

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 1, subpart L have been approved under OMB control number 0910–0752.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <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 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF STATE

22 CFR Parts 35, 103, 127, and 138

[Public Notice: 11959]

RIN 1400–AF59

Department of State 2023 Civil Monetary Penalties Inflationary Adjustment

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This final rule is issued to adjust the civil monetary penalties (CMP) for regulatory provisions maintained and enforced by the Department of State. The revised CMP adjusts the amount of civil monetary penalties assessed by the Department of State based on the December 2022 guidance from the Office of Management and Budget and by recent legislation. For penalties adjusted according to the December 2022 guidance, the new amounts will apply only to those penalties assessed on or after the effective date of this rule, regardless of the date on which the underlying facts or violations occurred. For the penalty adjusted according to recent legislation, the new amounts will apply only to those penalties assessed

for violations occurring on or after December 27, 2022.

DATES: This final rule is effective on January 11, 2023.

FOR FURTHER INFORMATION CONTACT: Alice Kottmyer, Attorney-Adviser, Office of Management, kottmyeram@state.gov. ATTN: Regulatory Change, CMP Adjustments, (202) 647–2318.

SUPPLEMENTARY INFORMATION: The Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101–410, as amended by the Debt Collection Improvement Act of 1996, Pub. L. 104–134, required the head of each agency to adjust its CMPs for inflation no later than October 23, 1996 and required agencies to make adjustments at least once every four years thereafter. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Section 701 of Pub. L. 114–74 (the 2015 Act) further amended the 1990 Act by requiring agencies to adjust CMPs, if necessary, pursuant to a “catch-up” adjustment methodology prescribed by the 2015 Act, which mandated that the catch-up adjustment take effect no later than August 1, 2016. Additionally, the 2015 Act required agencies to make annual adjustments to their respective CMPs in accordance with guidance issued by the Office of Management and Budget (OMB).

Based on these statutes, the Department of State (the Department) published a final rule in June 2016¹ to implement the “catch-up” provisions; and annual updates to its CMPs in January 2017,² January 2018,³ March 2019 (delayed due to the Government shutdown),⁴ January 2020,⁵ February 2021 (delayed due to transition issues),⁶ and January 2022.⁷

On December 15, 2022, OMB notified agencies that the annual cost-of-living adjustment multiplier for fiscal year (FY) 2023, based on the Consumer Price Index, is 1.07745. Additional information may be found in OMB Memorandum M–23–05 at: <https://www.whitehouse.gov/wp-content/uploads/2022/12/M-23-05-CMP-CMP-Guidance.pdf>. This final rule amends Department CMPs for fiscal year 2023, with the exception of the CMP for violation of 22 U.S.C 2778 at 22 CFR 127.10(a)(1)(i), which is amended in accordance with section 9708 of the James M. Inhofe National Defense

Authorization Act for Fiscal Year 2023, Pub. L. 117–263.

Overview of the Areas Affected by This Rule

Within the Department of State (title 22, Code of Federal Regulations), this rule affects four areas:

(1) Part 35, which implements the Program Fraud Civil Remedies Act of 1986 (PFCRA), codified at 31 U.S.C. 3801–3812;

(2) Part 103, which implements the Chemical Weapons Convention Implementation Act of 1998 (CWC Act) (22 U.S.C. 6761);

(3) Part 127, which implements the penalty provisions of sections 38(e), 39A(c), and 40(k) of the Arms Export Control Act (AECA) (22 U.S.C. 2778(e), 2779a(c), and 2780(k)); and

(4) Part 138, which implements section 319 of Pub. L. 101–121, codified at 31 U.S.C. 1352, which prohibits recipients of Federal contracts, grants, and loans from using appropriated funds for lobbying the executive or legislative branches of the Federal Government in connection with a specific contract.

Specific Changes to 22 CFR Made by this Rule

I. Part 35

The PFCRA, enacted in 1986, authorizes agencies, with approval from the Department of Justice, to pursue individuals or firms for false claims. Applying the FY 2023 inflationary adjustment of 1.07745, the new maximum penalty is \$13,508 for each false claim or statement, up to a maximum of \$405,270.

II. Part 103

The CWC Act provided domestic implementation of the Convention on the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and on Their Destruction. The penalty provisions of the CWC Act are codified at 22 U.S.C. 6761. Applying the FY 2023 multiplier, the new maximum amounts are as follows: prohibited acts related to inspections, \$45,429; for recordkeeping violations, \$9,086.

III. Part 127

The Assistant Secretary of State for Political-Military Affairs is responsible for the imposition of CMPs under the International Traffic in Arms Regulations (ITAR), which is administered by the Directorate of Defense Trade Controls (DDTC).

¹ 81 FR 36771 (Jun. 8, 2016).

² 82 FR 3168 (Jan. 11, 2017).

³ 83 FR 234 (Jan. 3, 2018).

⁴ 84 FR 9957 (Mar. 19, 2019).

⁵ 85 FR 2020 (Jan. 14, 2020).

