

Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the E.O. and, consequently, a tribal summary impact statement is not required.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public 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. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Su, M., Y. Ling, J. Yu, et al. "Small Proteins: Untapped Area of Potential Biological Importance," *Frontiers in Genetics*, vol. 4, p.286, 2013.
2. Galindo, M. I., J. I. Pueyo, S. Foux, et al. "Peptides Encoded by Short ORFs Control Development and Define a New Eukaryotic Gene Family" *PLoS Biology*, vol. 5, p. e106, 2007.
3. *FDA, Regulatory Impact Analysis, "Definition of the Term 'Biological Product,'" available at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

List of Subjects in 21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 600 is amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

- 1. The authority citation for part 600 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 356c, 356e, 360, 360i, 371, 374, 379k–1; 42 U.S.C. 216, 262, 263, 263a, 264.

- 2. Amend § 600.3 by revising paragraph (h) introductory text and adding paragraph (h)(6) to read as follows:

§ 600.3 Definitions.

* * * * *

(h) *Biological product* means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or

derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

* * * * *

(6) A protein is any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. When two or more amino acid chains in an amino acid polymer are associated with each other in a manner that occurs in nature, the size of the amino acid polymer for purposes of this paragraph (h)(6) will be based on the total number of amino acids in those chains, and will not be limited to the number of amino acids in a contiguous sequence.

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Dated: February 18, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

[FR Doc. 2020–03505 Filed 2–20–20; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of the Secretary of the Treasury

31 CFR Parts 27 and 50

Inflation Adjustment of Civil Monetary Penalties

AGENCY: Departmental Offices Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury ("Department" or "Treasury") publishes this final rule to adjust its civil monetary penalties ("CMPs") for inflation as mandated by the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (collectively referred to herein as "the Act"). This rule adjusts CMPs within the jurisdiction of two components of the Department to the maximum amount required by the Act.

DATES: The adjustments to the CMPs set forth in 31 CFR part 27 and 31 CFR part 50 are effective February 21, 2020.

FOR FURTHER INFORMATION CONTACT: For information regarding the Terrorism Risk Insurance Program's CMPs, contact Richard Ifft, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, Room 1410 MT, Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220, at (202) 622–2922 (not a toll-free number), or Lindsey Baldwin,

Senior Policy Analyst, Federal Insurance Office, at (202) 622–3220 (not a toll free number). Persons who have difficulty hearing or speaking may access these numbers via TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

For information regarding the Treasury-wide CMP, contact Richard Dodson, Senior Counsel, General Law, Ethics, and Regulation, 202–622–9949.

SUPPLEMENTARY INFORMATION:

I. Background

In order to improve the effectiveness of CMPs and to maintain their deterrent effect, the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 note ("the Inflation Adjustment Act"), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Pub. L. 114–74) ("the 2015 Act"), requires Federal agencies to adjust each CMP provided by law within the jurisdiction of the agency. The 2015 Act requires agencies to adjust the level of CMPs with an initial "catch-up" adjustment through an interim final rulemaking and to make subsequent annual adjustments for inflation, without needing to provide notice and the opportunity for public comment required by 5 U.S.C. 553. The Department's initial catch-up adjustment interim final rules were published on December 7, 2016 (Departmental Offices) (81 FR 88600), and for 31 CFR part 27, on February 11, 2019 (84 FR 3105). The Department's 2018 annual adjustment was published on March 19, 2018 (83 FR 11876), and the Department's 2019 annual adjustment was published on April 17, 2019 (84 FR 15955). The 2015 Act provides that any increase in a CMP shall apply to CMPs that are assessed after the date the increase takes effect, regardless of whether the underlying violation predated such increase.¹

II. Method of Calculation

The method of calculating CMP adjustments applied in this final rule is required by the 2015 Act. Under the 2015 Act and the Office of Management and Budget guidance required by the 2015 Act, annual inflation adjustments subsequent to the initial catch-up adjustment are to be based on the percent change between the Consumer Price Index for all Urban Consumers ("CPI-U") for the October preceding the date of the adjustment and the prior

¹ However, the increased CMPs apply only with respect to underlying violations occurring after the date of enactment of the 2015 Act, *i.e.*, after November 2, 2015.

year's October CPI-U. As set forth in Office of Management and Budget Memorandum M-20-05 of December 16, 2019, the adjustment multiplier for 2019 is 1.01764. In order to complete the 2019 annual adjustment, each current CMP is multiplied by the 2020 adjustment multiplier. Under the 2015 Act, any increase in CMP must be rounded to the nearest multiple of \$1.

