



13 October 2025

(25-6571)

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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> Sausages and similar products, of meat, meat offal, blood or insects; food preparations based on these products (HS code(s): 1601); Food technology (ICS code(s): 67)
<b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> <b>All trading partners</b> <input type="checkbox"/> <b>Specific regions or countries:</b>
<b>5. Title of the notified document:</b> Proposal To Remove the Color Additive Listing for Use of Orange B on Casings or Surfaces of Frankfurters and Sausages; Proposed Amendment; Proposed Order. <b>Language(s):</b> English. <b>Number of pages:</b> 3 <a href="https://www.federalregister.gov/d/2025-18023">https://www.federalregister.gov/d/2025-18023</a> <a href="https://members.wto.org/crnattachments/2025/SPS/USA/25_06553_00_e.pdf">https://members.wto.org/crnattachments/2025/SPS/USA/25_06553_00_e.pdf</a>
<b>6. Description of content:</b> The Food and Drug Administration (FDA or we) is proposing to issue an order that would remove the color additive regulation that allows for the use of Orange B for coloring the casings or surfaces of frankfurters and sausages. Based on certification data, it appears that Orange B is no longer used for coloring the casings or surfaces of frankfurters and sausages and has not been certified for use as a color additive in food marketed in the United States since 1978. Because the authorized use of Orange B appears to have been abandoned, we have tentatively concluded that this color additive regulation is outdated and unnecessary.
<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"/> <b>Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</b> <input type="checkbox"/> <b>World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</b> <input type="checkbox"/> <b>International Plant Protection Convention (e.g. ISPM number):</b> <input checked="" type="checkbox"/> <b>None</b> <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 (dd/mm/yy): Not applicable</p> <p>Proposed date of publication (dd/mm/yy): Not applicable</p>
<p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): Not applicable</p> <p><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 (dd/mm/yy): 17 October 2025</p> <p>Agency or authority designated to handle comments: <input checked="" 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. Please note that late, untimely filed comments will not be considered. The <a href="https://www.regulations.gov">https://www.regulations.gov</a> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of 17 October 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.</p> <p>Electronic Submissions</p> <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 comment, 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> <p>Written/Paper Submissions</p> <p>Submit written/paper submissions as follows:</p> <ul style="list-style-type: none"> <li>Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.</li> <li>For written/paper comments submitted to the Dockets Management Staff, 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".</li> </ul> <p>Instructions: All submissions received must include the Docket No. FDA- 2025-C-3543 for "Proposal to Remove the Color Additive Listing for Use of Orange B on Casings or Surfaces of Frankfurters and Sausages". Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions", publicly viewable at <a href="https://www.regulations.gov">https://www.regulations.gov</a> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, +(240) 402 7500.</p>

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

Text can be found in the Federal Register, Vol. 90, No. 178, Page 44786 or on the Internet at: <https://www.federalregister.gov/d/2025-18023>