⁶ 86 FR 7804 (Feb. 2, 2021).

⁷ 87 FR 1072 (Jan. 10, 2022).

(1) AECA Section 38(e)

Amended in accordance with section 9708 of Public Law 117–263, the new maximum penalty under 22 U.S.C. 2778 (22 CFR 127.10(a)(1)(i)) is the greater of \$1,200,000 or the amount that is twice the value of the transaction that is the basis of the violation with respect to which the penalty is imposed.

(2) AECA Section 39A(c)

Applying the multiplier, the new maximum penalty under 22 U.S.C. 2779a (22 CFR 127.10(a)(1)(ii)) is \$996,685, or five times the amount of

the prohibited payment, whichever is greater.

(3) AECA Section 40(k)

Applying the multiplier, the new maximum penalty under 22 U.S.C. 2780 (22 CFR 127.10(a)(1)(iii)) is \$1,186,338.

IV. Part 138

Section 319 of Public Law 101–121, codified at 31 U.S.C. 1352, provides penalties for recipients of Federal contracts, grants, and loans who use appropriated funds to lobby the executive or legislative branches of the Federal Government in connection with a specific contract, grant, or loan. Any

person who violates that prohibition is subject to a civil penalty. The statute also requires each person who requests or receives a Federal contract, grant, cooperative agreement, loan, or a Federal commitment to insure or guarantee a loan, to disclose any lobbying; there is a penalty for failure to disclose.

Applying the FY 2023 multiplier, the maximum penalties for both improper expenditures and failure to disclose, is: for first offenders, \$23,343; for others, not less than \$23,727, and not more than \$237,268.

Summary

FY 2023 MULTIPLIER: 1.07745

Citation in 22 CFR	FY22 Max penalties	New (FY 23) max penalties
\$ 35.3	\$12,537 up to \$376,138	\$13,508 up to \$405,270.
\$ 103.6(a)(1) <i>Prohibited Acts</i>	\$42,163	\$45,429.
\$ 103.6(a)(2) <i>Record-keeping Violations</i>	\$8,433	\$9,086.
\$ 127.10(a)(1)(i)	\$1,272,251	the greater of \$1,200,000 or the amount that is twice the value of the transaction that is the basis of the violation with respect to which the penalty is imposed.
\$ 127.10(a)(1)(ii)	\$925,041 or five times the amount of the prohibited payment, whichever is greater.	\$996,685, or five times the amount of the prohibited payment, whichever is greater.
\$ 127.10(a)(1)(iii)	\$1,101,061	\$1,186,338.
\$ 138.400 <i>First Offenders</i> ..	\$21,665	\$23,343.
\$ 138.400	\$22,021 up to \$220,213	\$23,727 up to \$237,268.

Effective Date of Penalties

The revised CMP amounts for all penalties other than the penalty at 22 CFR 127.10(a)(1)(i) will go into effect on the date this rule is published. All violations for which those CMPs are assessed on or after the effective date of this rule, regardless of whether the violation occurred before the effective date, will be assessed at the adjusted penalty level. For the penalty at 22 CFR 127.10(a)(1)(i) adjusted according to section 9708 of Public Law 117–263, the new amounts will apply only to those penalties assessed for violations occurring on or after December 27, 2022.

Future Adjustments and Reporting

The 2015 Act directed agencies to undertake an annual review of CMPs using a formula prescribed by the statute. Annual adjustments to CMPs are made in accordance with the guidance issued by OMB. As in this rulemaking, the Department of State will publish notification of annual inflation adjustments to CMPs in the **Federal Register** no later than January 15 of each year, with the adjusted amount taking effect immediately upon publication.

Regulatory Analysis and Notices

Administrative Procedure Act

The Department of State is publishing this rule using the “good cause” exception to the Administrative Procedure Act (5 U.S.C. 553(b)), as the Department has determined that public comment on this rulemaking would be impractical, unnecessary, or contrary to the public interest. This rulemaking is mandatory and entirely without agency discretion; it implements Public Law 114–74. *See* 5 U.S.C. 553(d)(3).

Regulatory Flexibility Act

Because this rulemaking is exempt from 5 U.S.C. 553, a regulatory flexibility analysis is not required.

Unfunded Mandates Reform Act of 1995

This rule does not involve a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule within the meaning of the Congressional Review Act, 5 U.S.C. 801 *et seq.*

Executive Orders 12372 and 13132

This amendment will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this amendment does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement.

Executive Orders 12866 and 13563

The Department believes that benefits of the rulemaking outweigh any costs, and there are no feasible alternatives to this rulemaking. Pursuant to M–23–05, the Office of Information and Regulatory Affairs (OIRA) has determined that agency regulations that (1) exclusively implement the annual adjustment, (2) are consistent with this guidance, and (3) have an annual impact of less than \$100 million, are generally not significant regulatory actions under E.O.

12866. Therefore, agencies are generally not required to submit regulations satisfying those criteria to OIRA for review. This regulation satisfies all of those criteria.

