

potential competitors to enter the marketplace by lowering their costs. The agency, therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Associates of Cape Cod dated March 22, 2004.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 866.3050 is added to subpart D to read as follows:

§ 866.3050 Beta-glucan serological assays.

(a) *Identification.* Beta-glucan serological assays are devices that consist of antigens or proteases used in serological assays. The device is intended for use for the presumptive diagnosis of fungal infection. The assay is indicated for use in patients with symptoms of, or medical conditions predisposing the patient to invasive fungal infection. The device can be used as an aid in the diagnosis of deep seated mycoses and fungemias.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan." See § 866.1(e) for the availability of this guidance document.

Dated: September 10, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04-21316 Filed 9-22-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 592

Rough Diamonds Control Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Treasury Department's Office of Foreign Assets Control is revising the Rough Diamonds Control Regulations previously issued as an interim final rule. The regulations carry out the purposes of Executive Order 13312 of July 29, 2003, which implemented the Clean Diamond Trade Act and the Kimberley Process Certification Scheme for rough diamonds. Based on its experience and that of other involved agencies, OFAC is revising certain reporting and recordkeeping requirements of the regulations.

DATES: Effective Date: September 23, 2004.

FOR FURTHER INFORMATION CONTACT: OFAC's Chief of Policy Planning and Program Management, tel.: (202) 622-4855, or Chief Counsel, tel.: (202) 622-2410.

SUPPLEMENTARY INFORMATION:

Background

On July 29, 2003, the President issued Executive Order 13312, to implement the Clean Diamond Trade Act (Pub. L. 108-19) and the multilateral Kimberley Process Certification Scheme for rough diamonds (KPCS). The Clean Diamond Trade Act requires the President, subject to certain waiver authorities, to prohibit the importation into, and exportation from, the United States of any rough diamond not controlled through the KPCS. This means shipments of rough diamonds between the United States and non-Participants in the KPCS generally are prohibited, and shipments between the United States and Participants are permitted only if they are handled in accordance with the standards, practices, and procedures of the KPCS set out in these regulations.

The Treasury Department's Office of Foreign Assets Control (OFAC), acting pursuant to Executive Order 13312 and delegated authority, published the Rough Diamonds Control Regulations, 31 CFR part 592 (the Regulations), as an interim final rule on August 4, 2003 (68 FR 45777). The Regulations, which are described in detail in the preamble to the interim final rule, implement the Clean Diamond Trade Act and the KPCS.

OFAC requested public comments on the Regulations. No public comments were received. However, based on its experience and that of other agencies that also participate in the implementation and administration of the Clean Diamond Trade Act and the KPCS, OFAC is revising the Regulations in four respects: (1) To specify that the ultimate consignee is responsible for retaining the original Kimberley Process Certificate accompanying an importation into the United States; (2) to require the ultimate consignee to report the receipt of a shipment of rough diamonds to the relevant foreign exporting authority within 15 calendar days of the date that the shipment arrived at a U.S. port of entry; (3) to advise persons engaged in the diamond trade of a pending requirement of U.S. Customs and Border Protection (Customs) that customs brokers, importers, and filers making entry of a shipment of rough diamonds either submit through Custom's Automated Broker Interface (ABI) system the unique identifying number of the Kimberley Process Certificate accompanying the shipment or, for non-ABI entries, indicate the certificate number on the Customs Form 7501 Entry Summary at each entry line; and (4) to clarify the country-of-origin reporting requirements for shipments of

parcels of mixed origin rough diamonds. OFAC is now issuing the Regulations as a final rule, incorporating these four revisions and the others described below.

Section 592.301 of the Regulations defines the term *Controlled through the Kimberley Process Certification Scheme*. OFAC is revising two subsections of this definition and adding a note to the section. First, § 592.301(a)(1) requires, among other things, that a shipment of rough diamonds imported into the United States be accompanied by a Kimberley Process Certificate validated by the relevant exporting authority. The certificate must be presented if demanded by Customs. Also, § 592.501 of the Regulations requires a United States person importing rough diamonds into the United States to maintain full and accurate records of the transaction for at least five years after the date of the transaction. OFAC has been advised that persons engaged in the diamond trade are uncertain which person should maintain possession of the original Kimberley Process Certificate accompanying an importation into the United States. To eliminate this uncertainty and to facilitate OFAC's and Customs' enforcement efforts, OFAC is revising § 592.301(a)(1) to specify that the ultimate consignee reported on the Customs Form 7501 Entry Summary or its electronic equivalent filed with Customs is responsible for retaining that certificate for a period of at least five years from the date of the importation.

