

**Figure 1 to Paragraph (g)(1) – Restart In-Flight by Windmilling****Restart In-Flight by Windmilling**

In case of an engine malfunction, determine the root cause and only continue if a safe restart is possible.

1. Max. demonstrated altitude for immediate restart by windmilling: 15,000 ft.
2. Max. demonstrated altitude for restart after 10 min. and ambient air temperature higher than ISA by windmilling: 10,000 ft.
3. Max. demonstrated altitude for restart after 5 min. and ambient air temperature between ISA and ISA minus 10°C by windmilling: 10,000 ft.
4. Max. demonstrated altitude for restart after 2 min. and ambient air temperature below ISA minus 10°C by windmilling: 10,000 ft.
5. Airspeed: See applicable Aircraft Flight Manual.
6. Power Levers – “IDLE”
7. Engine Master – “ON”

Move power lever slightly forward to a power rating that assures the referring engine is delivering thrust as a rotating propeller is not a guarantee for a running engine.

(2) For affected Austro Engine GmbH model E4 engines installed on Diamond Aircraft Industries (DAI) model Diamond Aircraft (DA) 42 NG and DA 42 M-NG airplanes, and for Austro Engine GmbH model E4P engines installed on DAI model DA 62 airplanes, using AFM Temporary Revision (TR) TR-MAM-42-973, and AFM TR TR-MAM-62-240, both dated August 12, 2016, updating the applicable AFM is an acceptable method to comply with paragraph (g)(1) of this AD.

**(h) Credit for Previous Actions**

You may take credit for actions required by paragraph (g) of this AD if you amended the AFM for the affected engine before the effective date of this AD in accordance with AD 2018-18-02.

**(i) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ECO Branch, send it to the attention of the person identified in paragraph (j)(1) of this AD. You may email your request to: [ANE-AD-AMOC@faa.gov](mailto:ANE-AD-AMOC@faa.gov).

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

**(j) Related Information**

(1) For more information about this AD, contact Mehdi Lamnyi, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781-238-7743; fax: 781-238-7199; email: [Mehdi.Lamnyi@faa.gov](mailto:Mehdi.Lamnyi@faa.gov).

(2) Refer to European Union Aviation Safety Agency (EASA) AD 2017-0103R1, dated February 25, 2019, for more information. You may examine the EASA AD in the AD docket on the internet at <https://www.regulations.gov> by searching for and locating it in Docket No. FAA-2020-0136.

(3) For Austro Engine GmbH service information identified in this AD, contact Austro Engine GmbH, Rudolf-Diesel-Strasse 11, A-2700 Weiner Neustadt, Austria; phone: +43 2622 23000; fax: +43 2622 23000-2711; website: [www.austroengine.at](http://www.austroengine.at). For Diamond Aircraft Industries service information identified in this AD, contact Diamond Aircraft Industries, N. A., Otto-Straße 5, A-2700 Wiener Neustadt, A2700, Austria; phone: +43 2622 26700; fax: +43 2622 26780; website: [www.diamondaircraft.com](http://www.diamondaircraft.com). You may view this referenced service information

at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781-238-7759.

Issued on March 10, 2020.

**Lance T. Gant,**

*Director, Compliance & Airworthiness Division, Aircraft Certification Service.*

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**BILLING CODE 4910-13-P**

**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 165**

[Docket Number USCG-2019-0317]

**RIN 1625-AA00**

**Safety Zones; Northern California and Lake Tahoe Area Annual Fireworks Events, San Francisco, CA**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to amend and establish several permanent safety zones in the Captain of the Port San Francisco zone. This action is necessary to provide for the safety of life on the navigable waters of the San Francisco Bay, Carquinez Strait, Mare Island Strait, Sacramento River, Lake Tahoe, and Monterey Bay during annual fireworks displays. This proposed rulemaking would prohibit persons and vessels from entering the safety zones unless authorized by the Captain of the Port San Francisco or a designated representative. We invite your comments on this proposed rulemaking.

