

§ 594.318 Agency or instrumentality of a foreign state.

The term *agency or instrumentality of a foreign state* has the meaning given that term in section 1603(b) of title 28, United States Code.

■ 18. Add § 594.319 to read as follows:

§ 594.319 HAMAS.

The term *HAMAS* means:

(a) The entity known as HAMAS and designated by the Secretary of State as a foreign terrorist organization pursuant to section 219 of the Immigration and Nationality Act (8 U.S.C. 1189); or

(b) Any person:

(1) The property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*); and

(2) Who is identified on the Specially Designated Nationals and Blocked Persons List (SDN List) maintained by OFAC as an agent, instrumentality, or affiliate of HAMAS.

Note 1 to § 594.319: The SDN List is accessible through the following page on OFAC's website: www.treasury.gov/sdn. Additional information pertaining to the SDN List can be found in appendix A to this chapter. Persons on the SDN List based on conduct described in § 594.201(a)(9), (10), (11) are identified by a special reference at the end of their entries on the SDN List—“[SHIELD–ACT]”—in addition to the reference to the regulatory part of this chapter pursuant to which their property and interests in property are blocked. For example, a person whose property and interests in property are blocked pursuant to the Global Terrorism Sanctions Regulations, § 594.201(a)(9), (10), or (11), and identified on the SDN List will have the program tag “[SDGT]” and “[SHIELD–ACT].”

■ 19. Add § 594.320 to read as follows:

§ 594.320 Hizballah.

The term *Hizballah* means:

(a) The entity known as Hizballah and designated by the Secretary of State as a foreign terrorist organization pursuant to section 219 of the Immigration and Nationality Act (8 U.S.C. 1189); or

(b) Any person:

(1) The property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*); and

(2) Who is identified on the Specially Designated Nationals and Blocked Persons List (SDN List) maintained by OFAC as an agent, instrumentality, or affiliate of Hizballah.

Note 1 to § 594.320: The SDN List is accessible through the following page on OFAC's website: www.treasury.gov/sdn. Additional information pertaining to the SDN List can be found in appendix A to this

chapter. Persons on the SDN List based on conduct described in § 594.201(a)(8), (10), and (11) are identified by a special reference at the end of their entries on the SDN List—“[SHIELD–ACT]”—in addition to the reference to the regulatory part of this chapter pursuant to which their property and interests in property are blocked. For example, a person whose property and interests in property are blocked pursuant to the Global Terrorism Sanctions Regulations, § 594.201(a)(8), (10), or (11), and identified on the SDN List will have the program tag “[SDGT]” and “[SHIELD–ACT]”. Persons on the SDN List based on conduct described in § 594.201(a)(6) and (7) are identified by a special reference at the end of their entries on the SDN List—“[HIFPAA]”—in addition to the reference to the regulatory part of this chapter pursuant to which their property and interests in property are blocked. For example, a person whose property and interests in property are blocked pursuant to the Global Terrorism Sanctions Regulations, § 594.201(a)(6) or (7), and identified on the SDN List will have the program tag “[SDGT]” and “[HIFPAA]”.

■ 20. Add § 594.321 to read as follows:

§ 594.321 Knowingly.

The term *knowingly*, with respect to conduct, a circumstance, or a result, means that a person has actual knowledge, or should have known, of the conduct, the circumstance, or the result.

■ 21. Add § 594.322 to read as follows:

§ 594.322 Arms or related materiel.

The term *arms or related materiel* means:

(a) Nuclear, biological, chemical, or radiological weapons or materials or components of such weapons;

(b) Ballistic or cruise missile weapons or materials or components of such weapons; or

(c) Destabilizing numbers and types of advanced conventional weapons.

Dated: July 18, 2019.

Bradley Smith,

Deputy Director, Office of Foreign Assets Control.

[FR Doc. 2019–15600 Filed 7–22–19; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2019–0597]

RIN 1625–AA00

Safety Zone; NAACP Fireworks, Detroit River, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 200-yard radius of a portion of the Detroit River, Detroit, MI. This zone is necessary to protect spectators and vessels from potential hazards associated with the NAACP Fireworks.

DATES: This temporary final rule is effective from 9:30 p.m. on July 23, 2019, through 11 p.m. on July 24, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2019–0597 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or email Tracy Girard, Prevention Department, Sector Detroit, Coast Guard; telephone 313–568–9564, or email Tracy.M.Girard@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Detroit
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable. The Coast Guard did not receive the final details of this fireworks display in time to publish an NPRM. As such, it is impracticable to publish an NPRM because we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule. Furthermore, immediate action is needed to allow the Coast Guard to enhance the safety of this event.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would inhibit the Coast Guard's ability to protect participants, mariners and vessels from the hazards associated with this event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Detroit (COTP) has determined that potential hazard associated with fireworks from 9:30 p.m. through 11 p.m. on July 23, 2019 will be a safety concern to anyone within a 200-yard radius of the launch site. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the fireworks are being displayed.

