

further enhanced for clarity in protecting research integrity.

With regard to enforcement authorities, the current regulations include in 42 CFR 50.606 and 45 CFR 94.6 a description of remedies available to HHS and a PHS Awarding Component when identifying concerns regarding FCOI or compliance with the regulations. In addition, 42 CFR 50.607 identifies other HHS regulations that apply, including uniform administrative requirements, as well as debarment and suspension procedures. The NPRM includes proposed revisions to all three of these sections. Among the proposed changes, with regard to matters determined to require corrective action under the regulations, we proposed revising paragraph 50.606(b) to incorporate by reference 45 CFR 74.14 (special award conditions), and proposed revising paragraph 94.6(b) to reference "other enforcement action" in addition to, or in lieu of, a Stop Work Order by the Contracting Officer. In section 50.607, we proposed minor revisions to update the CFR location or title of the existing references, but also specifically requested comment with regard to the necessity of this section.

In conjunction with the comment period extension, we seek public comment on whether the proposed changes to the regulations' references to the enforcement authorities available to the PHS, including those discussed above, should be further revised and clarified in the regulations. This includes comment on whether the regulations should include one or more descriptions of specific measures that the Department, including a PHS Awarding Component, may initiate as a result of particular types of identified FCOI or non-compliance under the regulations. As one example, the regulations potentially could describe situations in which an Investigator's identified FCOI or an Investigator's failure to comply with an Institution's FCOI policy or FCOI management plan necessitates notification to other Institutions (e.g., when the Investigator, or the PHS-funded research project on which he or she is working, transfers from one Institution to another).

In addition to possible clarification of enforcement authorities, the Department also seeks comment as to whether it should clarify how the regulations apply in circumstances in which an Investigator or a PHS-funded research project transfers from one Institution to another, or in which a new Institution, and Investigators at the new Institution, become involved in an ongoing PHS-funded research project (e.g., where the new Institution becomes a subgrantee

on the project). As one example, we proposed in the NPRM to revise substantially 42 CFR 50.604(f) and 45 CFR 94.4(f) such that these paragraphs would require an Institution, through its designated officials, to determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is a FCOI. We request comment as to whether the regulations should further clarify that, as part of the Institution's FCOI determination process, institutional officials must consider whether an Investigator's SFI was previously determined to be a FCOI and subject to a management plan with regard to other PHS-funded research project(s). Such consideration could be based on information in the Institution's own records or from publicly accessible sources (e.g., the Web site of an Institution that previously employed the Investigator). We welcome additional public comment on alternative approaches or additional clarifications that may be incorporated into the regulations to protect further the objectivity of PHS-funded research in situations involving a transfer of an Investigator or PHS-funded project between Institutions, or the introduction of a new Institution and Investigators to an existing PHS-funded project.

Dated: June 22, 2010.

**Francis S. Collins,**  
*Director, National Institutes of Health.*

Approved: July 6, 2010.

**Kathleen Sebelius,**  
*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 73

RIN 0920-AA34

#### **Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List**

**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:** The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a) (the Bioterrorism Act) requires the biennial review and republication of the HHS list of select agents and toxins.

Accordingly, we are soliciting public comment on the current HHS list of select agents and toxins, including whether any biological agent or toxin should be added to or removed from the list. We are also seeking comments as to whether we should "tier" the HHS select agent list based on the relative bioterrorism risk of each agent or toxin and possibly further "stratify" the security requirements for agents in the highest tier based on type of use or other factors.

**DATES:** We will consider all comments received on or before August 20, 2010.

**ADDRESSES:** Comments in response to this notice should be marked "Comments on the changes to the list of select agents and toxins" and mailed to: Centers for Disease Control and Prevention, Division of Select Agents and Toxins, 1600 Clifton Road, MS A-46, Atlanta, GA 30333. Comments may be e-mailed to: [SAPcomments@cdc.gov](mailto:SAPcomments@cdc.gov).

**FOR FURTHER INFORMATION CONTACT:** Robbin Weyant, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Rd., MS A-46, Atlanta, GA 30333. *Telephone:* (404) 718-2000.

**SUPPLEMENTARY INFORMATION:** The Bioterrorism Act requires the HHS Secretary to establish by regulation a list of each biological agent and toxin that has the potential to pose a severe threat to public health and safety. In determining whether to include an agent or toxin on the list, the HHS Secretary considers the effect on human health upon exposure to the agent or toxin; the degree of contagiousness of the agent; 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 the agent or toxin; the potential for the agent or toxin to be used as a biological weapon; and the needs of children and other vulnerable populations. The current list of HHS biological select agents and toxins can be found at <http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html>. The Bioterrorism Act requires that the HHS Secretary review and republish the HHS list of select agents and toxins on at least a biennial basis.

#### **Background**

The HHS Secretary last republished the HHS select agent and toxin list in the **Federal Register** on October 16, 2008 (73 FR 61363). The HHS select agent and toxin list, found in part 73 of Title 42 of the Code of Federal Regulations (42 CFR part 73), is divided

into two sections. The select agents and toxins listed in § 73.3 (HHS select agents and toxins) are those regulated only by HHS under the authority of the Bioterrorism Act. The select agents and toxins listed in § 73.4 (Overlap select agents and toxins) are those regulated by HHS under the authority of the Bioterrorism Act and regulated by Secretary of Agriculture (USDA) under the authority of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401).

