsys/pkg/FR-2016-01-04/pdf/2015-33011.pdf">https://www.gpo.gov/fdsys/pkg/FR-2016-01-04/pdf/2015-33011.pdf</a>
<b>6. Description of content:</b> The Food and Drug Administration has filed a petition, submitted by the Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, Consumers Union, Improving Kids' Environment, Center for Environmental Health, Environmental Working Group, Environmental Defense Fund, and James Huff, proposing that the food additive regulations be amended to no longer authorize the use of seven listed synthetic flavoring food additives and to establish zero tolerances for the additives.  The food additive petition was filed on 17 August 2015.
<b>7. Objective and rationale:</b> <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.
<b>8. Is there a relevant international standard? If so, identify the standard:</b> <input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text) <input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number) <input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number) <input checked="" type="checkbox"/> None <b>Does this proposed regulation conform to the relevant international standard?</b>

<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p>
<p>9. Other relevant documents and language(s) in which these are available:</p>
<p>10. Proposed date of adoption (<i>dd/mm/yy</i>): Not applicable Proposed date of publication (<i>dd/mm/yy</i>): Not applicable</p>
<p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (<i>dd/mm/yy</i>): Not applicable <input type="checkbox"/> Trade facilitating measure</p>
<p>12. Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (<i>dd/mm/yy</i>): 4 March 2016</p> <p>Agency or authority designated to handle comments: <input type="checkbox"/> National Notification Authority, <input type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>You may submit comments as follows:</p> <p>Electronic Submissions</p> <p>Submit electronic comments in the following way:</p> <p>Federal eRulemaking Portal: <a href="http://www.regulations.gov">http://www.regulations.gov</a>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <a href="http://www.regulations.gov">http://www.regulations.gov</a> 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 <a href="http://www.regulations.gov">http://www.regulations.gov</a>.</p> <p>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 in the document (see "Written/Paper Submissions", "Instructions", and "Confidential Submissions").</p> <p>Written/Paper Submissions</p> <p>Submit written/paper submissions as follows:</p> <p>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".</p> <p>Instructions: All submissions received must include the Docket No. FDA-2015-F-4317 for "Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, Consumers Union, Improving Kids' Environment, Center for Environmental Health, Environmental Working Group, Environmental Defense Fund, and James Huff; Filing of Food Additive Petition." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions", publicly viewable at <a href="http://www.regulations.gov">http://www.regulations.gov</a> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.</p> <p>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</p>

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>.

**13. 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. 1, page 42 or on the internet at: <https://www.gpo.gov/fdsys/pkg/FR-2016-01-04/pdf/2015-33011.pdf>.