

(b) *Classification*. Class II (special controls). The special controls for posterior cervical screw systems are:

(1) The design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use.

(2) Nonclinical performance testing must demonstrate the mechanical function and durability of the implant.

(3) Device components must be demonstrated to be biocompatible.

(4) Validation testing must demonstrate the cleanliness and sterility of, or the ability to clean and sterilize, the device components and device-specific instruments.

(5) Labeling must include the following:

(i) A clear description of the technological features of the device including identification of device materials and the principles of device operation;

(ii) Intended use and indications for use including levels of fixation;

(iii) Device specific warnings, precautions, and contraindications that include the following statements:

(A) "Precaution: Preoperative planning prior to implantation of posterior cervical screw systems should include review of cross-sectional imaging studies (e.g., CT and/or MRI) to evaluate the patient's cervical anatomy including the transverse foramen, neurologic structures, and the course of the vertebral arteries. If any findings would compromise the placement of these screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary."

(B) "Precaution: Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels."

(iv) Identification of magnetic resonance (MR) compatibility status;

(v) Cleaning and sterilization instructions for devices and instruments that are provided non-sterile to the end user, and;

(vi) Detailed instructions of each surgical step, including device removal.

Dated: March 22, 2019.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2019-06024 Filed 3-29-19; 8:45 am]

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DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

27 CFR Parts 478 and 479

[Docket No. ATF 2014R-42; AG Order No. 4419-2019]

Removal of Expired Regulations Concerning Commerce in Firearms and Ammunition and Machine Guns, Destructive Devices, and Certain Other Firearms

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule makes technical amendments to the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) regulations in the Code of Federal Regulations (CFR). These technical changes are being made to remove expired, obsolete, or unnecessary regulations; correct specific headings; and to reflect changes to nomenclature resulting from the transfer of ATF to the Department of Justice pursuant to the Homeland Security Act of 2002. The changes are designed to update and provide clarity throughout these regulations.

DATES: This rule is effective April 1, 2019.

FOR FURTHER INFORMATION CONTACT: Shermaine Kenner, Office of Regulatory Affairs, Enforcement Programs and Services, Bureau of Alcohol, Tobacco, Firearms, and Explosives, U.S. Department of Justice, 99 New York Avenue NE, Washington, DC 20226; telephone: (202) 648-7070 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

ATF administers regulations published in 27 CFR part 478, concerning commerce in firearms and ammunition, and part 479, concerning machine guns, destructive devices, and certain other firearms. ATF identified several technical amendments that are needed to provide clarity and accuracy to these regulations.

The technical changes made in this rule include the removal of expired regulations and regulations that are no longer applicable; the correction of section headings for accuracy; and a change in nomenclature resulting from the transfer of ATF to the Department of Justice from the Department of the Treasury pursuant to the Homeland Security Act of 2002.

Several sections are being removed or amended because the statute that formed the basis of those regulations is no longer in effect. The Public Safety and Recreational Firearms Act (the Act), enacted as part of the Violent Crime Control and Law Enforcement Act of 1994, Public Law 103-322, Title XI (1994), established a 10-year prohibition on the manufacture, transfer, or possession of "semiautomatic assault weapons," as defined in the Act, as well as large capacity feeding devices. The Act expired on September 13, 2004, and ATF is removing or amending the following regulatory provisions that had, in whole or in part, implemented that Act and are therefore no longer effective:

Sections 478.40, 478.40a, 478.119, 478.132, and 478.153 are being removed and reserved as they are no longer effective.

Section 478.57 is being amended to remove paragraphs (b) and (c) as they are no longer effective.

Section 478.92 is being amended to remove the section heading and replace it with a heading that does not contain "large capacity ammunition feeding devices", and to remove paragraphs (a)(3) and (c), as they are no longer effective.

Section 478.116 is being amended to remove all references to "ammunition feeding device" as those references are no longer effective.

Section 478.171 is being amended to remove the last sentence referencing exportation of semiautomatic assault weapons as it is no longer effective.

