Federal Register

Tuesday,
August 6, 2002

Part V

Department of Health and Human Services

Centers for Disease Control and Prevention

OMB Approval of Data Collection; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of OMB Approval of Data Collection

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: General notice.

SUMMARY: The purpose of this Notice is to announce OMB approval of data collection, ''Notification of Possession of Select Agents,'' under the Paperwork Reduction Act of 1995 (PRA). The OMB Control Number for this data collection is 0920–0561. The data collection will expire January 31, 2003.

FOR FURTHER INFORMATION CONTACT: Anne O'Connor, Assistant Reports Clearance Officer, Centers for Disease Control and Prevention, Office of Program Planning and Evaluation, 1600 Clifton Road NE, Mailstop D–24, Atlanta, Georgia 30333. Telephone: (404) 498–1210.

SUPPLEMENTARY INFORMATION:

Background

On June 12, 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (The Act). The Act requires that all persons in possession of any ''Select Agent'' notify the Secretary of the Department of Health and Human Services (DHHS) by September 10, 2002. Section 213(b) of The Act requires all persons in possession of any ''High Consequence Livestock Pathogen or Toxin'' notify the Secretary of the U.S. Department of Agriculture (USDA) by October 8, 2002. The Centers for Disease Control and Prevention (CDC) has been designated as the agency responsible for providing guidance on this notification to the Secretary, DHHS. The Animal and Plant Health Inspection Service (APHIS) has been designated as the agency responsible for providing guidance on this notification to the Secretary, USDA. In order to minimize the reporting burden to the public, CDC and APHIS created a common notification form.

In compliance with requirements of the Paperwork Reduction Act of 1995 (PRA), CDC published a notice in the **Federal Register** on July 2, 2002 inviting public comment on the proposed data collection regarding: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of the information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. The public was asked to submit their comments within 14 days of the publication of the notice.

Discussion of Comments

CDC received a number of comments to the **Federal Register** Notice regarding five issues related to the proposed data collection.

Comment: Many commenters requested a definition of the term 'facility.' *CDC Response:* The Guidance Document (see below) provides a definition of facility. For the purposes of this data collection, facility is defined as any individual, or government agency, university, corporation, company, partnership, society, association, firm or other legal entity located at a single geographic site. A single geographic site is a building or complex of buildings at a single mailing address.

Comment: A number of commenters were concerned that clinical and diagnostic laboratories were being required to submit the notification form because they interpreted sections of The Act as exempting these facilities from submitting the notification form. *CDC Response:* Although exemption of these laboratories was discussed during the development of this legislation, Congress explicitly rejected any broad exclusion of these facilities. A fuller explanation of Congressional intent on this subject is contained in the House Conference Report No. 107–481 to accompany H.R. 3448, May 21, 2002, at page 122. Congress permits exemption of such clinical and diagnostic laboratories from registration requirements, ''* * * only if they report the identification of select agents to the Secretary and either promptly transfer the agent to a registered person or destroy the agent on site in accordance with regulations established by the Secretary.'' The conference report further explains that laboratories which possess select agents for *reference purposes* must register and be subject to this full regulatory program. Although all clinical and diagnostic laboratories must participate in this *initial notification* phase under the legislation, DHHS and USDA will promptly develop, through rule-making, the regulations that will allow exemptions for those laboratories who only possess, use, or transfer select agents contained in specimens presented for *diagnosis, verification,* or *proficiency testing.* In order to comply with Congressional intent, CDC and APHIS are requiring all clinical and diagnostic laboratories that possess any agent or toxin listed on the notification form to submit a form to the address provided.

Comment: A number of commenters asked that CDC reconsider the requirement that facilities that do not possess a select agent complete and submit a declaration of non-possession. *CDC response:* CDC recognizes that The Act does not explicitly address this particular issue of a non-possession declaration. Asking respondents to declare non-possession is a critical means of ensuring that DHHS is knowledgeable of the potential universe of possessors of regulated agents and is necessary in order to effectively carry out the statutory intent of responsibly governing the transfer, possession, and use of biological agents or toxins.

Comment: Other commenters were concerned that CDC had underestimated the amount of time necessary to review instructions, gather the data, and enter it onto the form. *CDC Response:* CDC recognizes that many respondents will need less than two hours to complete the form and that other respondents will need more than two hours. However, given the vast universe of respondents, CDC feels that an average of two hours to review the instructions, gather the data, and complete the form is a reasonable estimate.