Second, § 592.301(a)(3) of the Regulations originally required the importer of record in the United States to confirm receipt of a shipment of rough diamonds to the relevant foreign exporting authority. OFAC is revising this subsection to specify which person involved in an importation is required now to report the receipt of a shipment in an effective and timely manner. As revised, § 592.301(a)(3) specifies that the ultimate consignee reported on the Customs Form 7501 Entry Summary or its electronic equivalent filed with Customs is the person responsible for reporting receipt of the shipment to the foreign exporting authority. Also, the revised § 592.301(a)(3) now requires that the ultimate consignee must report specified information about the shipment to the foreign exporting authority within 15 calendar days of the date that the shipment arrived at a U.S. port of entry.

OFAC also is adding a note to § 592.301 to reflect a pending Customs requirement that customs brokers, importers, and filers making entry of a shipment of rough diamonds either

submit through Customs' Automated Broker Interface (ABI) system the unique identifying number of the Kimberley Process Certificate accompanying the shipment or, for non-ABI entries, indicate the certificate number on the Customs Form 7501 Entry Summary at each entry line. This requirement will take effect on November 1, 2004. The submission of the Kimberley Process Certificate number will facilitate the Census Bureau's compilation of statistical data relating to the importation of rough diamonds.

Section 592.307 of the Regulations defines the term *Kimberley Process Certificate* to include a requirement that the certificate identify the country of origin for a shipment of one or more parcels of rough diamonds of unmixed (*i.e.*, from the same) origin. The definition's silence with respect to the treatment of a shipment that includes a parcel of mixed origin rough diamonds has prompted questions from importers as to whether the certificate may be used and how it should be completed, in such circumstances. A shipment including a parcel of mixed-origin rough diamonds is to be entered into the United States with the Kimberley Process Certificate validated by the relevant exporting authority, and the certificate need not indicate the countries of origin of the diamonds. With respect to such a shipment, however, OFAC is adding a note to § 592.307(b) to state that the country-of-origin field must be filled in with asterisks. The note also advises that the shipment still must comply with all other country-of-origin reporting requirements imposed by law.

OFAC is also revising the definition of *Effective date* in § 592.302 of the Regulations in light of the new reporting requirements imposed by § 592.301(a)(3), as well as revising § 592.801 to reflect the Office of Management and Budget's (OMB) issuance of three control numbers authorizing the collections of information in the Regulations. Finally, OFAC is revising § 592.602 to reflect properly the basis upon which the Director of OFAC may decide to issue a prepenalty notice and to make other minor corrections.

Electronic and Facsimile Availability

This file is available for download without charge in ASCII and Adobe Acrobat readable (*.PDF) formats at GPO Access. GPO Access supports HTTP, FTP, and Telnet at fedbbs.access.gpo.gov. It may also be accessed by modem dialup at (202) 512-1387 followed by typing "/GO/FAC."

Paper copies of this document can be obtained by calling the Government Printing Office at (202) 512-1530. Additional information concerning the programs administered by OFAC is available for download from the Office's Internet Home Page at: <http://www.treas.gov/ofac> or via FTP at [ofacftp.treas.gov](ftp://ofacftp.treas.gov). Facsimiles of information are available through the Office's 24-hour fax-on-demand service: call (202) 622-0077 using a fax machine, a fax modem, or (within the United States) a touch-tone telephone.

Executive Order 12866, Administrative Procedure Act, Regulatory Flexibility Act, and Paperwork Reduction Act

Because the regulations involve a foreign affairs function, the provisions of Executive Order 12866 and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601-612) does not apply.

With respect to section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the collections of information in §§ 592.301(a)(1), 592.501, and 592.603 of the Regulations are made pursuant to OFAC's Reporting, Procedures and Penalties Regulations (31 CFR part 501) and have been approved by OMB under control number 1505-0164. *See* 31 CFR 501.901. The collection of information in § 592.301(a)(4) relating to the Census Bureau's Foreign Trade Statistics Regulations (15 CFR part 30) has been approved by OMB under control number 0607-0152. *See* Automated Export System Mandatory Filing for Exports (Reexports) of Rough Diamonds, 68 FR 59877 (Oct. 20, 2003).

