

We are issuing these revised sections of the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.” 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.

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production.

Section 103 of FSMA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), by adding section 418 (21 U.S.C. 350g) with requirements for hazard analysis and risk-based preventive controls for establishments that are required to register as food facilities under our regulations in 21 CFR part 1, subpart H, in accordance with section 415 of the FD&C Act (21 U.S.C. 350d). We have established regulations to implement these requirements within part 117 (21 CFR part 117).

The multichapter draft guidance for industry is intended to explain our current thinking on how to comply with the requirements for hazard analysis and risk-based preventive controls under part 117, principally in subparts C and G. One revised draft that we are announcing in this document is “Introduction and General Information Applicable to This Guidance.” We revised the draft Introduction that we made available in 2016 to address comments submitted regarding the draft Introduction, include all draft definitions that we subsequently included in chapters we have made available, and add draft recommendations for training applicable to most topics covered in the multichapter guidance. We also added two administrative features. One feature is a comprehensive bibliography of references that we cited within the chapters previously made available, as well as references that we expect to cite in the additional chapters that we have included in the table of contents. Another feature is a compilation of

resources that could be useful to persons who use the multichapter guidance.

The second revised draft that we are announcing in this document is “Appendix 1: Known or Reasonably Foreseeable Hazards (“Potential Hazards”).” We revised the draft Appendix 1 that we made available in 2016 to add text providing context for what the Appendix is, how it was developed, and how it should be used. To address comments submitted regarding the draft Appendix, we made several changes, including: (1) significantly revised product categories (which emphasize ingredients that go into foods rather than finished foods that can be formulated with many variations of such ingredients); (2) replaced a series of tables listing known or reasonably foreseeable (“potential”) process-related hazards with a discussion of such hazards; (3) provided a general discussion of food allergen hazards rather than identify known or reasonably foreseeable (“potential”) food allergen hazards that could apply to multiple product categories; and (4) identified scientific, technical, or regulatory information that we considered when identifying some hazards that are known or reasonably foreseeable (“potential”), but less common, hazards in some food categories.

We intend to announce the availability for public comment of additional chapters of the draft guidance as we complete them. The titles of the additional chapters that we expect to make available for public comment are included in the table of contents for the complete multichapter guidance.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in part 117 have been approved under OMB control number 0910-0751.

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.

Dated: January 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF EDUCATION

34 CFR Chapter VI

[Docket ID ED-2023-OPE-0123]

Negotiated Rulemaking Committee; Announcement of Fourth Session of Committee Meetings—Title IV Federal Student Aid Programs, Student Debt Relief

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice of intent to establish negotiated rulemaking committee; amendment.

SUMMARY: On August 31, 2023, we announced our intention to establish the Student Debt Relief Negotiated Rulemaking Committee (Committee) to develop proposed regulations related to the modification, waiver, release, or compromise of Federal student loans under the Higher Education Act of 1965, as amended (HEA). We now announce a fourth session of Committee negotiations on February 22 and 23, 2024.

DATES: The dates, times, and location of the fourth Committee meeting are set out in the *Amended Schedule for Negotiation Sessions* section under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: For information about the content of this document, including information about the negotiated rulemaking process or the schedule for negotiations, please contact Rene Tiongquico. Telephone: (202) 453-7513. Email: rene.tiongquico@ed.gov.

For information about negotiated rulemaking, see “The Negotiated Rulemaking Process for Title IV Regulations—Frequently Asked Questions” at <https://www2.ed.gov/policy/highered/reg/hearulemaking/he08/neg-reg-faq.html>.

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7-1-1.

SUPPLEMENTARY INFORMATION: On August 31, 2023, we published in the **Federal Register** (88 FR 60163) an announcement of our intent to establish the Committee under section 492 of the HEA to develop proposed regulations related to section 432(a) of the HEA, which relate to the modification, waiver, or compromise of Federal

student loans by the Department. In that announcement, we set a schedule for Committee meetings and requested nominations for individual negotiators who represent key stakeholder constituencies for the issue to be negotiated to serve on the Committee. The Committee met on October 10–11, November 6–7, and December 11–12, 2023. During the negotiation sessions, the Committee discussed proposed regulations presented by the Department. At the end of the third negotiation session, the Committee took final consensus checks on each of the proposed regulations presented by the Department. In addition to the proposed regulations presented by the Department, the Committee discussed whether and how the Department could identify borrowers who are facing hardship but whose situations may not be reflected in either existing regulations or in the proposed regulations considered by the Committee.

Based upon a continued review of information related to hardship, the Department will convene the Committee for a fourth session to discuss only proposed regulations relating to that issue. The Committee will not discuss the proposed regulations for which it already conducted final consensus checks.

Amended Schedule for Negotiation Sessions: The Committee will meet for a fourth session on February 22–23, 2024.

Session times will be from 10 a.m. to 12 p.m. and 1 p.m. to 4 p.m., with a public comment period from approximately 3 p.m. to 4 p.m., Eastern time on February 22, 2024. The Department will hold public comment only on February 22, 2024.

This session will be conducted virtually and available for the public to view. Individuals who wish to observe the Committee meetings must register. We will post a registration link closer to the start of negotiations on our website at www2.ed.gov/policy/highered/reg/hearulemaking/2023/index.html. The Department will also post recordings and transcripts of the meetings on that site.

We will provide information on how to request time to speak on our website at www2.ed.gov/policy/highered/reg/hearulemaking/2023/index.html.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or

text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at www.govinfo.gov. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You may also access the documents of the Department published in the **Federal Register** by using the article search feature at www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Program Authority: 20 U.S.C. 1098a.

Nasser H. Paydar,

Assistant Secretary, Office of Postsecondary Education.

[FR Doc. 2024-02107 Filed 2-1-24; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R09-OAR-2022-0494; FRL-9931-01-R9]

Air Plan Approval; Nevada; Clark County Department of Environment and Sustainability; Nonattainment New Source Review; 2015 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the State of Nevada addressing the nonattainment new source review (NNSR) requirements for the 2015 ozone National Ambient Air Quality Standards (NAAQS). This SIP revision addresses the Clark County Department of Environment and Sustainability (DES or “Department”) portion of the Nevada SIP. This action is being taken pursuant to the Clean Air Act (CAA or “Act”) and its implementing regulations.

DATES: Comments must be received on or before March 4, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R09-

OAR-2022-0494, at <https://www.regulations.gov>. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www2.epa.gov/dockets/commenting-epa-dockets>. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT:

Amita Muralidharan, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947-4140 or by email at muralidharan.amita@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, “we,” “us,” and “our” refer to the EPA.

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I. Background and Purpose

On October 26, 2015, the EPA promulgated a revised ozone NAAQS of 0.070 parts per million (ppm).¹ Upon promulgation of a new or revised NAAQS, the CAA requires the EPA to designate as nonattainment any area that is violating the NAAQS based on the three most recent years of ambient

¹ 80 FR 65292 (October 26, 2015).