

display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

- * 1. Memorandum from S. West-Barnette, Division of Food Ingredients, Regulatory Review Branch, to M. Honigfort, Division of Food Ingredients, Regulatory Review Branch, June 6, 2024.
2. SCF. Reports of the Scientific Committee for Food (21st series), 1989. Available at: http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_21.pdf (accessed January 16, 2024).
3. JECFA, Evaluation of Certain Food Additives and Contaminants: Thirty-seventh Report, 1991. Available at: <https://www.who.int/publications/i/item/9241208066> (accessed January 16, 2024).
4. JECFA, Safety Evaluation of Certain Food Additives: Eighty-sixth Report, 2020. Available at: <https://www.who.int/publications/i/item/9789240004580> (accessed January 16, 2024).
- * 5. CFSAN CAC Full Committee Review, Memorandum of Meeting, October 15, 2019.
- * 6. Memorandum from J. Gingrich, Division of Food Ingredients, Toxicology Review Branch, to S. West-Barnette, Division of Food Ingredients, Regulatory Review Branch, June 18, 2024.
- * 7. Memorandum from D. Doell, Chemistry Review Group, Division of Petition Review (DPR), Office of Food Additive Safety (OFAS), CFSAN, FDA, to J. Kidwell, Regulatory Review Group I, DPR, OFAS, CFSAN, FDA, September 18, 2015.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 74 is amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

- 1. The authority citation for part 74 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

§ 74.303 [Removed]

- 2. Remove § 74.303.
- 3. Revise § 74.1303 to read as follows:

§ 74.1303 FD&C Red No. 3.

(a) *Identity.* (1) The color additive FD&C Red No. 3 is principally the monohydrate of 9 (*o*-carboxyphenyl)-6-

hydroxy-2,4,5,7-tetraiodo-3H-xanthen-3-one, disodium salt, with smaller amounts of lower iodinated fluoresceins.

(2) Color additive mixtures for ingested drug used made with FD&C Red No. 3 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring ingested drugs.

(b) *Specifications.* FD&C Red No. 3 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Volatile matter (at 135 °C) and chlorides and sulfates (calculated as the sodium salts), total not more than 13 percent.

(2) Water-insoluble matter, not more than 0.2 percent.

(3) Unhalogenated intermediates, total not more than 0.1 percent.

(4) Sodium iodide, not more than 0.4 percent.

(5) Triiodoresorcinol, not more than 0.2 percent.

(6) 2(2',4'-Dihydroxy-3', 5'-diiodobenzoyl) benzoic acid, not more than 0.2 percent.

(7) Monoiodofluoresceins not more than 1.0 percent.

(8) Other lower iodinated fluoresceins, not more than 9.0 percent.

(9) Lead (as Pb), not more than 10 parts per million.

(10) Arsenic (as As), not more than 3 parts per million.

(11) Total color, not less than 87.0 percent.

(c) *Uses and restrictions.* FD&C Red No. 3 may be safely used for coloring ingested drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Red No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1303 [Removed]

- 4. Effective January 18, 2028 remove § 74.1303.

Dated: January 10, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025-00830 Filed 1-15-25; 8:45 am]

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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 16

[Docket No. TTB-2025-0001; Notice No. 236]

Civil Monetary Penalty Inflation Adjustment—Alcoholic Beverage Labeling Act

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notification of civil monetary penalty adjustment.

SUMMARY: This document informs the public that the maximum penalty for violations of the Alcoholic Beverage Labeling Act (ABLA) is being adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended. Prior to the publication of this document, any person who violated the provisions of the ABLA was subject to a civil penalty of not more than \$25,561, with each day constituting a separate offense. This document announces that this maximum penalty is being increased to \$26,225.

DATES: The new maximum civil penalty for violations of the ABLA takes effect on January 16, 2025 and applies to penalties that are assessed after that date.

FOR FURTHER INFORMATION CONTACT: Vonzella C. Johnson, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; (202) 508-0413.

Background

Statutory Authority for Federal Civil Monetary Penalty Inflation Adjustments

The Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act), Public Law 101-410, 104 Stat. 890, 28 U.S.C. 2461 note, as Act of 2015, Public Law 114-74, section 701, 129 Stat. 584, requires the regular adjustment and evaluation of civil monetary penalties to maintain their deterrent effect and helps to ensure that penalty amounts imposed by the Federal Government are properly accounted for and collected. A “civil monetary penalty” is defined in the Inflation Adjustment Act as any penalty, fine, or other such sanction that is: (1) For a specific monetary amount as provided by Federal law, or has a maximum amount provided for by Federal law; (2) assessed or enforced by an agency pursuant to Federal law; and

(3) assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts.

The Inflation Adjustment Act, as amended, requires agencies to adjust civil monetary penalties by the inflation adjustment described in section 5 of the Inflation Adjustment Act. The Act also provides that any increase in a civil monetary penalty shall apply only to civil monetary penalties, including those whose associated violation predated such an increase, which are assessed after the date the increase takes effect.