Comment: Several commenters asked about the list of Select Agents on the form. *CDC Response:* The notification form contains the list of Select Agents that was published in the **Federal Register** on October 24, 1996. As part of the rule-making process, CDC will publish another notice in the **Federal Register** requesting public comment on proposed changes to the list of select agents.

OMB Approved Guidance Document and Form

After considering the comments, CDC and APHIS submitted the Guidance Document and Notification Form (see below) to OMB for approval under the Paperwork Reduction Act. On July 31, 2002, OMB approved the Guidance Document and Notification Form under OMB Control No. 0920–0561. Upon OMB approval, CDC and APHIS plan to conduct a targeted mailing of the Guidance Document and form to approximately 190,000 facilities. If facilities have not received a copy of the Guidance Document and form within 10 days of publication of this notice, they

should call 866–567–4232 to request a copy of the Guidance Document and form. The Guidance Document and form will also be available at both the CDC Web site (*http://www.cdc.gov/od/ohs/lrsat.htm*) and the APHIS Web site (*http://www.aphis.usda.gov/vs/ncie*).

Dated: August 1, 2002.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[Approved Guidance Document and Notification Form follow.]

BILLING CODE 4163–18–P

Notification of Possession of Select Agents or High Consequence Livestock Pathogens and Toxins

Guidance Document

Introduction

Section 202(a) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("The Act") requires that all persons in possession of any "Select Agent" notify the Secretary of the Department of Health and Human Services (DHHS) by September 10, 2002. Section 213(b) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires all persons in possession of any "High Consequence Livestock Pathogens and Toxins" notify the Secretary of the Department of Agriculture (USDA) by October 8, 2002. The Act requires that both Secretaries be notified when an individual possesses agents that appear on both the "Select Agent" list and the "High Consequence Livestock Pathogens and Toxins" list. These agents are referred to as "Overlap Agents".

The Centers for Disease Control and Prevention (CDC) has been designated as the agency responsible for providing guidance on this notification to the Secretary, DHHS. The Animal and Plant Health Inspection Service (APHIS) has been designated as the agency responsible for providing guidance on this notification to the Secretary, USDA. In order to minimize the reporting burden to the public, DHHS/CDC and the USDA/APHIS have developed a common reporting form for this data collection. This form is designed to assist facilities with compliance with this legal obligation.

Step One. Who must respond to this request?

All facilities, including research, clinical, and diagnostic laboratories, that possess any agent or toxin listed on the attached notification form are required to complete the form and return it to the address provided below. All facilities receiving this form by mail must complete the appropriate responses. Exemptions to the notification of possession will be limited to persons or facilities that possess products that are, bear, or contain select agents or toxins that have been cleared, approved, licensed, or registered under the Federal Food, Drug, and Cosmetic Act, Section 351 of the Public Health Service Act, the Virus-Serum-Toxin Act, and the Federal Insecticide, Fungicide, and Rodenticide Act.

Since the Act was signed into law, CDC has received a number of inquiries about the inclusion of all clinical, and diagnostic laboratories during the initial notification of possession phase. Although exemption of these laboratories was discussed during the development of this legislation, Congress explicitly rejected any broad exclusion of these facilities.

A fuller explanation of Congressional intent on this subject is contained in the House Conference Report No. 107-481 to accompany H.R. 3448, May 21, 2002, at page 122. As discussed, Congress permits exemption of such clinical and diagnostic laboratories from registration requirements "...only if they report the identification of select agents to the

Secretary and either promptly transfer the agent to a registered person or destroy the agent on site in accordance with regulations established by the Secretary."

This conference report goes on to make it clear that such laboratories which possess select agents for reference purposes must register and be subject to this full regulatory program. Although all clinical and diagnostic laboratories must participate in this initial notification phase under the legislation, DHHS and USDA will promptly develop, through rulemaking, the regulations that will allow exemptions for those laboratories who only possess, use, or transfer select agents contained in specimens presented for diagnosis, verification, or proficiency testing. Therefore, in order to comply with Congressional intent, CDC and APHIS are requiring all clinical and diagnostic laboratories that possess any agent or toxin listed on the notification form to submit a form to the address provided.

Step Two. Who should complete this form?