The final rule makes two additional technical changes. First, § 478.95 is being amended to reflect the correct section number as a result of the transfer of ATF to the Department of Justice from the Department of Treasury pursuant to the Homeland Security Act of 2002. Second, § 479.32 is being amended to remove paragraphs (a) and (c) referencing special occupational tax rates prior to January 1988, as the information is obsolete.

II. Statutory Orders and Executive Review

A. Executive Orders 12866, 13563, and 13771

This rule has been drafted and reviewed in accordance with Executive Orders 12866, "Regulatory Planning and Review," section 1(b), The Principles of Regulation; Executive Order 13563, "Improving Regulation and Regulatory Review," section 1(b), General Principles of Regulation; and Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs."

This rule makes technical corrections to eliminate outdated and incorrect terminology and improve the clarity of the regulations, and makes no substantive changes. The Department has determined that this final rule is not a “significant regulatory action” as defined in Executive Order 12866, section 3(f). Accordingly, this final rule has not been reviewed by the Office of Management and Budget.

Finally, because this rule is not a significant regulatory action, it is not subject to the requirements of Executive Order 13771. There are no costs associated with this regulation; however, it benefits the industry in that it removes outdated regulations and provides clarity for the regulated industry. Because there are no costs associated with this final rule, there are no monetized benefits. This rule is considered a deregulatory action under Executive Order 13771.

B. Executive Order 13132

This final rule will not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, “Federalism,” the Attorney General has determined that this regulation does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

C. Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, “Civil Justice Reform.”

D. Administrative Procedure Act

Under the Administrative Procedure Act (“APA”), 5 U.S.C. 553(b)(3)(B), an agency may, for good cause, find the usual requirements of prior notice and comment are impracticable, unnecessary, or contrary to the public interest. Currently, 27 CFR parts 478 and 479 contain references to expired regulations and have obsolete, outdated, and incorrect terminology that may be confusing to the public. The rule makes technical corrections to improve the clarity and accuracy of the regulations and makes no substantive changes. For these reasons, the agency has determined that publishing a notice of proposed rulemaking and providing opportunity for public comment is unnecessary.

Further, the APA permits an agency to make this rule effective upon the date of

publication because it is not a substantive rule. See 5 U.S.C. 553(d). Furthermore, the Department finds that there is good cause for the final rule to take effect upon publication, since the revisions made by this rule are minor, non-substantive, and technical, and there is no reason to delay these changes. *Id.*

E. Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 603, 604, and 605(b), a Regulatory Flexibility Analysis is not required for this final rule because the Department was not required to publish a general notice of proposed rulemaking for this matter.

F. Unfunded Mandates Reform Act of 1995

This rule will not 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 one 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, 2 U.S.C. 1531–1535.

G. Paperwork Reduction Act of 1995

This final rule does not impose any new reporting or recordkeeping requirements under the Paperwork Reduction Act, 44 U.S.C. 3501–3521.

H. Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act, 5 U.S.C. 804.

List of Subjects

27 CFR Part 478

Administrative practice and procedure, Arms and munitions, Customs duties and inspection, Exports, Imports, Intergovernmental relations, Law enforcement officers, Military personnel, Penalties, Reporting and recordkeeping requirements, Research, Seizures and forfeitures, Transportation.

27 CFR Part 479

Administrative practice and procedure, Arms and munitions, Excise taxes, Exports, Imports, Military personnel, Penalties, Reporting and recordkeeping requirements, Seizures and forfeitures, Transportation.

Authority and Issuance

Accordingly, for the reasons discussed in the preamble, 27 CFR parts 478 and 479 are amended as follows:

PART 478—COMMERCE IN FIREARMS AND AMMUNITION

- 1. The authority citation for 27 CFR part 478 continues to read as follows:

Authority: 5 U.S.C. 552(a); 18 U.S.C. 921–931; 44 U.S.C. 3504(h).

§ 478.40 [Removed and Reserved]

- 2. Remove and reserve § 478.40.

