

b.2.a. Cultivation chambers designed to be sterilized or disinfected in situ;

b.2.b. Cultivation chamber holding devices; or

b.2.c. Process control units capable of simultaneously monitoring and controlling two or more fermentation system parameters (e.g., temperature, pH, nutrients, agitation, dissolved oxygen, air flow, foam control).

Technical Notes to 2B352.b: 1. Fermenters include bioreactors (including single-use (disposable) bioreactors), chemostats and continuous-flow systems.

2. Cultivation chamber holding devices controlled by 2B352.b.2.b include single-use cultivation chambers with rigid walls.

c. Centrifugal separators capable of the continuous separation of pathogenic microorganisms, without the propagation of aerosols, and having all of the following characteristics:

c.1. One or more sealing joints within the steam containment area;

c.2. A flow rate greater than 100 liters per hour;

c.3. "Parts" or "components" of polished stainless steel or titanium; and

c.4. Capable of in-situ steam sterilization in a closed state.

Technical Note to 2B352.c: Centrifugal separators include decanters.

d. Cross (tangential) flow filtration equipment and "accessories", as follows:

d.1. Cross (tangential) flow filtration equipment capable of separation of microorganisms, viruses, toxins or cell cultures having all of the following characteristics:

d.1.a. A total filtration area equal to or greater than 1 square meter (1 m²); and

d.1.b. Having any of the following characteristics:

d.1.b.1. Capable of being sterilized or disinfected in-situ; or

d.1.b.2. Using disposable or single-use filtration "parts" or "components".

N.B.: 2B352.d.1 does not control reverse osmosis and hemodialysis equipment, as specified by the manufacturer.

d.2. Cross (tangential) flow filtration "parts" or "components" (e.g., modules, elements, cassettes, cartridges, units or plates) with filtration area equal to or greater than 0.2 square meters (0.2 m²) for each "part" or "component" and designed for use in cross (tangential) flow filtration equipment controlled by 2B352.d.1.

Technical Note: In this ECCN, "sterilized" denotes the elimination of all viable microbes from the equipment through the use of either physical (e.g., steam) or chemical agents. "Disinfected" denotes the destruction of potential microbial infectivity in the equipment through the use of chemical agents with a germicidal effect. "Disinfection" and "sterilization" are distinct from "sanitization", the latter referring to cleaning procedures designed to lower the microbial content of equipment without necessarily achieving elimination of all microbial infectivity or viability.

e. Steam, gas or vapor sterilizable freeze-drying equipment with a condenser capacity of 10 kg of ice or greater in 24 hours (10 liters of water or greater in 24 hours) and less than

1000 kg of ice in 24 hours (less than 1,000 liters of water in 24 hours).

f. Spray-drying equipment capable of drying toxins or pathogenic microorganisms having all of the following characteristics:

f.1. A water evaporation capacity of ≥0.4 kg/h and ≤400 kg/h;

f.2. The ability to generate a typical mean product particle size of ≤10 micrometers with existing fittings or by minimal modification of the spray-dryer with atomization nozzles enabling generation of the required particle size; and

f.3. Capable of being sterilized or disinfected in situ.

g. Protective and containment equipment, as follows:

g.1. Protective full or half suits, or hoods dependent upon a tethered external air supply and operating under positive pressure.

Technical Note to 2B352.g.1: 2B352.g.1 does not control suits designed to be worn with self-contained breathing apparatus.

g.2. Biocontainment chambers, isolators, or biological safety cabinets having all of the following characteristics, for normal operation:

g.2.a. Fully enclosed workspace where the operator is separated from the work by a physical barrier;

g.2.b. Able to operate at negative pressure;

g.2.c. Means to safely manipulate items in the workspace; and

g.2.d. Supply and exhaust air to and from the workspace is high-efficiency particulate air (HEPA) filtered.

Note 1 to 2B352.g.2: 2B352.g.2 controls class III biosafety cabinets, as specified in the WHO Laboratory Biosafety Manual (3rd edition, Geneva, 2004) or constructed in accordance with national standards, regulations or guidance.

Note 2 to 2B352.g.2: 2B352.g.2 does not control isolators "specially designed" for barrier nursing or transportation of infected patients.

h. Aerosol inhalation equipment designed for aerosol challenge testing with microorganisms, viruses or toxins, as follows:

h.1. Whole-body exposure chambers having a capacity of 1 cubic meter or greater;

h.2. Nose-only exposure apparatus utilizing directed aerosol flow and having a capacity for the exposure of 12 or more rodents, or two or more animals other than rodents, and closed animal restraint tubes designed for use with such apparatus.

i. Spraying or fogging systems and "parts" and "components" therefor, as follows:

i.1. Complete spraying or fogging systems, "specially designed" or modified for fitting to aircraft, "lighter than air vehicles," or "UAVs," capable of delivering, from a liquid suspension, an initial droplet "VMD" of less than 50 microns at a flow rate of greater than 2 liters per minute;

i.2. Spray booms or arrays of aerosol generating units, "specially designed" or modified for fitting to aircraft, "lighter than air vehicles," or "UAVs," capable of delivering, from a liquid suspension, an initial droplet "VMD" of less than 50 microns at a flow rate of greater than 2 liters per minute;

i.3. Aerosol generating units "specially designed" for fitting to the systems as specified in paragraphs i.1 and i.2 of this ECCN.