Executive Order 12988

The Department of State has reviewed the amendment in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian Tribal governments, and will not preempt Tribal law. Accordingly, Executive Order 13175 does not apply to this rulemaking.

Paperwork Reduction Act

This rulemaking does not impose or revise any information collections subject to 44 U.S.C. Chapter 35.

List of Subjects

22 CFR Part 35

Administrative practice and procedure, Claims, Fraud, Penalties.

22 CFR Part 103

Administrative practice and procedure, Chemicals, Classified information, Foreign relations, Freedom of information, International organization, Investigations, Penalties, Reporting and recordkeeping requirements.

22 CFR Part 127

Arms and munitions, Crime, Exports, Penalties, Seizures and forfeitures.

22 CFR Part 138

Government contracts, Grant programs, Loan programs, Lobbying, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth above, 22 CFR parts 35, 103, 127, and 138 are amended as follows:

PART 35—PROGRAM FRAUD CIVIL REMEDIES

- 1. The authority citation for part 35 continues to read as follows:

Authority: 22 U.S.C. 2651a; 31 U.S.C. 3801 *et seq.*; Pub. L. 114–74, 129 Stat. 584.

§ 35.3 [Amended]

- 2. In § 35.3:
- a. Remove “\$12,537” and add in its place “\$13,508”, wherever it occurs.
- b. In paragraph (f), remove “\$376,138” and add in its place “\$405,270”.

PART 103—REGULATIONS FOR IMPLEMENTATION OF THE CHEMICAL WEAPONS CONVENTION AND THE CHEMICAL WEAPONS CONVENTION IMPLEMENTATION ACT OF 1998 ON THE TAKING OF SAMPLES AND ON ENFORCEMENT OF REQUIREMENTS CONCERNING RECORDKEEPING AND INSPECTIONS

- 3. The authority citation for part 103 continues to read as follows:

Authority: 22 U.S.C. 2651a; 22 U.S.C. 6701 *et seq.*; Pub. L. 114–74, 129 Stat. 584.

§ 103.6 [Amended]

- 4. In § 103.6:
- a. In paragraph (a)(1), remove “\$42,163” and add in its place “\$45,429”; and
- b. In paragraph (a)(2), remove “\$8,433” and add in its place “\$9,086”.

PART 127—VIOLATIONS AND PENALTIES

- 5. The authority citation for part 127 continues to read as follows:

Authority: Sections 2, 38, and 42, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2791); 22 U.S.C. 401; 22 U.S.C. 2651a; 22 U.S.C. 2779a; 22 U.S.C. 2780; E.O. 13637, 78 FR 16129; Pub. L. 114–74, 129 Stat. 584.

§ 127.10 [Amended]

- 6. In § 127.10:
- a. In paragraph (a)(1)(i), remove “\$1,272, 251” and add in its place “the greater of \$1,200,000 or the amount that is twice the value of the transaction that is the basis of the violation with respect to which the penalty is imposed”; and
- b. In paragraph (a)(1)(ii), remove “\$925,041” and add in its place “\$996,685”; and
- c. In paragraph (a)(1)(iii), remove “\$1,101,061” and add in its place “\$1,186,338”.

PART 138—RESTRICTIONS ON LOBBYING

- 7. The authority citation for part 138 continues to read as follows:

Authority: 22 U.S.C. 2651a; 31 U.S.C. 1352; Pub. L. 114–74, 129 Stat. 584.

§ 138.400 [Amended]

- 8. In § 138.400:
- a. Remove “\$22,021” and “\$220,213” and add in their place “\$23,727” and “\$237,268”, respectively, wherever they occur.

- b. In paragraph (e), remove “\$21,665” and add in its place “\$23,343”.

Kevin E. Bryant,

Deputy Director, Office of Directives Management, Department of State.

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 591

Publication of Venezuela Sanctions Regulations Web General Licenses 1, 2, 4, and Subsequent Iterations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of Web General Licenses.

SUMMARY: The Department of the Treasury’s Office of Foreign Assets Control (OFAC) is publishing seven general licenses (GLs) issued in the Venezuela Sanctions program: GLs 1, 2, 2A, 4, 4A, 4B, and 4C, each of which was previously made available on OFAC’s website.

DATES: GL 1 was issued on August 25, 2017. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC’s website: www.treas.gov/ofac.

Background

On August 25, 2017, OFAC issued GLs 1, 2, and 4 to authorize certain transactions otherwise prohibited by Executive Order (E.O.) 13808 of August 24, 2017, “Imposing Additional Sanctions with Respect to the Situation in Venezuela” (82 FR 41155, August 29, 2017). Subsequently, OFAC issued one further iteration of GL 2 and three further iterations of GL 4. On August 5, 2019 OFAC issued GL 2A pursuant to E.O. 13808 and E.O. 13884 of August 5, 2019, “Blocking Property of the Government of Venezuela” (84 FR 38843, August 7, 2019). GL 2A superseded GL 2. On March 22, 2019 OFAC issued GL 4A pursuant to E.O.