§ 478.40a [Removed]

- 3. Remove § 478.40a.

§ 478.57 [Amended]

- 4. Amend § 478.57 by removing paragraphs (b) and (c) and redesignating paragraph (a) as an undesignated paragraph.

- 5. Amend § 478.92 by revising the section heading, removing and reserving paragraph (a)(3), and removing paragraph (c) to read as follows:

§ 478.92 Identification of firearms and armor piercing ammunition by licensed manufacturers and licensed importers.

* * * * *

§ 478.95 [Amended]

- 6. Amend § 478.95 by removing “178.94” and adding in its place “478.94” and removing “(a)” and “(b)”.

§ 478.116 [Amended]

- 7. Amend § 478.116 by removing “ammunition, or ammunition feeding device as defined in § 478.119(b)” and “ammunition, or ammunition feeding device” everywhere they appear and adding in their place “or ammunition”.

§ 478.119, 478.132, and 478.153 [Removed and Reserved]

- 8. Remove and reserve §§ 478.119, 478.132, and 478.153.

§ 478.171 [Amended]

- 9. Amend § 478.171 by removing “semiautomatic assault weapons” in the last sentence of the paragraph.

PART 479—MACHINE GUNS, DESTRUCTIVE DEVICES, AND CERTAIN OTHER FIREARMS

- 10. The authority citation for 27 CFR part 479 continues to read as follows:

Authority: 26 U.S.C. 5812; 26 U.S.C. 5822; 26 U.S.C. 7801; 26 U.S.C. 7805.

§ 479.32 [Amended]

- 11. Amend § 479.32 by removing paragraphs (a) and (c) and redesignating paragraph (b) as an undesignated paragraph.

Dated: March 25, 2019.

William P. Barr,

Attorney General.

[FR Doc. 2019-06264 Filed 3-29-19; 8:45 am]

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DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

27 CFR Part 555

[Docket No. ATF 2002R-226F; AG Order No. 4418-2019]

RIN 1140-AA27

Separation Distances of Ammonium Nitrate and Blasting Agents From Explosives or Blasting Agents

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives, Department of Justice.

ACTION: Final rule.

SUMMARY: The Department of Justice is amending the regulations of the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) to remove the reference to an outdated guidance document in an explanatory note following the table of separation distances of ammonium nitrate and blasting agents from explosives or blasting agents. This final rule also clarifies that those separation distance requirements apply to all ammonium nitrate.

DATES: *Effective Date:* May 31, 2019.

FOR FURTHER INFORMATION CONTACT: Denise Brown, Enforcement Programs and Services, Office of Regulatory Affairs, Bureau of Alcohol, Tobacco, Firearms, and Explosives, U.S. Department of Justice, 99 New York Avenue NE, Washington, DC 20226; telephone: (202) 648-7070.

SUPPLEMENTARY INFORMATION:

I. Background

The Attorney General has delegated to the Director of ATF responsibility for administering and enforcing title XI, Regulation of Explosives, of the Organized Crime Control Act of 1970 (OCCA), Public Law 91-452, as amended, 18 U.S.C. chapter 40. See 18 U.S.C. 847; 28 CFR 0.130. Congress has declared that the purpose of the OCCA, is to reduce the “hazard to persons and property arising from misuse and unsafe or insecure storage of explosive materials.” Public Law 91-452, title XI, sec. 1101. Regulations in 27 CFR part 555 implement title XI.

The regulations at 27 CFR 555.220 set forth a table of separation distances of

ammonium nitrate and blasting agents from explosives or blasting agents (the § 555.220 Table of Distances) followed by six explanatory notes. In this table, the term “separation distance” means the minimum distance that must be maintained between stores of certain materials, such as high explosives, and blasting agents. The third note states that the distances specified in the § 555.220 Table of Distances “apply to ammonium nitrate that passes the insensitivity test prescribed in the definition of ammonium nitrate fertilizer issued by the Fertilizer Institute” in its “Definition and Test Procedures for Ammonium Nitrate Fertilizer.”