Technical Notes to 2B352.i: 1. Aerosol generating units are devices "specially designed" or modified for fitting to aircraft and include nozzles, rotary drum atomizers and similar devices.

2. This ECCN does not control spraying or fogging systems, "parts" and "components," as specified in 2B352.i, that are demonstrated not to be capable of delivering biological agents in the form of infectious aerosols.

3. Droplet size for spray equipment or nozzles "specially designed" for use on aircraft or "UAVs" should be measured using either of the following methods (pending the adoption of internationally accepted standards):

a. Doppler laser method,

b. Forward laser diffraction method.

j. Nucleic acid assemblers and synthesizers that are both:

j.1 Partly or entirely automated; and

j.2. Designed to generate continuous nucleic acids greater than 1.5 kilobases in length with error rates less than 5% in a single run.

* * * * *

Richard E. Ashooh,

Assistant Secretary for Export Administration.

[FR Doc. 2020-11625 Filed 6-16-20; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2020-0252]

RIN 1625-AA00

Safety Zone; San Diego Bay, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the navigable waters in the vicinity of the General Dynamics NASSCO shipyard in San Diego Bay, San Diego, CA, during the launch of the M/V Matsonia. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards associated with the launching and subsequent berthing of the M/V Matsonia. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port San Diego.

DATES: This rule is effective from 6 p.m. through 9 p.m. on July 2, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2020–0252 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 rule, call or email Lieutenant Briana Biagas, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone 619–278–7656, email D11MarineEventsSD@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code
M/V Motor Vessel

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 it is impracticable. This urgent safety zone is required to protect the maritime public and the surrounding waterways from hazards associated with the launching of the M/V Matsonia. It is impracticable to publish an NPRM because the Coast Guard must establish this safety zone by July 2, 2020. The Coast Guard lacks sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

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 be impracticable because this rule is needed to protect mariners, commercial and recreational waterway users, and the M/V Mastonia from dangers associated with the launching and berthing of the M/V Matsonia on July 2, 2020.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port San Diego (COTP) has determined that potential hazards associated with launching of the M/V Matsonia on July 2, 2020, will be a safety concern for anyone in the vicinity of the General Dynamics NASSCO shipyard. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the M/V Matsonia is being launched and towed to a nearby berth.

IV. Discussion of the Rule

This rule establishes a safety zone from 6 p.m. until 9 p.m. on July 2, 2020. The safety zone will cover all navigable waters of the San Diego Bay created by connecting the following points: Beginning at 32°41′23.4″ N, 117°8′39.6″ W (Point A); thence running northwesterly to 32°41′14.4″ N, 117°9′3″ W (Point B); thence running southeasterly to 32°41′3″ N, 117°8′43.8″ W (Point C); thence running east to 32°41′12″ N, 117°8′20.4″ W (Point D); thence running north to the beginning point. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the M/V Matsonia is being launched, then towed to berth. 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 and limited duration of the safety zone. This safety zone impacts a small designated area of the San Diego Bay for a very limited period during the evening when vessel traffic is normally low. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow 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 call or email 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.

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, Rev. 1, associated implementing instructions, 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 only three hours that will prohibit entry within certain navigable waters of San Diego Bay in the vicinity of the General Dynamics NASSCO shipyard. It is categorically excluded from further review under paragraph

L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email 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.T11–024 to read as follows:

§ 165.T11–024 Safety Zone; San Diego Bay, San Diego, CA.

(a) *Location.* The following area is a safety zone. All waters of San Diego Bay, from surface to bottom, encompassed by a line connecting the following points beginning at 32°41′23.4″ N, 117°8′39.6″ W (Point A); thence running northwesterly to 32°41′14.4″ N, 117°9′3″ W (Point B); thence running southeasterly to 32°41′3″ N, 117°8′43.8″ W (Point C); thence running east to 32°41′12″ N, 117°8′20.4″ W (NAD 83) (Point D); thence running north to the beginning point.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port San Diego (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety

zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF Channel 16. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 6 p.m. through 9 p.m. on July 2, 2020.

Dated: May 29, 2020.

T. J. Barelli,

Captain, U.S. Coast Guard, Captain of the Port Sector San Diego.

[FR Doc. 2020–12089 Filed 6–16–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF EDUCATION

34 CFR Part 668

[Docket ID ED–2020–OPE–0078]

RIN 1840–ZA04

Eligibility of Students at Institutions of Higher Education for Funds Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Interim final rule.

SUMMARY: The Department of Education (Department) issues this interim final rule so that institutions of higher education may appropriately determine which individuals attending their institution are eligible to receive emergency financial aid grants to students under the Coronavirus Aid, Relief, and Economic Security (CARES) Act (March 27, 2020).

DATES: These regulations are effective June 17, 2020. We must receive your comments on or before July 17, 2020.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

If you are submitting comments electronically, we strongly encourage you to submit any comments or attachments in Microsoft Word format. If you must submit a comment in Adobe Portable Document Format (PDF), we strongly encourage you to convert the