The collection of information in § 592.301(a)(3) of the Regulations has been submitted to and approved by OMB pending public comment and has been assigned OMB control number 1505-0198. Section 592.301(a)(3) specifies that the ultimate consignee identified on the Customs Form 7501 Entry Summary filed with Customs is required to report specified information about the shipment of rough diamonds imported into the United States to the foreign exporting authority within 15 calendar days of the date that the shipment arrived at a U.S. port of entry. This collection of information is needed to monitor the integrity of international rough diamond shipments, and the information collected will be used to further the compliance, enforcement, and civil penalty programs of OFAC,

U.S. Customs and Border Protection, and the Bureau of Immigration and Customs Enforcement. See sections 5(a) and 8 of the Clean Diamond Trade Act.

With respect to all of the foregoing collections of information, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The likely respondents and recordkeepers affected by the new collection of information in § 592.301(a)(3) are business organizations and individuals engaged in the international diamond trade. The estimated annual number of respondents and recordkeepers is 250, and the estimated total annual number of responses is 3,000.

The estimated total annual reporting and/or recordkeeping burden is estimated to be 500 hours. The estimated average annual burden per respondent/recordkeeper is 2 hours, based on an estimated annual frequency of 10 to 15 responses and an estimated time per response of 10 minutes.

Comments are invited on: (a) Whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques and other forms of information technology; and (e) estimated capital or start-up costs of operation, maintenance, and purchase of services to provide information.

Comments concerning the above information, the accuracy of these burden estimates, and suggestions for reducing this burden should be directed to OMB, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with a copy to Chief of Records, Attention: Request for Comments, Office of Foreign Assets Control, Department of the Treasury, 1500 Pennsylvania Avenue, NW., Washington, DC 20220. Any such comments should be submitted not later than November 22, 2004. All comments on the collection of information in § 592.301(a)(3) will be a matter of public record.

List of Subjects in 31 CFR Part 592

Administrative practice and procedure, Foreign trade, Exports,

Imports, Kimberley Process, Penalties, Reporting and recordkeeping requirements, Rough diamond.

■ For the reasons set forth in the preamble, 31 CFR chapter V, part 592 is revised to read as follows:

PART 592—ROUGH DIAMONDS CONTROL REGULATIONS

Subpart A—Relation of This Part to Other Laws and Regulations

Sec.

592.101 Relation of this part to other laws and regulations.

Subpart B—Prohibitions

592.201 Prohibited importation and exportation of any rough diamond; permitted importation and exportation of any rough diamond.

592.202 Evasions; attempts; conspiracies.

Subpart C—General Definitions

592.301 Controlled through the Kimberley Process Certification Scheme.

592.302 Effective date.

592.303 Entity.

592.304 Exporting authority.

592.305 Importation into the United States.

592.306 Importing authority.

592.307 Kimberley Process Certificate.

592.308 Participant.

592.309 Person.

592.310 Rough diamond.

592.311 United States.

592.312 United States person; U.S. person.

Subpart D—Interpretations

592.401 Reference to amended sections.

592.402 Effect of amendment.

592.403 Transshipment or transit through the United States.

592.404 Importation into or release from a bonded warehouse or foreign trade zone.

Subpart E—Records and Reports

592.501 Records and reports.

Subpart F—Penalties

592.601 Penalties.

592.602 Prepenalty notice.

592.603 Response to prepenalty notice; informal settlement.

592.604 Penalty imposition or withdrawal.

592.605 Administrative collection; referral to United States Department of Justice.

Subpart G—Procedures

592.701 Procedures.

592.702 Delegation by the Secretary of the Treasury.

Subpart H—Paperwork Reduction Act

592.801 Paperwork Reduction Act notice.

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); Pub. L. 108–19, 117 Stat. 631 (19 U.S.C. 3901–3913); E.O. 13312, 68 FR 45151 3 CFR, 2003 Comp., p. 246.

Subpart A—Relation of This Part to Other Laws and Regulations

§ 592.101 Relation of this part to other laws and regulations.

This part is separate from, and independent of, the other parts of this chapter, with the exception of part 501 of this chapter, the recordkeeping and reporting requirements and procedures of which apply to this part. Actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. Differing foreign policy and national security circumstances may result in differing interpretations of similar language among the parts of this chapter. No license or authorization contained in or issued pursuant to those other parts authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to any other provision of law or regulation authorizes any transaction prohibited by this part.

Subpart B—Prohibitions

§ 592.201 Prohibited importation and exportation of any rough diamond; permitted importation or exportation of any rough diamond.

(a) Except to the extent provided in paragraph (b) of this section, and notwithstanding the existence of any rights or obligations conferred or imposed by any contract entered into or any license or permit granted prior to the effective date, the importation into, or exportation from, the United States on or after July 30, 2003, of any rough diamond, from whatever source, is prohibited, unless the rough diamond has been controlled through the Kimberley Process Certification Scheme.