**DATES:** Comments and related material must be received by the Coast Guard on or before May 18, 2020.

**ADDRESSES:** You may submit comments identified by docket number USCG–2019–0317 using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this proposed rulemaking, call or email Lieutenant Jennae Cotton, Waterways Management, U.S. Coast Guard; telephone 415–399–3585, email [SFWaterways@uscg.mil](mailto:SFWaterways@uscg.mil).

**SUPPLEMENTARY INFORMATION:**

**I. Table of Abbreviations**

CFR Code of Federal Regulations  
 COTP Captain of the Port San Francisco  
 DHS Department of Homeland Security  
 NPRM Notice of proposed rulemaking  
 § Section  
 U.S.C. United States Code

**II. Background, Purpose, and Legal Basis**

Fireworks displays in 33 CFR part 165.1191 are held annually on the navigable waters within the Captain of the Port San Francisco (COTP) zone. After conducting a review of the fireworks displays listed in 33 CFR part 165.1191, the specifications for eight of the events listed in the table no longer accurately reflect the actual event parameters, and three annual fireworks displays are not listed in the table. The COTP has determined that potential hazards associated with the fireworks used in these displays would be a safety concern for anyone within the safety zones during the fireworks displays. The purpose of this rulemaking is to ensure safety on the navigable waters within the safety zones for the fireworks displays before, during, and after the

scheduled events. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034.

**III. Discussion of Proposed Rule**

The COTP is proposing to amend Table 1 to § 165.1191. Eight fireworks displays will be amended, and three fireworks displays will be added.

The fireworks events we propose to amend are listed numerically in Table 1 of this section as item 7, “San Francisco Independence Day Fireworks,” item 8, “Fourth of July Fireworks, Berkeley Marina,” item 9, “Fourth of July Fireworks, City of Richmond,” item 19, “Red, White, and Tahoe Blue Fireworks, Incline Village, NV,” item 22, “Monte Foundation Fireworks,” item 24, “San Francisco New Years Eve Fireworks,” item 25, “Sacramento New Years Eve Fireworks,” and item 27, “Feast of Lanterns Fireworks.”

The display locations for items 7, 8, 9, 25, and 27 no longer accurately reflect the display locations for the events, so this rule proposes to insert updated location descriptions into the table.

The name of item 19 has changed from “Red, White, and Tahoe Blue Fireworks, Incline Village, NV” to “Incline Village Independence Day Fireworks” and would be updated in the table to reflect the name change.

The display dates listed in items 22, 24, and 27 do not accurately reflect the display dates for the fireworks displays, so this rule proposes to update them as follows. Item 22, “Monte Foundation Fireworks” currently states the date as the second Saturday in October, but the fireworks have occurred on the second Saturday or Sunday in October. Item 24, “San Francisco New Years Eve Fireworks” currently states it occurs on New Years Eve, but the event has lasted into the early hours of New Year’s Day, so we propose adding January 1st as a display date as well to be more accurate. Item 27, “Feast of Lanterns Fireworks” currently states it occurs on the last Saturday of July, but due to the variance in the event dates, we are amending the dates to say a Saturday or Sunday in July. As stated in § 165.1191(a), the Coast Guard will provide exact dates, times, and other details concerning the fireworks listed in table 1 to § 165.1191 in the Local Notice to Mariners at least 20 days prior to the event.

The Regulated Area description for item 22, “Monte Foundation Fireworks”, would be revised to clarify the safety zone will be in the navigable waters around and under the Capitola Pier.

This rule proposes to add three safety zones covering three reoccurring fireworks events to Table 1 in 33 CFR

165.1191. The three new fireworks events would be listed in Table 1 of this section as item 31, “Fourth of July Fireworks, City of Benicia,” item 32, “Fourth of July Fireworks, City of Vallejo,” and item 33 “Berkeley Winter on the Waterfront Fireworks.” All three of these fireworks displays occurred in previous years 2017, 2018, and 2019. Both the Benicia, CA fireworks and the City of Vallejo, CA fireworks will occur annually on the Fourth of July. The Berkeley, CA fireworks displays will occur annually on the second Saturday or Sunday in December. The Coast Guard believes it is beneficial to include these additional fireworks displays in the list of reoccurring permanent regulations to increase public awareness of when safety zones would be enforced in these marine areas. The regulatory text we are proposing appears at the end of this document.