Each facility should designate a Responsible Facility Official (RFO) to complete this form. The purpose of the RFO is to ensure management oversight of this notification requirement. The RFO should be either a safety officer, and/or senior management official of the facility who has been authorized to complete this form. Whenever possible, the RFO should not be an individual who actually possesses, uses or transfers such agents and toxins. The RFO must review and sign the 'Notification of Possession of Select Agents or High Consequence Livestock Pathogens and Toxins" form and will be the individual contacted if questions concerning the form arise. The RFO should consult with others (e.g., principal investigators) as necessary to obtain the information required to complete the form. The RFO should provide one form that represents a summary of all agents from his or her facility.

For the purpose of completing this notification form, a facility is defined as any individual or government agency, university, corporation, company, partnership, society, association, firm or other legal entity located at a single geographic site. A single geographic site is a building or complex of buildings at a single mailing address.

Step Three. How does the RFO fill out this form?

A. **All RFOs** must complete boxes #1-6.

B. Review the agents listed in box #7 and check each agent or toxin used or possessed by your facility. For each agent checked, check the appropriate descriptive category or categories, if known (e.g., viable, recombinant organisms, etc.). Definitions for the categories are listed below.

C. Provide the information in boxes #8-14. For box #8, Type of Facility, select the box that best describes your facility. For box #9, Type of Work Performed, check all boxes that apply to the facility.

D. **If your facility does not possess any agents on this list**, provide only the information requested in boxes #15-18.

E. Return the form to the address below.

F. Facilities that possess DHHS Select Agents or USDA/DHHS Overlap Agents must submit completed forms by September 10, 2002. Facilities that possess only USDA High Consequence Livestock Pathogens and Toxins must submit completed forms by October 8, 2002.

G. Do not report quantities of agents or toxins.

Definitions of Categories

- **Viable**: Capable of replication on its own, in cell culture, or in an appropriate host.
- **Recombinant organism, Nucleic acid, or Genetic elements from agent** include any of the following:
  - Nonviable agents
  - Full-length nucleic acid from any of the viruses on the list. For Variola major virus (Smallpox), any segment that exceed 100 nucleotides in length.
  - Natural or synthetic nucleic acids from bacteria, fungi, or viruses on the list that encode for either a functional toxin or virulence factor sufficient to cause disease, or natural or synthetic nucleic acid that encodes for a functional toxin of any of the toxins listed, if: (1) expressed *in vivo*; (2) in an expression vector or host chromosome; or (3) in a carrier plasmid.
- **Altered USDA or FDA approved vaccine strains**: Vaccine strains that have been modified from their original licensed, approved, or registered forms.

Obtaining extra copies of this form

Please call 866-567-4232 to obtain additional copies of this form. The notification form and Guidance Document is viewable on both the CDC website (http://www.cdc.gov/od/ohs/lrsat.htm) and the APHIS website (http://www.aphis.usda.gov/vs/ncie).

Return this form to:

Analytical Sciences, Inc.
Attn: FSO
P.O. Box 341809
Bethesda, MD 20827

Help Line: 866-567-4232
(8:00 am to 8:00 pm EDT)

NOTE: If you desire confirmation of delivery, please return your completed Notification Form using the **US Postal Service Priority Mail** in the 9.5" x 12" cardboard Priority Mail envelope (EP-14G) and complete and attach a fluorescent green **US Postal Service Delivery Confirmation Receipt** (PS Form 152) label to the envelope. You may track the delivery of your Notification form via the US Postal Service Web site at http://www.usps.com/shipping/deliveryconfirm.htm or by calling 800-222-1811 toll-free. Do **not** use the fluorescent pink US Postal Service Signature Confirmation Receipt (PS Form 153) or send the form via Certified Mail (PS Form 3800) as ASI will be unable to sign for these forms and they will be returned to you.