(b) The prohibitions in paragraph (a) of this section regarding the importation into, or exportation from, the United States of any rough diamond not controlled through the Kimberley Process Certification Scheme do not apply to an importation from, or exportation to, any country with respect to which the Secretary of State has granted a waiver pursuant to section 4(b) of the Clean Diamond Trade Act (Pub. L. 108–19) and section 2(a)(i) of Executive Order 13312.

Note to § 592.201. An importation of any rough diamond from, or an exportation of any rough diamond to, a non-Participant is not controlled through the Kimberley Process Certification Scheme and thus is not permitted, except in the following circumstance. The Secretary of State may, pursuant to section 4(b) of the Clean Diamond Trade Act, waive the prohibitions contained in section 4(a) of that Act with

respect to a particular country for periods of not more than one year each. The Secretary of State will publish a notice in the **Federal Register** identifying any country with respect to which a waiver applies and specifying the relevant time period during which the waiver will apply.

§ 592.202 Evasions; attempts; conspiracies.

(a) Notwithstanding the existence of any rights or obligations conferred or imposed by any contract entered into or any license or permit granted prior to July 30, 2003, any transaction by a United States person anywhere, or any transaction that occurs in whole or in part within the United States, on or after the effective date that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in this part is prohibited.

(b) Notwithstanding the existence of any rights or obligations conferred or imposed by any contract entered into or any license or permit granted prior to July 30, 2003, any conspiracy formed to violate any of the prohibitions of this part is prohibited.

Subpart C—General Definitions

§ 592.301 Controlled through the Kimberley Process Certification Scheme.

(a) Except as otherwise provided in paragraph (b) of this section, the term *controlled through the Kimberley Process Certification Scheme* refers to the following requirements that apply, as appropriate, to the importation into the United States from a Participant, or to the exportation from the United States to a Participant, of any shipment including any rough diamond:

(1) *Kimberley Process Certificate.* A shipment of rough diamonds imported into, or exported from, the United States must be accompanied by an original Kimberley Process Certificate. The certificate must be presented in connection with an importation or exportation of rough diamonds if demanded by United States customs officials. Pursuant to 31 CFR §§ 501.601 and 501.602, the person identified as the ultimate consignee (see Customs Directive 3550–079A) on the Customs Form 7501 Entry Summary or its electronic equivalent filed with U.S. Customs and Border Protection in connection with an importation of rough diamonds must retain the original Kimberley Process Certificate for a period of at least five years from the date of importation and must make such certificate available for examination upon demand.

(2) *Tamper-resistant container.* A shipment of rough diamonds imported

into, or exported, from the United States must be sealed in a tamper-resistant container;

(3) *Notification requirements for importations into the United States.* The person identified as the ultimate consignee (see Customs Directive 3550–079A) on the Customs Form 7501 Entry Summary or its electronic equivalent filed with U.S. Customs and Border Protection in connection with an importation of rough diamonds must report that person's receipt of a shipment of rough diamonds to the relevant foreign exporting authority within 15 calendar days of the date that the shipment arrived at the U.S. port of entry. The report must refer to the relevant Kimberley Process Certificate by its unique identifying number; specify the number of parcels in the shipment; specify the total carat weight of the shipment; and identify the importer and exporter of the shipment. The report need not be in any particular form and may be submitted electronically or by mail or courier; and

(4) *Validation of Kimberley Process Certificate for exportations from the United States.* With respect to the exportation of rough diamonds from the United States and regardless of the destination, the U.S. Census Bureau requires the filing of export information through the Automated Export System. Submission of export information through the Automated Export System must be done in advance and must be confirmed by the return of an Internal Transaction Number. The return to the filer of the Internal Transaction Number shall constitute the validation of the Kimberley Process Certificate for an exportation of rough diamonds from the United States to a Participant. The exporter is required to report the Internal Transaction Number on the Kimberley Process Certificate accompanying any exportation from the United States. The Internal Transaction Number is a unique confirmation number generated by the Automated Export System to the filer who provides in a timely manner the complete commodity shipment data when such data have been accepted by the system.

(b) The Secretary of State, consistent with section 3(2)(B) of the Clean Diamond Trade Act (Pub. L. 108–19), may modify the requirements set forth in paragraph (a) of this section upon making a determination that a Participant has established an alternative system of control for rough diamonds that meets substantially the standards, practices, and procedures of the Kimberley Process Certification Scheme.