**IV. Regulatory Analyses**

We developed this proposed 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 NPRM has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM 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 limited duration and narrowly tailored geographic areas of the safety zones. Although this rule restricts access to the waters encompassed by the safety zones, the effect of this rule will not be significant because the local waterway users will be notified via public Notice to Mariners to ensure the safety zones will result in minimum impact. The entities most likely to be affected are waterfront facilities, commercial vessels, and pleasure craft engaged in recreational activities.

### 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 proposed rule would 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 zones may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator for the following reasons: (i) This rule will encompass only a small portion of each affected waterway for a limited period of time for each fireworks event, and (ii) the maritime public will be advised in advance of these safety zones via Notice to Mariners.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

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 proposed 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. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

### C. Collection of Information

This proposed rule would 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 proposed 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 proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would 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 proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

### 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 proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

### F. Environment

We have analyzed this proposed 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 made a preliminary determination 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 proposed rule involves safety zones of limited sizes and durations. Normally such actions are 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 preliminary Record of Environmental Consideration supporting this determination is available in the docket. We seek any comments or information that may lead

to the discovery of a significant environmental impact from this proposed rule.

### 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.

### V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, visit <https://www.regulations.gov/privacyNotice>.

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at <https://www.regulations.gov> and can be viewed by following that website’s instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

### 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 is proposing to amend 33 CFR part 165 as follows:

**PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS**

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.

27, and add Item 31, Item 32, and Item 33 in Table 1 to § 165.1191 to read as follows:

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

■ 2. Revise Item 7, Item 8, Item 9, Item 19, Items 22, Item 24, Item 25, and Item

§ 165.1191 **Northern California and Lake Tahoe Area Annual Fireworks Events.**

TABLE 1 TO § 165.1191

*	*	*	*	*	*	*
<b>7. San Francisco Independence Day Fireworks</b>						
Sponsor .....	The City of San Francisco.					
Event Description .....	Fireworks Display.					
Date .....	July 4th.					
Location 1 .....	A barge located approximately 1000 feet off San Francisco Pier 39.					
Location 2 .....	A barge located approximately 700 feet off of the San Francisco Municipal Pier at Aquatic Park.					
Regulated Area .....	100-foot radius around each fireworks barge during the loading, transit, setup, and until the commencement of the scheduled display. Increases to a 1000-foot radius upon commencement of the fireworks display.					
*	*	*	*	*	*	*
<b>8. Fourth of July Fireworks, Berkeley Marina</b>						
Sponsor .....	Berkeley Marina.					
Event Description .....	Fireworks Display.					
Date .....	July 4th.					
Location .....	A barge located near the Berkeley Marina Pier.					
Regulated Area .....	100-foot radius around the fireworks barge during the loading, transit, setup, and until the commencement of the scheduled display. Increases to a 1000-foot radius upon commencement of the fireworks display.					
*	*	*	*	*	*	*
<b>9. Fourth of July Fireworks, City of Richmond</b>						
Sponsor .....	Various Sponsors.					
Event Description .....	Fireworks Display.					
Date .....	Week of July 4th.					
Location .....	A barge located in the Richmond Harbor in Richmond, CA.					
Regulated Area .....	100-foot radius around the fireworks barge during the loading, transit, setup, and until the commencement of the scheduled display. Increases to a 560-foot radius upon commencement of the fireworks display.					
*	*	*	*	*	*	*
<b>19. Incline Village Independence Day Fireworks</b>						
Sponsor .....	Various Sponsors.					
Event Description .....	Fireworks Display.					
Date .....	Week of July 4th.					
Location .....	500–1000 feet off Incline Village, NV in Crystal Bay.					
Regulated Area .....	100-foot radius around the fireworks launch barge during the loading of pyrotechnics aboard the fireworks barge and during the transit of the fireworks barge from the loading location to the display location. Increases to a 1000-foot radius upon commencement of the fireworks display.					
*	*	*	*	*	*	*
<b>22. Monte Foundation Fireworks</b>						
Sponsor .....	Monte Foundation.					
Event Description .....	Fireworks Display.					
Date .....	Second Saturday or Sunday in October.					
Location .....	Capitola Pier in Capitola, CA.					
Regulated Area .....	1000-foot radius safety zone in the navigable waters around and under the Capitola Pier.					
*	*	*	*	*	*	*
<b>24. San Francisco New Year's Eve Fireworks</b>						
Sponsor .....	City of San Francisco.					
Event Description .....	Fireworks Display.					
Date .....	December 30th through January 1st.					
Location .....	1000 feet off the Embarcadero near the Ferry Plaza in San Francisco, CA.					