The Fertilizer Institute (TFI) is a voluntary, non-profit trade association that currently has more than 160 members. See Membership List, The Fertilizer Institute, <http://www.tfi.org/about-tfi/members> (last visited February 13, 2019). Members include importers, wholesalers, retailers, and others involved in the fertilizer industry. *Id.*

The Agricultural Nitrogen Institute, a predecessor organization of TFI, first developed the “Definition and Test Procedures for Ammonium Nitrate Fertilizer” guidance document. See The Fertilizer Institute, Definition and Test Procedures for Ammonium Nitrate Fertilizer (Aug. 1984), available at <https://www.atf.gov/resource-center/docs/guide/definition-and-test-procedures-ammonium-nitrate-fertilizer/download> (last visited February 13, 2019). In May 1984, TFI assembled a task force of industry and government representatives who were “experts on the physical and chemical characteristics of ammonium nitrate fertilizer” to review and update the document. *Id.* at i. “Based on that review and the technical expertise and experience of the task force members, TFI published” a revised guidance document in August 1984 (the August 1984 guidance). *Id.* The August 1984 guidance defines ammonium nitrate fertilizer as “solid ammonium nitrate containing a minimum of 33.0% nitrogen, having a minimum pH of 4.0 in a 10% aqueous solution, 0.20% maximum carbon, 0.010% maximum elemental sulfur, 0.150% maximum chloride as Cl, or particulated elemental metals sufficient to release 4.60 ml, maximum, of hydrogen from 50.0 gram sample and which will pass the detonation resistance test in Section 2.0 and the burning test in Section 4.0.” *Id.* at 1.

A. The Fertilizer Institute Petition

On March 19, 2002, TFI filed a petition with ATF requesting that ATF

amend the explosives regulations at § 555.220 to remove the reference to the August 1984 guidance. TFI explained that the document is outdated because TFI last published it in 1984, will not review or update it, and cannot ensure that its procedures are still valid. TFI recognized that ATF may require an alternate method of determining the insensitivity of ammonium nitrate fertilizer and suggested that ATF reference certain Department of Transportation (DOT) regulations.

The DOT regulations include several definitions and two hazardous classifications (Class 5.1 and Class 9) for ammonium nitrate based fertilizers based, in part, on the amount of combustible material included in the fertilizer. See 49 CFR 172.101. Class 5.1 ammonium nitrate based fertilizer is defined as a uniform mixture of fertilizer with ammonium nitrate as the main ingredient within the following composition limits: (1) Not less than 90 percent ammonium nitrate with not more than 0.2 percent total combustible, organic material calculated as carbon, and with added matter, if any, that is inorganic and inert when in contact with ammonium nitrate; or (2) less than 90 percent but more than 70 percent ammonium nitrate with other inorganic materials, or more than 80 percent but less than 90 percent ammonium nitrate mixed with calcium carbonate or dolomite or mineral calcium sulphate, and not more than 0.4 percent total combustible, organic material calculated as carbon; or (3) ammonium nitrate based fertilizers containing mixtures of ammonium nitrate and ammonium sulphate with more than 45 percent but less than 70 percent ammonium nitrate, and not more than 0.4 percent total combustible, organic material calculated as carbon such that the sum of the percentage of compositions of ammonium nitrate and ammonium sulphate exceeds 70 percent. See 49 CFR 172.102(c)(1), code/special provision 150.

The 5.1 ammonium nitrate fertilizer classification can only be used for substances that are too insensitive for acceptance into Class 1 (explosive) when tested in accordance with Test Series 2 in the United Nations (UN) Manual of Tests and Criteria, Part 1. See 49 CFR 172.101, 172.102(c)(1) code/special provisions 52 and 150. To determine whether a material falls within Class 5, Division 5.1, DOT requires regulated parties to conduct tests in accordance with international standards in the UN Manual of Tests and Criteria. See 49 CFR 173.127(a).

Class 9 ammonium nitrate based fertilizer is defined as a uniform,