Note 1 to § 592.301. The Secretary of State will periodically publish in the **Federal Register** an up-to-date listing of all Participants and their importing and exporting authorities. Where appropriate, such listing also will describe any modification of the requirements set forth in paragraph (a) of this section.

Note 2 to § 592.301. Pursuant to 31 CFR §§ 501.601 and 501.602, the recordkeeping and reporting requirements imposed by § 592.501 apply to all U.S. persons engaged in the importation into, or exportation from, the United States of any shipment of rough diamonds.

Note 3 to § 592.301. Effective November 1, 2004, customs brokers, importers, and filers making entry of a shipment of rough diamonds must either submit through U.S. Customs' Automated Broker Interface (ABI) system the unique identifying number of the Kimberley Process Certificate accompanying the shipment or, for non-ABI entries, indicate the certificate number on the Customs Form 7501 Entry Summary at each entry line.

§ 592.302 Effective date.

The term *effective date* refers to the effective date of the applicable prohibitions and directives contained in this part as follows:

(a) With respect to all provisions of this part except for § 592.301(a)(3), 12:01 a.m., eastern daylight time, July 30, 2003; and

(b) With respect to § 592.301(a)(3), September 23, 2004.

§ 592.303 Entity.

The term *entity* means a partnership, association, trust, joint venture, corporation, or other organization.

§ 592.304 Exporting authority.

(a) The term *exporting authority* means one or more entities designated by a Participant from whose territory a shipment of rough diamonds is being exported as having the authority to validate the Kimberley Process Certificate.

(b) The exporting authority for the United States is the U.S. Bureau of the Census.

Note to § 592.304. The Secretary of State will periodically publish in the **Federal Register** an up-to-date listing of the exporting authorities of all Participants.

§ 592.305 Importation into the United States.

The term *importation into the United States* means the bringing of goods into the United States.

§ 592.306 Importing authority.

(a) The term *importing authority* means one or more entities designated by a Participant into whose territory a shipment of rough diamonds is being

imported as having the authority to enforce the laws and regulations of the Participant regulating imports, including the verification of the Kimberley Process Certificate accompanying the shipment.

(b) The importing authorities for the United States are the U.S. Bureau of Customs and Border Protection or, in the case of a territory or possession of the United States with its own customs administration, analogous officials.

Note to § 592.306. The Secretary of State will periodically publish in the **Federal Register** an up-to-date listing of the importing authorities of all Participants.

§ 592.307 Kimberley Process Certificate.

The term *Kimberley Process Certificate* means a tamper- and forgery-resistant document that bears the following information in any language, provided that an English translation is incorporated:

(a) The title “Kimberley Process Certificate” and the statement: “The rough diamonds in this shipment have been handled in accordance with the provisions of the Kimberley Process Certification Scheme for rough diamonds”;

(b) Country of origin for shipment of parcels of unmixed (*i.e.*, from the same) origin;

Note to paragraph (b). A shipment including a parcel of mixed-origin rough diamonds is to be entered into the United States with the Kimberley Process Certificate accompanying the shipment, and the certificate need not indicate the countries of origin of the diamonds. With respect to such a shipment, the country-of-origin field on the certificate must be filled in with asterisks. The shipment must, however, still comply with all other country-of-origin reporting requirements imposed by statute or regulation.

(c) Unique numbering with the Alpha 2 country code, according to ISO 3166-1;

(d) Date of issuance;

(e) Date of expiry;

(f) Name of issuing authority;

(g) Identification of exporter and importer;

(h) Carat weight/mass;

(i) Value in U.S. dollars;

(j) Number of parcels in the shipment;

(k) Relevant Harmonized Commodity Description and Coding System; and

(l) Validation by the exporting authority.

Note to paragraph (l). See § 592.301(a)(4) for procedures governing the validation of the Kimberley Process Certificate when exporting from the United States.

§ 592.308 Participant.

The term *Participant* means a state, customs territory, or regional economic integration organization identified by the Secretary of State as one for which rough diamonds are controlled through the Kimberley Process Certification Scheme.

Note to § 592.308. The Secretary of State will periodically publish in the **Federal Register** an up-to-date listing of all Participants.

§ 592.309 Person.

The term *person* means an individual or entity.

§ 592.310 Rough diamond.

The term *rough diamond* means any diamond that is unworked or simply sawn, cleaved, or bruted and classifiable under subheading 7102.10, 7102.21, or 7102.31 of the Harmonized Tariff Schedule of the United States.

§ 592.311 United States.

The term *United States*, when used in the geographic sense, means the several States, the District of Columbia, and any commonwealth, territory, or possession of the United States.

§ 592.312 United States person; U.S. person.