TABLE 1 TO § 165.1191—Continued

Regulated Area ..... 100-foot radius around the fireworks launch barge during the loading of pyrotechnics aboard the fireworks barge and during the transit of the fireworks barge from the loading location to the display location. Increases to a 1000-foot radius upon commencement of the fireworks display.

\* \* \* \* \*

**25. Sacramento New Year's Eve Fireworks**

Sponsor ..... Various Sponsors.  
 Event Description ..... Fireworks Display.  
 Date ..... New Year's Eve, December 31st.  
 Location ..... Near the Tower Bridge, Sacramento River, Sacramento, CA.  
 Regulated Area ..... The navigable waters of the Sacramento River within 700 feet of the two shore-based launch locations near the Tower Bridge in Sacramento, CA and the bridge-based launch location on the Tower Bridge in Sacramento, CA.

\* \* \* \* \*

**27. Feast of Lanterns Fireworks**

Sponsor ..... Feast of Lanterns, Inc.  
 Event Description ..... Fireworks Display.  
 Date ..... A Saturday or Sunday in July.  
 Location ..... Near Lover's Point Park in Pacific Grove, CA.  
 Regulated Area ..... The area of navigable waters within a 1000-foot radius of the launch platform located on the beach near Lover's Point Park.

\* \* \* \* \*

**31. Benicia Fourth of July Fireworks**

Sponsor ..... City of Benicia, CA.  
 Event Description ..... Fireworks Display.  
 Date ..... July 4th.  
 Location ..... Carquinez Strait, Benicia, CA.  
 Regulated Area ..... 1000-foot radius safety zone around the fireworks launch platform located on the Benicia First Street Pier.

\* \* \* \* \*

**32. Vallejo Fourth of July Fireworks**

Sponsor ..... City of Vallejo, CA.  
 Event Description ..... Fireworks Display.  
 Date ..... July 4th.  
 Location ..... Mare Island Strait, Vallejo, CA.  
 Regulated Area ..... 100-foot radius around the fireworks barge during the loading, transit, setup, and until the commencement of the scheduled display. Increases to a 1000-foot radius upon commencement of the fireworks display.

\* \* \* \* \*

**33. Berkeley Winter on the Waterfront Fireworks**

Sponsor ..... City of Berkeley, CA.  
 Event Description ..... Two Fireworks Displays.  
 Date ..... Second Saturday or Sunday in December.  
 Location ..... Near the entrance to the Berkeley Marina in Berkeley, CA.  
 Regulated Area ..... 100-foot radius around the fireworks barge during the loading, transit, setup, and until the commencement of the scheduled display. Increases to a 500-foot radius upon commencement of the first fireworks display and remains in effect until after the conclusion of the second fireworks display.

Dated: March 9, 2020.

**Howard H. Wright,**

*Captain, U.S. Coast Guard, Alternate Captain of the Port, San Francisco.*

[FR Doc. 2020-05174 Filed 3-16-20; 8:45 am]

BILLING CODE 9110-04-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 73

[Docket No. CDC-2020-0024]

RIN 0920-AA71

#### Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Advance notice of proposed rulemaking and request for comments.

**SUMMARY:** In accordance with section 351a of the Public Health Service Act, the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS; hereafter referred to as HHS/CDC) has initiated a review of the HHS list of biological agents and toxins that have the potential to pose a severe threat to public health and safety (HHS select agents and toxins). This review was initiated within two years of the completion of the previous review. In reviewing the list, HHS/CDC is considering whether to propose amending the HHS list of select agents and toxins.

**DATES:** Comments should be received on or before May 18, 2020.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2020-0024 or Regulation Identifier Number (RIN) 0920-AA71, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21-7, Atlanta, Georgia 30329, ATTN: RIN 0920-AA71.

