

designee, to decide whether a national emergency has developed or is developing in the importing country, whether the investigational new drug will be used solely for that national emergency, and whether prompt exportation of the investigational new drug is necessary. Persons who wish to obtain a determination from the Secretary should direct their requests to Secretary's Operations Center, Office of Emergency Operations and Security Programs, Office of Public Health Emergency Preparedness, Office of the Secretary, Department of Health and Human Services, 200 Independence Ave. SW., Washington, DC 20201. Requests may be also be sent by FAX: 202-619-7870 or by e-mail: HHS.SOC@hhs.gov.

(B) Exportation may proceed without prior FDA authorization.

(c) *Limitations.* Exportation under paragraph (b) of this section may not occur if:

(1) For drugs exported under paragraph (b)(1) of this section, the IND pertaining to the clinical investigation is no longer in effect;

(2) For drugs exported under paragraph (b)(2) of this section, the requirements in section 802(b)(1), (f), or (g) of the act are no longer met;

(3) For drugs exported under paragraph (b)(3) of this section, the requirements in section 802(c), (f), or (g) of the act are no longer met;

(4) For drugs exported under paragraph (b)(4) of this section, the conditions underlying the certification or the statements submitted under paragraph (b)(5) of this section are no longer met; or

(5) For any investigational new drugs under this section, the drug no longer complies with the laws of the importing country.

(d) *Insulin and antibiotics.* New insulin and antibiotic drug products may be exported for investigational use in accordance with section 801(e)(1) of the act without complying with this section.

Dated: November 16, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP Jacksonville 05-154]

RIN 1625-AA87

Security Zone; St. John's River, Jacksonville, FL to Ribault Bay

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary moving security zone around foreign naval submarines in transit within the area between 12 nautical miles seaward from the baseline at the mouth of the St. John's River to Ribault Bay. The security zone includes all waters within 500 yards in any direction of the submarine. This rule prohibits entry into the security zone without the permission of the Captain of the Port (COTP) Jacksonville or his designated representative. Persons or vessels that receive permission to enter the security zone must proceed at a minimum safe speed, must comply with all orders issued by the COTP or his designated representative, and must not proceed any closer than 100 yards, in any direction, to the submarine. This security zone is needed to ensure public safety and to prevent sabotage or terrorist acts against the submarine.

DATES: This rule is effective from 8 a.m. on November 9, 2005, until 11:59 p.m. on December 1, 2005.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket [COTP Jacksonville 05-154] and are available for inspection and copying at Coast Guard Sector Jacksonville Prevention Department, 7820 Arlington Expressway, Suite 400, Jacksonville, Florida 32211, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ensign Kira Peterson at Coast Guard Sector Jacksonville Prevention Department, Florida telephone: (904) 232-2640, ext. 108.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a NPRM. Publishing a NPRM, which would incorporate a comment period before a final rule

could be issued, and delay the rule's effective date, is contrary to the public interest because immediate action is necessary to protect the public and waters of the United States.

For the same reasons, 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**. The Coast Guard will issue a broadcast notice to mariners and will place Coast Guard vessels in the vicinity of this zone to advise mariners of the restrictions.

Background and Purpose

This rule is needed to protect foreign navy submarines from damage or injury from sabotage or other subversive acts, accidents or other causes of a similar nature, or to secure the observance of rights and obligations of the United States. Although this rule is effective from 8 a.m. on November 9, 2005, until 11:59 p.m. on December 1, 2005, the Coast Guard will only enforce this rule when a foreign navy submarine is transiting within the area between 12 nautical miles seaward from the baseline at the mouth of the St. John's River to Ribault Bay. Anchoring, mooring, or transiting within this zone is prohibited, unless authorized by the Captain of the Port, Jacksonville, Florida, or his designated representative. The temporary security zone encompasses all waters within 500 yards around the foreign naval submarine. Vessels or persons authorized to enter the zone must proceed at a minimum safe speed, must comply with all orders issued by the COTP or his designated representative, and must not proceed any closer than 100 yards, in any direction, to the submarine.

Regulatory Evaluation

This regulation is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential cost and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under the order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS) because these regulations will only be in effect for a short period of time and the impact on routine navigation is expected to be minimal.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we considered whether this rule would have a

significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their field, 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 upon a substantial number of small entities because the regulation will only be enforced for a short period of time within a 22-day window, during vessel transits, and the impact on routine navigation is expected to be minimal. Vessels may still transit safely around the zone and, upon permission of the Captain of the Port or his designated representative, may transit at minimum safe speed through that portion of the security zone between 100 and 500 yards from the submarine.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or government jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding this rule.