The Inflation Adjustment Act, as amended, provides that the inflation adjustment does not apply to civil monetary penalties under the Internal Revenue Code of 1986 or the Tariff Act of 1930.

Alcoholic Beverage Labeling Act

The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the Federal Alcohol Administration Act (FAA Act) pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). In addition, the Secretary of the Treasury has delegated certain administrative and enforcement authorities to TTB through Treasury Order 120-01.

The FAA Act contains the Alcoholic Beverage Labeling Act (ABLA) of 1988, Public Law 100-690, 27 U.S.C. 213-219a, which was enacted on November 18, 1988. Section 204 of the ABLA, codified in 27 U.S.C. 215, requires that a health warning statement appear on the labels of all containers of alcoholic beverages manufactured, imported, or bottled for sale or distribution in the United States, as well as on containers of alcoholic beverages that are manufactured, imported, bottled, or labeled for sale, distribution, or shipment to members or units of the U.S. Armed Forces, including those located outside the United States.

The health warning statement requirement applies to containers of alcoholic beverages manufactured, imported, or bottled for sale or distribution in the United States on or after November 18, 1989. The statement reads as follows:

Government Warning: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery and may cause health problems.

Section 204 of the ABLA also specifies that the Secretary of the Treasury shall have the power to ensure the enforcement of the provisions of the ABLA and issue regulations to carry

them out. In addition, section 207 of the ABLA, codified in 27 U.S.C. 218, provides that any person who violates the provisions of the ABLA is subject to a civil penalty of not more than \$10,000, with each day constituting a separate offense.

Most of the civil monetary penalties administered by TTB are imposed by the Internal Revenue Code of 1986, and thus are not subject to the inflation adjustment mandated by the Inflation Adjustment Act. The only civil monetary penalty enforced by TTB that is subject to the inflation adjustment is the penalty imposed by the ABLA at 27 U.S.C. 218.

TTB Regulations

The TTB regulations implementing the ABLA are found in 27 CFR part 16, and the regulations implementing the Inflation Adjustment Act with respect to the ABLA penalty are found in 27 CFR 16.33. This section indicates that, in accordance with the ABLA, any person who violates the provisions of this part is subject to a civil penalty of not more than \$10,000. Further, pursuant to the provisions of the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended, this civil penalty is subject to periodic cost-of-living adjustments.

Accordingly, any person who violates the provisions of 27 CFR part 16 is subject to a civil penalty of not more than the amount listed at <https://www.ttb.gov/laws-regulations-and-public-guidance/other/penalties>. Each day constitutes a separate offense.

To adjust the penalty, § 16.33(b) indicates that TTB will provide notice in the **Federal Register** and at the website mentioned above of cost-of-living adjustments to the civil penalty for violations of 27 CFR part 16.

Penalty Adjustment

In this document, TTB is publishing its yearly adjustment to the maximum ABLA penalty, as required by the amended Inflation Adjustment Act.

As mentioned earlier, the ABLA contains a maximum civil monetary penalty. For such penalties, section 5 of the Inflation Adjustment Act indicates that the inflation adjustment is determined by increasing the maximum penalty by the cost-of-living adjustment. The cost-of-living adjustment means the percentage increase (if any) between the Consumer Price Index for All Urban Consumers (CPI-U) for the October preceding the date of the adjustment and the prior year's October CPI-U.

The CPI-U in October 2023 was 307.671, and the CPI-U in October 2024 was 315.664. The rate of inflation between October 2023 and October 2024

was therefore 2.598 percent. When applied to the current ABLA penalty of \$25,561 this rate of inflation yields a raw (unrounded) inflation adjustment of \$664.0748. Rounded to the nearest dollar, the inflation adjustment is \$664, meaning that the new maximum civil penalty for violations of the ABLA will be \$26,225.

The new maximum civil penalty will apply to all penalties that are assessed after January 16, 2025. TTB has also updated its web page at <https://www.ttb.gov/laws-regulations-and-public-guidance/other/penalties> to reflect the adjusted penalty.

Dated: January 10, 2025.

Amy R. Greenberg,

Acting Assistant Administrator, Headquarters Operations.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 257

[EPA-HQ-OLEM-2020-0107; FRL-7814.1-04-OLEM]

RIN 2050-AH34

Hazardous and Solid Waste Management System: Disposal of Coal Combustion Residuals From Electric Utilities; Legacy CCR Surface Impoundments; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is taking direct final action to correct errors and clarify several provisions published in the **Federal Register** on May 8, 2024. This May 8, 2024 rule (Legacy Final Rule) established regulatory requirements for legacy coal combustion residuals (CCR) surface impoundments and CCR management units, among other things, under the Resource Conservation and Recovery Act (RCRA).

DATES: This final rule is effective on May 16, 2025 without further notice unless EPA receives adverse comment by March 17, 2025. If EPA receives adverse comment, the Agency will publish a timely withdrawal in the **Federal Register** informing the public about the specific regulatory paragraph or amendment that will not take effect.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OLEM-2020-0107. All documents in the docket are listed on