

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/comments/s7-2026-37/list-rules-be-reviewed-pursuant-regulatory-flexibility-act>); or
- Send an email to rule-comments@sec.gov. Please include File Number S7–2026–37 on the subject line.

Paper Comments

- Send paper comments to Vanessa A. Countryman, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number S7–2026–37. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method of submission. The Commission will post all comments on the Commission's website (<https://www.sec.gov/rules-regulations/public-comments/s7-2026-37>). Do not include personally identifiable information in submissions; you should submit only information that you wish to make available publicly. The Commission may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

FOR FURTHER INFORMATION CONTACT: Sandra Sojka, General Attorney, Office of the General Counsel, 202–551–4928.

SUPPLEMENTARY INFORMATION: The Regulatory Flexibility Act (“RFA”), codified at 5 U.S.C. 601 through 612, requires an agency to review its rules that have a significant economic impact upon a substantial number of small entities within 10 years of the publication of such rules as final rules. 5 U.S.C. 610(a). The purpose of the review is “to determine whether such rules should be continued without change, or should be amended or rescinded . . . to minimize any significant economic impact of the rules upon a substantial number of such small entities.” 5 U.S.C. 610(a). The RFA sets forth specific considerations that must be addressed in the review of each rule:

- The continued need for the rule;
- The nature of complaints or comments received concerning the rule from the public;
- The complexity of the rule;
- The extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent

feasible, with state and local governmental rules; and

- The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule. 5 U.S.C. 610(b).

The list below includes rules adopted in 2017 that may have a significant economic impact on a substantial number of small entities (but excludes rules that have been substantially changed since adoption, rules that are minor amendments to previously adopted rules, and rules that are ministerial, procedural, or technical in nature). Where the Commission has previously made a determination of a rule's impact on small businesses, the determination is noted on the list.

The Commission particularly solicits public comment on whether the rules in the release listed below affect small businesses in new or different ways than when first adopted. The release listed below is scheduled for review by staff of the Commission.

Title: Exhibit Hyperlinks and HTML Format.

Citation: 17 CFR 229.601, 17 CFR 232.11, 17 CFR 232.102, 17 CFR 232.105, 17 CFR 239.40, 17 CFR 249.20f.

Authority: 15 U.S.C. 77c, 77e, 77f, 77g, 77h, 77j, 77k, 77s, 77s(a), 77z–2, 77z–3, 77aa(25), 77aa(26), 77ddd, 77eee, 77ggg, 77hhh, 77iii, 77jjj, 77nnn, 77sss, 77sss(a), 78a *et seq.*, 78c, 78c(b), 78i, 78j, 78j–3, 78l, 78m, 78n, 78n–1, 78o, 78o(d), 78o–7 note, 78u–5, 78w, 78w(a), 78ll, 78 mm, 80a–2(a), 80a–3, 80a–6(c), 80a–8, 80a–9, 80a–10, 80a–13, 80a–20, 80a–24, 80a–26, 80a–29, 80a–30, 80a–31(c), 80a–37, 80a–38(a), 80a–39, 80b–11; 7201 *et seq.*; 12 U.S.C. 5461 *et seq.*; 18 U.S.C. 1350; Sec. 953(b) Pub. L. 111–203, 124 Stat. 1904; Sec. 102(a)(3) Pub. L. 112–106, 126 Stat. 309 (2012); Sec. 107 Pub. L. 112–106, 126 Stat. 313 (2012); Sec. 71003 and Sec. 84001, Pub. L. 114–94, 129 Stat. 1312; and Sec. 72001 Pub. L. 114–94, 129 Stat. 1312 (2015), unless otherwise noted.

Description: The Commission adopted amendments to require registrants that file registration statements and reports subject to the exhibit requirements under Item 601 of Regulation S–K, or that file Forms F–10 or 20–F, to include a hyperlink to each exhibit listed in the exhibit index of these filings. To enable the inclusion of such hyperlinks, the amendments also require that registrants submit all such filings in HyperText Markup Language (“HTML”) format.

Prior RFA Analysis: When the Commission adopted the amendments on March 1, 2017, it published a Final Regulatory Flexibility Analysis in the adopting releases, Release Nos. 33–10322; 34–80132, available at: <https://www.govinfo.gov/content/pkg/FR-2017-03-17/pdf/2017-04365.pdf>. The

Commission solicited comment on the Initial Regulatory Flexibility Analysis published in the proposing releases, Release Nos. 33–10201, 34–78737 (Sept. 12, 2016), available at: <https://www.govinfo.gov/content/pkg/FR-2016-09-12/pdf/2016-21313.pdf>, and considered comments received at that time.

By the Commission.

Dated: October 20, 2026.

J. Matthew DeLesDernier,
Deputy Secretary.

[FR Doc. 2026–21657 Filed 10–22–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 109

[Docket No. FDA–2025–D–4023]

Action Levels for Cadmium in Processed Food Intended for Babies and Young Children; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft guidance for industry entitled “Action Levels for Cadmium in Processed Food Intended for Babies and Young Children.” The draft guidance, when finalized, will establish action levels for cadmium in certain processed foods intended for babies and young children less than 2 years old. The draft guidance is intended to set achievable action levels that will help further reduce cadmium in the food supply.

DATES: Submit either electronic or written comments on the draft guidance by December 22, 2026 to ensure that the Agency considers your comments on the draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit either electronic or written/paper comments on FDA guidances at any time 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):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- 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."

Instructions: All submissions received must include the Docket No. FDA-2025-D-4023 for "Action Levels for Cadmium in Processed Food Intended for Babies and Young Children; Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- *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://](https://www.regulations.gov)

www.regulations.gov. Submit both copies to the Dockets Management Staff. 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.govinfo.gov/content/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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Food Chemical Safety, Dietary Supplements, and Innovation; Human Foods Program; Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Eileen Abt, Office of Food Chemical Safety, Dietary Supplements, and Innovation; Human Foods Program; Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1529; or Barbara Little, Office of Regulations and International Programs; Human Foods Program; Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled "Action Levels for Cadmium in Processed Food Intended for Babies and Young Children." We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current

thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

This draft guidance, when finalized, would, in accordance with § 109.6 (21 CFR 109.6), establish the following action levels for cadmium in processed food intended for babies and young children less than 2 years old: 10 parts per billion (ppb) for fruits, vegetables (excluding single-ingredient carrots), and mixtures (including grain- and meat-based mixtures); 25 ppb for single-ingredient carrots; 45 ppb for dry infant cereals; 20 ppb for yogurts, puddings, and custards; and 25 ppb for single-ingredient meats. Consistent with § 109.6(d), these action levels would reflect levels of cadmium at which FDA may regard the food as adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1)). We intend to consider these action levels, in addition to other factors, when considering whether to bring enforcement action in a particular case.

We request comments on these proposed action levels in general, including on whether there may be sufficient data or information that would support different levels for these categories of foods.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

This draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/FoodGuidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-21670 Filed 10-22-26; 11:15 am]

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