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).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of

compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

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 State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Although this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

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.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have significant adverse effect

on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction, from further environmental documentation. Under figure 2-1, paragraph (34)(g), of the Instruction, an "Environmental Analysis Check List" and a "Categorical Exclusion Determination" are not required for this rule.

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: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR

1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. A new temporary § 165.T07–154 is added to read as follows:

§ 165.T07–154 Security Zone; St. John’s River, Jacksonville, FL to Ribault Bay.

(a) *Regulated area.* The Coast Guard is establishing a temporary moving security zone for a foreign navy submarine within the area 12 nautical miles seaward from the baseline at the mouth of the St. John’s River to Ribault Bay. The temporary security zone encompasses all waters within 500 yards in any direction around a foreign navy submarine transiting within the area between 12 nautical miles seaward of the sea buoy at the entrance to the St. John’s River to Ribault Bay.

(b) *Definitions.* The following definitions apply to this section:

Designated representatives means Coast Guard Patrol Commanders including Coast Guard coxswains, petty officers and other officers operating Coast Guard vessels, and Federal, State, and local officers designated by or assisting the Captain of the Port (COTP), Jacksonville, Florida, in the enforcement of the regulated navigation areas and security zones.

Minimum Safe Speed means the speed at which a vessel proceeds when it is fully off plane, completely settled in the water and not creating excessive wake. Due to the different speeds at which vessels of different sizes and configurations may travel while in compliance with this definition, no specific speed is assigned to minimum safe speed. In no instance should minimum safe speed be interpreted as a speed less than that required for a particular vessel to maintain steerageway. A vessel is not proceeding at minimum safe speed if it is:

- (1) On a plane;
- (2) In the process of coming up onto or coming off a plane; or
- (3) Creating an excessive wake.

(c) *Regulations.* In accordance with the general regulations in § 165.33 of this part, anchoring, mooring or transiting in this zone is prohibited unless authorized by the Coast Guard Captain of the Port Jacksonville, FL or his designated representative. Persons or vessels that receive permission to enter the security zone must proceed at a minimum safe speed, must comply with all orders issued by the COTP or his designated representative, and must not proceed any closer than 100 yards, in any direction, to the submarine.

(d) *Dates.* This section is effective from 8 a.m. on November 9, 2005, until 11:59 p.m. on December 1, 2005.

Dated: November 9, 2005.

David L. Lersch,

Captain, U.S. Coast Guard, Captain of the Port Jacksonville.

[FR Doc. 05–23236 Filed 11–22–05; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP Western Alaska–04–003]

RIN 1625–AA00

Safety Zone; Bering Sea, Aleutian Islands, Unalaska Island, AK

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; change of effective period.

SUMMARY: The Coast Guard is extending the effective period of the safety zone in the Bering Sea, Unalaska Island, Alaska. The zone is needed to facilitate safe salvage operations related to the grounding of the merchant vessel (M/V) SELENDANG AYU. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Commander, Seventeenth Coast Guard District, the Coast Guard Captain of the Port, Western Alaska, or their on-scene representative. The intended effect of the proposed safety zone is to mitigate safety risks to salvage personnel.

DATES: The effective period of § 165.T17–010 is extended from November 30, 2005 through October 31, 2006.

ADDRESSES: Documents indicated in this preamble as being available in the docket are available for inspection and copying at Coast Guard Marine Safety Office Anchorage, 510 “L” Street, Suite 100, Anchorage, AK 99501. Normal Office hours are 7:30 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LT Meredith Gillman, Marine Safety Office Anchorage, at (907) 271–6700.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM and for making this regulation effective less than 30 days after its publication in the **Federal Register**. Any delay encountered in this regulation’s effective date would be contrary to

public interest because immediate action is needed to prevent unauthorized vessel traffic from hindering salvage operations.

The Coast Guard will terminate the zone when salvage operations are complete and the area adjacent to the grounded vessel is considered safe to vessel traffic.

Background and Purpose

The M/V SELENDANG AYU ran aground at a position of 53.634° N, 167.125° W on December 9, 2004. The vessel then broke in half and discharged its fuel oil into the water. A marine salvor is removing sections of the wreck from the bow and stern sections of the grounded vessel, as well as from the adjacent shoreline. The safety zone is necessary to prevent unauthorized vessels from impeding salvage operations.

Discussion of Rule

The Unified Command, which is responding to the grounding of the M/V Selendang Ayu, identified the safety zone in the area where subsequent salvage operations will be taking place. This area is defined by a circle centered at 53 degrees, 38 minutes North; 167 degrees, 7 minutes, 20 seconds West with a radius of 750 yards. All coordinates reference Datum: NAD 1983.

Regulatory Evaluation

This rule is not a “significant regulatory action” under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential cost and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not significant under the regulatory policies and procedures of the Department of Homeland Security (DHS). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DHS is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. 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.