The term *United States person* or *U.S. person* means any United States citizen; any alien admitted for permanent residence into the United States; any entity organized under the laws of the United States or any jurisdiction within the United States (including its foreign branches); or any person in the United States.

Subpart D—Interpretations

§ 592.401 Reference to amended sections.

Except as otherwise specified, reference to any provision in this part or chapter or to any other regulation refers to the same as currently amended.

§ 592.402 Effect of amendment.

Unless otherwise specifically provided, any amendment, modification, or revocation of any provision in or appendix to this part or chapter or of any order, regulation, ruling, or instruction issued by or under the direction of the Director of the Office of Foreign Assets Control does not affect any act done or omitted, or any civil or criminal suit or proceeding commenced or pending prior to such amendment, modification, or revocation. All penalties, forfeitures, and liabilities under any such order, regulation, ruling, or instruction continue and may be enforced as if such

amendment, modification, or revocation had not been made.

§ 592.403 Transshipment or transit through the United States.

The prohibitions in § 592.201 apply to the importation into, or exportation from, the United States, for transshipment or transit, of any rough diamond intended or destined for any country other than the United States, unless the shipment is sealed in a tamper-resistant container, accompanied by a Kimberley Process Certificate, and leaves the United States in the identical state in which it entered. The validation, recordkeeping, and reporting procedures applicable to importations and exportations do not apply in this case.

§ 592.404 Importation into or release from a bonded warehouse or foreign trade zone.

The requirements of the Kimberley Process Certification Scheme apply to all imported shipments of a rough diamond, regardless of whether they are destined for entry into, or withdrawal from, a bonded warehouse or a foreign trade zone of the United States.

Subpart E—Records and Reports

§ 592.501 Records and reports.

For provisions relating to required records and reports, see part 501, subpart C, of this chapter. Recordkeeping and reporting requirements imposed by part 501 of this chapter with respect to the prohibitions contained in this part are considered requirements arising pursuant to this part.

Subpart F—Penalties

§ 592.601 Penalties.

(a) Attention is directed to section 8 of the Clean Diamond Trade Act (the “Act”) (Pub. L. 108–19), which provides that:

(1) A civil penalty not to exceed \$10,000 per violation may be imposed on any person who violates, or attempts to violate, any order or regulation issued under the Act;

(2) Whoever willfully violates, or willfully attempts to violate, any order or regulation issued under this Act shall, upon conviction, be fined not more than \$50,000, or, if a natural person, may be imprisoned for not more than 10 years, or both; and any officer, director, or agent of any corporation who willfully participates in such violation may be punished by a like fine, imprisonment, or both; and

(3) Those customs laws of the United States, both civil and criminal, including those laws relating to seizure

and forfeiture, that apply to articles imported in violation of such laws shall apply with respect to any rough diamond imported in violation of the Act.

Note to paragraph (a). As reflected in paragraphs (a)(1) and (2) of this section, section 8(a) of the Clean Diamond Trade Act (Pub. L. 108-19) establishes penalties with respect to any violation of any regulation issued under the Act. OFAC prepenalty, penalty, and administrative collection procedures relating to such violations are set forth below in §§ 592.602 through 592.605. Section 8(c) of the Act also authorizes the U.S. Bureau of Customs and Border Protection and the U.S. Bureau of Immigration and Customs Enforcement, as appropriate, to enforce the penalty provisions set forth in paragraph (a) of this section and to enforce the laws and regulations governing exports of rough diamonds, including with respect to the validation of the Kimberley Process Certificate by the U.S. Bureau of the Census. The Office of Foreign Assets Control civil penalty procedures set forth below are separate from, and independent of, any penalty procedures that may be followed by the U.S. Bureau of Customs and Border Protection and the U.S. Bureau of Immigration and Customs Enforcement in their exercise of the authorities set forth in section 8(c) of the Clean Diamond Trade Act.

(b) The criminal penalties provided in the Act are subject to increase pursuant to 18 U.S.C. 3571.

(c) Attention is also directed to 18 U.S.C. 1001, which provides that whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device, a material fact, or makes any materially false, fictitious, or fraudulent statement or representation or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry shall be fined under title 18, United States Code, or imprisoned not more than five years, or both.

(d) Violations of this part may also be subject to relevant provisions of other applicable laws.

§ 592.602 Prepenalty notice.