IV. Discussion of the Rule

This rule establishes a safety zone from 9:30 p.m. through 11 p.m. on July 23, 2019. The safety zone will encompass all U.S. navigable waters of the Detroit River, Detroit, MI, within a 200-yard radius of position 42°19.529' N, 083°02.436' W (NAD 83). No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-year of the safety zone. Vessel traffic will be able to safely

transit around this safety zone which will impact a small designated area of the Detroit River from 9:30 p.m. through 11 p.m. on July 23, 2019. Moreover, the Coast Guard will issue Broadcast Notice to Mariners (BNM) via VHF-FM marine channel 16 about the zone and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting one and a half hours on two nights that will prohibit entry into a designated area. It is categorically excluded from further review under paragraph L[60](a) in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures 5090.1. A

Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 165.T09–0597 to read as follows:

§ 165.T09–0597 Safety Zone; NAACP Fireworks, Detroit, MI.

(a) *Location.* A safety zone is established to include all U.S. navigable waters of the Detroit River, Detroit, MI, within a 200-yard radius of position 42°19.529' N, 083°02.436' W (NAD 83).

(b) *Enforcement period.* The regulated area described in paragraph (a) will be enforced from 9:30 p.m. until 11 p.m. on July 23, 2019. In the case of inclement weather on July 23, 2019, this safety zone will be enforced from 9:30 p.m. to 11 p.m. on July 24, 2019.

(c) *Regulations.* (1) No vessel or person may enter, transit through, or anchor within the safety zone unless authorized by the Captain of the Port Detroit (COTP), or his or her on-scene representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or his or her on-scene representative.

(3) The “on-scene representative” of COTP is any Coast Guard commissioned, warrant or petty officer or a Federal, State, or local law enforcement officer designated by or assisting the Captain of the Port Detroit to act on his or her behalf.

(4) Vessel operators shall contact the COTP or his or her on-scene representative to obtain permission to enter or operate within the safety zone. The COTP or his or her on-scene representative may be contacted via VHF Channel 16 or at (313) 568–9464. Vessel operators given permission to enter or operate in the regulated area must comply with all directions given to them by the COTP or his or her on-scene representative.

Dated: July 17, 2019.

Jeffrey W. Novak,
Captain, U.S. Coast Guard, Captain of the Port Detroit.

[FR Doc. 2019–15624 Filed 7–22–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 26

[EPA–HQ–ORD–2018–0280; FRL–9996–48–ORD]

RIN 2080–AA13

Protection of Human Research Subjects

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On January 19, 2017, the Environmental Protection Agency (EPA), acting in concert with other agencies, promulgated revisions to the “Common Rule.” EPA’s codification of these revisions is in 40 CFR part 26, subpart A. These revisions went into effect on July 19, 2018, and compliance with the new provisions was required beginning on January 21, 2019. In addition to the core protections found in the Common Rule, EPA has promulgated regulations that are specific to research involving human subjects conducted or sponsored by EPA or submitted to EPA for regulatory purposes. The revisions to the Common Rule create discrepancies within some of these EPA-specific regulations. This final rule harmonizes the EPA-specific regulations with revisions to the Common Rule in order to resolve those discrepancies.

DATES: This rule is effective on September 23, 2019.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–ORD–2018–0280, is available at <https://www.regulations.gov> or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in the

EPA WJC West Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Tom Sinks, Director, Office of Science Advisor, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460 (Mail Code: 8105R); telephone number: 202–564–3099; email address: sinks.tom@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of particular interest to those who conduct human research on substances regulated by EPA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What action is the Agency taking?

The Agency is finalizing the amendments to its human studies rules as proposed in December 2018 (83 FR 62760) (FRL–9987–01–ORD). These amendments include the following:

- Revisions to regulatory citation references in subparts C and D;
- Harmonization, where appropriate, of language in subpart K with revisions in subpart A due to revisions to the Common Rule, 82 FR 7149 (January 19, 2017); and
- Correction of a typographical error in subpart M.

C. What is the Agency’s authority for taking this action?

These amendments are authorized under the following legal authorities. The amendments to subparts C and D, which relate to research conducted or sponsored by EPA are authorized pursuant to 5 U.S.C. 301. The amendments to subparts K and M, which govern third-party research involving intentional human exposure to pesticides or to other substances where such research is used for purposes of pesticide decision-making are authorized under sections 3(a) and