To fulfill this statutory mandate, CDC's Division of Select Agents and Toxins (DSAT) has initiated its biennial review process which will include consultation with subject matter experts including the Intragovernmental Select Agents and Toxins Technical Advisory Committee (ISATTAC). The ISATTAC is comprised of Federal government employees from the CDC, the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the USDA/Animal and Plant Health Inspection Service (APHIS), USDA/Agricultural Research Service (ARS), USDA/Center for Veterinary Biologics (CVB), the Department of Homeland Security (DHS), and the Department of Defense (DOD).

The purpose of this advanced notice of proposed rulemaking is to seek public comment on (1) the appropriateness of the current HHS list of select agents and toxins, (2) whether there are other agents or toxins that should be added to the HHS list, (3) whether agents or toxins currently on the HHS list should be deleted from the list, (4) whether the HHS select agent list should be tiered based on the relative bioterrorism risk of each agent or toxin, and (5) whether the security requirements for agents in the highest tier should be further stratified based on type of use or other factors.

A recent report by the National Research Council recommended that the select agent list should be ordered based on the potential of an agent to be used as a biothreat, and a graded series of security procedures should be applied so that the greatest resources and scrutiny go to securing agents that pose a maximum risk (<http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12774>). As noted above, we are also seeking public comment on whether the HHS list should be tiered based on the relative bioterrorism risk of each agent or toxin and whether the security requirements for agents in the highest tier should be further stratified based on type of use or other factors. If a commenter believes that the HHS list should be tiered and/or stratified, we would also be

interested in what criteria should be used to designate higher-risk agents, and what, if any, changes we should make in security requirements for what would be determined to be higher-risk agents.

If implemented, tiering of the HHS select agent list could allow for the application of more stringent security measures for those select agents or toxins which pose a higher risk to public health and safety if stolen or misused. If implemented, stratification of the HHS select agent list could allow for varying levels of security requirements for entities that possess the highest tier agents, based on use of the agent or other factors. If a commenter believes that tiering and/or stratification of the HHS select agent list is advisable, we would be interested in comments as to what criteria should be used to designate which agents and toxins pose a higher bioterrorism risk and what criteria should be used for stratifying the highest risk agents. For example, the tiering and/or stratification of the HHS select agent list might consider the relative ease with which a particular agent or toxin might be disseminated or transmitted between humans or throughout the environment; the potential for high mortality rates; the potential for a major public health impact; whether misuse of an agent or toxin might result in public panic or other social or economic disruption; and whether the agent or toxin requires Federal, State and local officials to take special action in planning for major public health disasters (quarantine needs, eradicated agent or toxin). Additionally, we would also be interested in what corresponding changes should be made to the security requirements found in 42 CFR 73.11 to increase protection for higher tier agents or toxins; whether those security requirements should be stratified based on the use of the agent or other factors; and whether such changes should be prescriptive (the imposition of specific restraints, restrictions, or requirements) or risk-based (security requirement based on a security risk assessment), or a combination of prescriptive and risk-based.

Following the conclusion of CDC review, we will publish another notice in the **Federal Register** either proposing that the select agent and toxin list remain the same, or that specific biological agents or toxins be added to or deleted from the list. If appropriate, we will also propose any changes to the Select Agent regulations (42 CFR Part 73) to implement a tiering and/or stratification schema along with any corresponding amendments to the current security requirements in the

Select Agent regulations that might be required for higher-risk agents and toxins.

This action has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

**Authority:** 42 U.S.C. 262a.

Dated: January 8, 2010.

**Kathleen Sebelius,**  
*Secretary.*

**Editorial Note:** This document was received in the Office of the Federal Register on July 15, 2010.

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## DEPARTMENT OF TRANSPORTATION

### Pipeline and Hazardous Materials Safety Administration

#### 49 CFR Parts 171 and 173

[Docket No. PHMSA-2010-0017 (HM-245)]

RIN 2137-AE56

#### Hazardous Materials: Incorporation of Certain Cargo Tank Special Permits Into Regulations

**AGENCY:** Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** The Pipeline and Hazardous Materials Safety Administration is proposing to amend the Hazardous Materials Regulations to incorporate provisions contained in certain widely used or longstanding cargo tank special permits that are granted to multiple parties and have an established safety record. Special permits allow a company or individual to package or ship a hazardous material in a manner that varies from the regulations provided an equivalent level of safety is maintained. The proposed revisions are intended to provide wider access to the regulatory flexibility offered in the special permits and eliminate the need for numerous renewal requests, thereby, facilitating commerce activity and reducing paperwork burdens while maintaining an appropriate level of safety.

**DATES:** Comments must be received by August 20, 2010. A 30 day comment period is appropriate for this rulemaking because it proposes to incorporate long-standing, widely used special permits into the HMR. These