(a) *When required.* If the Director of the Office of Foreign Assets Control has reason to believe that there has occurred a violation of any provision of this part or a violation of the provisions of any regulation or order issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under the Clean Diamond Trade Act, and the Director determines that further civil proceedings are warranted, the Director shall notify the

alleged violator of the agency's intent to impose a monetary penalty by issuing a prepenalty notice. The prepenalty notice shall be in writing. The prepenalty notice may be issued whether or not another agency has taken any action with respect to the matter.

(b) *Contents of notice*—(1) *Facts of violation.* The prepenalty notice shall describe the violation, specify the laws and regulations allegedly violated, and state the amount of the proposed monetary penalty.

(2) *Right to respond.* The prepenalty notice also shall inform the respondent of the respondent's right to make a written presentation within the applicable 30-day period set forth in § 592.603 as to why a monetary penalty should not be imposed or why, if imposed, the monetary penalty should be in a lesser amount than proposed.

(c) *Informal settlement prior to issuance of prepenalty notice.* At any time prior to the issuance of a prepenalty notice, an alleged violator may request in writing that, for a period not to exceed sixty (60) days, the agency withhold issuance of the prepenalty notice for the exclusive purpose of effecting settlement of the agency's potential civil monetary penalty claims. In the event the Director grants the request, under terms and conditions within his discretion, the Office of Foreign Assets Control will agree to withhold issuance of the prepenalty notice for a period not to exceed 60 days and will enter into settlement negotiations of the potential civil monetary penalty claim.

§ 592.603 Response to prepenalty notice; informal settlement.

(a) *Deadline for response.* The respondent may submit a response to the prepenalty notice within the applicable 30-day period set forth in this paragraph. The Director of the Office of Foreign Assets Control may grant, at his discretion, an extension of time in which to submit a response to the prepenalty notice. The failure to submit a response within the applicable time period set forth in this paragraph shall be deemed to be a waiver of the right to respond.

(1) *Computation of time for response.* A response to the prepenalty notice must be postmarked or date-stamped by the U.S. Postal Service (or foreign postal service, if mailed abroad) or courier service provider (if transmitted to the Office of Foreign Assets Control by courier) on or before the 30th day after the postmark date on the envelope in which the prepenalty notice was mailed. If the respondent refused delivery or otherwise avoided receipt of

the prepenalty notice, a response must be postmarked or date-stamped on or before the 30th day after the date on the stamped postal receipt maintained at the Office of Foreign Assets Control. If the prepenalty notice was personally delivered to the respondent by a non-U.S. Postal Service agent authorized by the Director, a response must be postmarked or date-stamped on or before the 30th day after the date of delivery.

(2) *Extensions of time for response.* If a due date falls on a federal holiday or weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the Director's discretion, only upon the respondent's specific request to the Office of Foreign Assets Control.

(b) *Form and method of response.* The response must be submitted in writing and may be handwritten or typed. The response need not be in any particular form. A copy of the written response may be sent by facsimile, but the original also must be sent to the Office of Foreign Assets Control Civil Penalties Division by mail or courier and must be postmarked or date-stamped, in accordance with paragraph (a) of this section.

(c) *Contents of response.* A written response must contain information sufficient to indicate that it is in response to the prepenalty notice and must include the Office of Foreign Assets Control identification number listed on the prepenalty notice.

(1) A written response must include the respondent's full name, address, telephone number, and facsimile number, if available, or those of the representative of the respondent.

(2) A written response should either admit or deny each specific violation alleged in the prepenalty notice and also state if the respondent has no knowledge of a particular violation. If the written response fails to address any specific violation alleged in the prepenalty notice, that alleged violation shall be deemed to be admitted.

(3) A written response should include any information in defense, evidence in support of an asserted defense, or other factors that the respondent requests the Office of Foreign Assets Control to consider. Any defense or explanation previously made to the Office of Foreign Assets Control or any other agency must be repeated in the written response. Any defense not raised in the written response will be considered waived. The written response also should set forth the reasons why the respondent believes the penalty should not be imposed or why, if imposed, it should be in a lesser amount than proposed.

(d) *Failure to respond.* Where the Office of Foreign Assets Control receives no response to a prepenalty notice within the applicable time period set forth in paragraph (a) of this section, a penalty notice generally will be issued, taking into account the mitigating and/or aggravating factors present in the record. If there are no mitigating factors present in the record, or the record contains a preponderance of aggravating factors, the proposed prepenalty amount generally will be assessed as the final penalty.