Procedural Matters

1. Administrative Procedure Act

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Section 701(b)) requires agencies, beginning in 2017, to make annual adjustments for inflation to CMPs, without needing to provide notice and the opportunity for public comment and a delayed effective date required by 5 U.S.C. 553. Additionally, the methodology used, effective 2017, for adjusting CMPs for inflation is provided by statute, with no discretion provided to agencies regarding the substance of the adjustments for inflation to CMPs. The Department is charged only with performing ministerial computations to determine the dollar amount of adjustments for inflation to CMPs. Accordingly, prior public notice, an opportunity for public comment, and a delayed effective date are not required for this rule.

2. Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

3. Executive Order 12866

This rule is not a significant regulatory action as defined in section 3.f of Executive Order 12866.

4. Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104-13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this rule because there are no new or revised recordkeeping or reporting requirements.

List of Subjects

31 CFR Part 27

Administrative Practice and Procedure, Penalties.

31 CFR Part 50

Insurance, Terrorism.

Authority and Issuance

For the reasons set forth in the preamble, part 27 and part 50 of title 31

of the Code of Federal Regulations are amended as follows:

PART 27—CIVIL PENALTY ASSESSMENT FOR MISUSE OF DEPARTMENT OF THE TREASURY NAMES, SYMBOLS, ETC.

■ 1. The authority citation for part 27 continues to read as follows:

Authority: 31 U.S.C. 321, 333

■ 2. Amend § 27.3 by revising paragraph (c) to read as follows:

§ 27.3 Assessment of civil penalties.

* * * * *

(c) *Civil Penalty.* An assessing official may impose a civil penalty on any person who violates the provisions of paragraph (a) of this section. The amount of a civil monetary penalty shall not exceed \$8,116 for each and every use of any material in violation of paragraph (a), except that such penalty shall not exceed \$40,576 for each and every use if such use is in a broadcast or telecast.

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PART 50—TERRORISM RISK INSURANCE PROGRAM

■ 3. The authority citation for part 50 is revised to read as follows:

Authority: 5 U.S.C. 301; 31 U.S.C. 321; Title I, Pub. L. 107-297, 116 Stat. 2322, as amended by Pub. L. 109-144, 119 Stat. 2660, Pub. L. 110-160, 121 Stat. 1839, Pub. L. 114-1, 129 Stat. 3, and Pub. L. 116-94, 133 Stat. 2534 (15 U.S.C. 6701 note); Pub. L. 114-74, 129 Stat. 601, Title VII (28 U.S.C. 2461 note).

■ 4. Amend § 50.83(a) to read as follows:

§ 50.83 Adjustment of civil monetary penalty amount.

(a) *Inflation Adjustment.* Any penalty under the Act and these regulations may not exceed the greater of \$1,419,442 and, in the case of any failure to pay, charge, collect or remit amounts in accordance with the Act or these regulations such amount in dispute.

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David B. Dwyer,

Executive Secretary.

[FR Doc. 2020-02712 Filed 2-20-20; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R05-OAR-2018-0634; FRL-10005-34-Region 5]

Air Plan Approval; Indiana; Revisions to NO_x SIP Call and CAIR Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving under the Clean Air Act (CAA) a request from the Indiana Department of Environmental Management (IDEM) to revise the Indiana State Implementation Plan (SIP) to incorporate the following: A new rule concerning nitrogen oxide (NO_x) emissions for the ozone season from Electric Generating Units (EGUs) and large non-EGUs; revisions concerning NO_x emission rate limits for specific source categories; the repeal of the NO_x Budget Trading Program; and the repeal of the Clean Air Interstate Rule (CAIR) NO_x ozone season trading program. This SIP revision will ensure continued compliance by EGUs and large non-EGUs with the requirements of the NO_x SIP Call.

DATES: This direct final rule is effective April 21, 2020, unless EPA receives adverse comments by March 23, 2020. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R05-OAR-2018-0634 at <http://www.regulations.gov> or via email to arra.sarah@epa.gov. For comments submitted at [Regulations.gov](http://www.regulations.gov), follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [Regulations.gov](http://www.regulations.gov). For either manner of submission, 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. 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