*Instructions:* All submissions received must include the agency name and RIN for this rulemaking. All relevant comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

*Docket Access:* For access to the docket to read background documents or comments received, or to download an electronic version of the advance

notice of proposed rulemaking, go to <http://www.regulations.gov>. Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m. at 1600 Clifton Road NE, Atlanta, GA, 30329. Please call ahead to 1-866-694-4867 and ask for a representative in the Division of Select Agents and Toxins (DSAT) to schedule your visit. Please be aware that comments and other submissions from members of the public are made available for public viewing without changes.

**FOR FURTHER INFORMATION CONTACT:**

Samuel S. Edwin Ph.D., Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21-7, Atlanta, Georgia 30329. Telephone: (404) 718-2000.

**SUPPLEMENTARY INFORMATION:** The preamble to this advance notice of proposed rulemaking is organized as follows:

- I. Public Participation
- II. Background
- III. Modifications to the List of Select Agents and Toxins Being Considered
  - A. Agents and Toxins Under Consideration
    - i. Botulinum Neurotoxin Producing Species of *Clostridium*
    - ii. *Coxiella burnetii*
    - iii. *Rickettsia prowazekii*
    - iv. *Bacillus anthracis* (Pasteur Strain)
    - v. *Brucella Abortus*, *Brucella Melitensis*, and *Brucella Suis*
    - vi. Venezuelan Equine Encephalitis Virus (VEEV) 1AB and 1C
    - vii. Short, Paralytic Alpha Conotoxins
    - viii. Diacetoxyscirpenol
    - ix. *Staphylococcal* Enterotoxins
    - x. New World Hantaviruses:
      1. Sin Nombre Virus
      2. Andes Virus
    - xi. Old World Hantaviruses:
      1. Hantaan Virus
      2. Dobrava Virus
  - B. Toxins Being Considered for Revision to Exclusion Amounts (*i.e.*, the Amount Below Which the Toxin Is Not Subject to Regulatory Oversight)
    - i. Saxitoxin
    - ii. Tetrodotoxin
    - iii. Botulinum neurotoxin
  - C. Designating Nipah Virus as a Tier 1 Select Agent
- IV. References

#### I. Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Comments are welcomed on any topic related to this advance notice of proposed rulemaking.

In addition, HHS/CDC invites comments specifically as to whether there are additional biological agents or toxins that should be added or removed from the HHS list of select agents and

toxins based on the following criteria outlined under 42 U.S.C. 262a(a)(1)(B):

- (1) “The effect on human health of exposure to the agent or toxin”
- (2) “The degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans”
- (3) “The availability and effectiveness of pharmacotherapies to treat or immunizations to prevent any illness resulting from infection by the agent or exposure to the toxin”
- (4) “Any other criteria including the needs of children and other vulnerable populations” and any other criteria that the commenter believes should be considered.

Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Commenters should not include any information in their comments or supporting materials that they consider confidential or inappropriate for public disclosure. HHS/CDC will carefully consider all comments submitted.

#### II. Background

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Response Act) (42 U.S.C. 262a(a)(1)), the HHS Secretary must establish by regulation a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety. In determining whether to include a biological agent or toxin on the list, the Bioterrorism Response Act (42 U.S.C. 262a(a)(1)(B)) requires that the HHS Secretary consider the following criteria: The effect on human health of exposure to an agent or toxin; the degree of contagiousness of the agent and the methods by which the agent or toxin is transferred to humans; the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent illnesses resulting from an agent or toxin; and any other criteria including the needs of children and other vulnerable populations that the HHS Secretary deems relevant.

Under 42 U.S.C. 262a(a)(2), the HHS Secretary must review and republish the list of HHS select agents and toxins at least biennially. For this review, HHS/CDC evaluated as discussed below each agent and toxin based on: The degree of pathogenicity (ability of an organism to cause disease); dissemination efficacy; aerosol stability; matrix stability; ease of production; ability to genetically manipulate or alter; severity of illness; case fatality rate; long-term health effects; rate of transmission; available treatment; status of host immunity (*e.g.* whether an individual has already been