(e) *Informal settlement.* In addition to or as an alternative to a written response to a prepenalty notice, the respondent or respondent's representative may contact the Office of Foreign Assets Control as advised in the prepenalty notice to propose the settlement of allegations contained in the prepenalty notice and related matters. However, the requirements set forth in paragraph (f) of this section as to oral communication by the representative must first be fulfilled. In the event of settlement at the prepenalty stage, the claim proposed in the prepenalty notice will be withdrawn, the respondent will not be required to take a written position on allegations contained in the prepenalty notice, and the Office of Foreign Assets Control will make no final determination as to whether a violation occurred. The amount accepted in settlement of allegations in a prepenalty notice may vary from the civil penalty that might finally be imposed in the event of a formal determination of violation. In the event no settlement is reached, the time limit specified in paragraph (a) of this section for written response to the prepenalty notice will remain in effect unless additional time is granted by the Office of Foreign Assets Control.

(f) *Representation.* A representative of the respondent may act on behalf of the respondent, but any oral communication with the Office of Foreign Assets Control prior to a written submission regarding the specific allegations contained in the prepenalty notice must be preceded by a written letter of representation, unless the prepenalty notice was served upon the respondent in care of the representative.

§ 592.604 Penalty imposition or withdrawal.

(a) *No violation.* If, after considering any response to the prepenalty notice and any relevant facts, the Director of the Office of Foreign Assets Control determines that there was no violation by the respondent named in the prepenalty notice, the Director shall notify the respondent in writing of that

determination and of the cancellation of the proposed monetary penalty.

(b) *Violation.* (1) If, after considering any written response to the prepenalty notice, or default in the submission of a written response, and any relevant facts, the Director of the Office of Foreign Assets Control determines that there was a violation by the respondent named in the prepenalty notice, the Director is authorized to issue a written penalty notice to the respondent of the determination of the violation and the imposition of the monetary penalty.

(2) The penalty notice shall inform the respondent that payment or arrangement for installment payment of the assessed penalty must be made within 30 days of the date of mailing of the penalty notice by the Office of Foreign Assets Control.

(3) The penalty notice shall inform the respondent of the requirement to furnish the respondent's taxpayer identification number pursuant to 31 U.S.C. 7701 and that such number will be used for purposes of collecting and reporting on any delinquent penalty amount.

(4) The issuance of the penalty notice finding a violation and imposing a monetary penalty shall constitute final agency action. The respondent has the right to seek judicial review of that final agency action in federal district court.

§ 592.605 Administrative collection; referral to United States Department of Justice.

In the event that the respondent does not pay the penalty imposed pursuant to this part or make payment arrangements acceptable to the Director of the Office of Foreign Assets Control within 30 days of the date of mailing of the penalty notice, the matter may be referred for administrative collection measures by the Department of the Treasury or to the United States Department of Justice for appropriate action to recover the penalty in a civil suit in a federal district court.

Subpart G—Procedures

§ 592.701 Procedures.

For procedures relating to rulemaking and requests for documents pursuant to the Freedom of Information and Privacy Acts (5 U.S.C. 552 and 552a), see part 501, subpart E, of this chapter.

§ 592.702 Delegation by the Secretary of the Treasury.

Any action that the Secretary of the Treasury is authorized to take pursuant to Executive Order 13312 (FR vol. 68, No. 147, July 31, 2003) and any further Executive orders relating to the Clean Diamond Trade Act (Pub. L. 108-19)

may be taken by the Director of the Office of Foreign Assets Control or by any other person to whom the Secretary of the Treasury has delegated authority so to act.

Subpart H—Paperwork Reduction Act

§ 592.801 Paperwork Reduction Act notice.

For approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) of the information collections relating to the recordkeeping and reporting requirements of §§ 592.301(a)(1), subpart C, § 592.501, subpart E, and 592.603, subpart F, see § 501.901 of this chapter. The information collection requirements in §§ 592.301(a)(3) and (a)(4), subpart C, have been approved by the OMB and assigned control numbers 1505-0198 and 0607-0152, respectively. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

Dated: August 20, 2004.

R. Richard Newcomb,

Director, Office of Foreign Assets Control.

Approved: September 2, 2004.

Juan Zarate,

Assistant Secretary (Terrorist Financing), Department of the Treasury.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IA-191-1191; FRL-7812-5]

Approval and Promulgation of Air Quality Implementation Plans; Iowa Update to Materials Incorporated by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; notice of administrative change.

SUMMARY: EPA is updating the materials submitted by Iowa that are incorporated by reference (IBR) into the state implementation plan (SIP). The regulations affected by this update have been previously submitted by the state agency and approved by EPA. This update affects the SIP materials that are available for public inspection at the Office of the Federal Register (OFR), Office of Air and Radiation Docket and Information Center, and the Regional Office.