



28 January 2022

(22-0712)

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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 (FDA)
<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): 3923, 3924, 4811; ICS Code(s): 67
<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> Food Additives: Food Contact Substance Notification That Is No Longer Effective; Proposed Rule. <b>Language(s):</b> English. <b>Number of pages:</b> 10 <a href="https://www.govinfo.gov/content/pkg/FR-2022-01-26/pdf/2022-01527.pdf">https://www.govinfo.gov/content/pkg/FR-2022-01-26/pdf/2022-01527.pdf</a> <a href="https://members.wto.org/crnattachments/2022/SPS/USA/22_1012_00_e.pdf">https://members.wto.org/crnattachments/2022/SPS/USA/22_1012_00_e.pdf</a>
<b>6. Description of content:</b> The Food and Drug Administration (FDA or we) is proposing to amend its regulations relating to the procedures by which we determine that a premarket notification for a food contact substance (FCN) is no longer effective. The proposed rule, if finalized, would, among other things, ensure that manufacturers or suppliers have the opportunity to provide input before we could determine that an FCN is no longer effective. The proposed rule also would provide additional reasons that could be the basis for FDA to determine that an FCN is no longer effective. We are proposing these changes to better enable FDA to respond to new information on the safety and use of food contact substances, as well as manufacturers' business decisions, which would also improve our FCN program's efficiency.
<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>

<input type="checkbox"/> Yes <input type="checkbox"/> No <b>If no, describe, whenever possible, how and why it deviates from the international standard:</b>	
<b>9.</b>	<b>Other relevant documents and language(s) in which these are available:</b>
<b>10.</b>	<b>Proposed date of adoption (dd/mm/yy):</b> Not applicable <b>Proposed date of publication (dd/mm/yy):</b> Not applicable
<b>11.</b>	<b>Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy):</b> Not applicable <input type="checkbox"/> Trade facilitating measure
<b>12.</b>	<b>Final date for comments: <input checked="" type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy):</b> 29 March 2022 <b>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:</b> <p>Submit electronic comments in the following way:</p> <ul style="list-style-type: none"> <li>Federal eRulemaking Portal: <a href="https://www.regulations.gov">https://www.regulations.gov</a>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <a href="https://www.regulations.gov">https://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="https://www.regulations.gov">https://www.regulations.gov</a>.</li> <li>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").</li> </ul>
<b>13.</b>	<b>Text(s) available from: <input type="checkbox"/> National Notification Authority, <input type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</b> <p>Text can be found in the Federal Register, Vol. 87, No. 17, Page 3949 or on the internet at: <a href="https://www.govinfo.gov/content/pkg/FR-2022-01-26/pdf/2022-01527.pdf">https://www.govinfo.gov/content/pkg/FR-2022-01-26/pdf/2022-01527.pdf</a></p>