FORM APPROVED
OMB NO. 0920-0561
EXP DATE 01/31/2003

NOTIFICATION OF POSSESSION OF SELECT AGENTS OR HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS

USDA

1. NAME OF FACILITY	2. NAME OF RESPONSIBLE FACILITY OFFICIAL (RFO) AND ADDRESS, IF DIFFERENT FROM FACILITY
3. ADDRESS OF FACILITY	4. TITLE OF RFO 5. RFO TELEPHONE NUMBER 6. RFO FAX NUMBER

7. CHECK ("X") FOR EACH AGENT(S) OR TOXIN(S) USED OR POSSESSED BY YOUR FACILITY (CHECK ONE OR MORE CATEGORIES AS APPROPRIATE)	VIABLE	RECOMBINANT ORGANISM, NUCLEIC ACID OR GENETIC ELEMENTS FROM AGENT	ALTERED USDA OR FDA APPROVED VACCINE STRAINS	REGISTERED WITH HHS SELECT AGENT PROGRAM
HHS SELECT AGENTS				
☐ CRIMEAN-CONGO HAEMORRHAGIC FEVER VIRUS				
☐ EBOLA VIRUSES				
☐ LASSA FEVER VIRUS				
☐ MARBURG VIRUS				
☐ *RICKETTSIA PROWAZEKII*				
☐ *RICKETTSIA RICKETTSII*				
☐ SOUTH AMERICAN HAEMORRHAGIC FEVER VIRUSES				
☐ TICK-BORNE ENCEPHALITIS COMPLEX VIRUSES				
☐ VARIOLA MAJOR VIRUS (SMALLPOX VIRUS)				
☐ VIRUSES CAUSING HANTAVIRUS PULMONARY SYNDROME				
☐ YELLOW FEVER VIRUS				
☐ *YERSINIA PESTIS*				
☐ ABRIN				
☐ CONOTOXINS				
☐ DIACETOXYSCIRPENOL				
☐ RICIN				
☐ SAXITOXIN				
☐ TETRODOTOXIN				
USDA-HHS OVERLAP AGENTS				
☐ *BACILLUS ANTHRACIS*				
☐ *BRUCELLA ABORTUS*				
☐ *BRUCELLA MELITENSIS*				
☐ *BRUCELLA SUIS*				
☐ *BURKHOLDERIA (PSEUDOMONAS) MALLEI*				
☐ *BURKHOLDERIA (PSEUDOMONAS) PSEUDOMALLEI*				
☐ *CLOSTRIDIUM BOTULINUM*				
☐ *COCCIDIOIDES IMMITIS*				
☐ *COXIELLA BURNETII*				
☐ EASTERN EQUINE ENCEPHALITIS VIRUS				
☐ EQUINE MORBILLIVIRUS (HENDRA VIRUS)/NIPAH VIRUS				
☐ *FRANCISELLA TULARENSIS*				
☐ RIFT VALLEY FEVER VIRUS				
☐ VENEZUELAN EQUINE ENCEPHALITIS VIRUS				
☐ AFLATOXINS				
☐ BOTULINUM TOXINS				
☐ *CLOSTRIDIUM PERFRINGENS* EPSILON TOXIN				
☐ SHIGATOXIN				
☐ STAPHYLOCOCCAL ENTEROTOXIN				
☐ T-2 TOXIN				

CHECK ("X") FOR EACH AGENT(S) OR TOXIN(S) USED OR POSSESSED BY YOUR FACILITY (CHECK ONE OR MORE CATEGORIES AS APPROPRIATE)	VIABLE	RECOMBINANT ORGANISM, NUCLEIC ACID OR GENETIC ELEMENTS FROM AGENT	ALTERED USDA OR FDA APPROVED VACCINE STRAINS	REGISTERED WITH HHS SELECT AGENT PROGRAM
USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS				
☐ AFRICAN HORSE SICKNESS VIRUS				
☐ AFRICAN SWINE FEVER VIRUS				
☐ AKABANE VIRUS				
☐ AVIAN INFLUENZA VIRUS (HIGHLY PATHOGENIC)				
☐ BLUE TONGUE VIRUS (EXOTIC)				
☐ BOVINE SPONGIFORM ENCEPHALOPATHY AGENT				
☐ CAMEL POX VIRUS				
☐ CLASSICAL SWINE FEVER VIRUS				
☐ *COWDRIA RUMINANTIUM* (HEARTWATER)				
☐ FOOT AND MOUTH DISEASE VIRUS				
☐ GOAT POX VIRUS				
☐ JAPANESE ENCEPHALITIS VIRUS				
☐ LUMPY SKIN DISEASE VIRUS				
☐ MALIGNANT CATARRHAL FEVER				
☐ MENANGLE VIRUS				
☐ *MYCOPLASMA CAPRICOLUM/M.F 38/M.MYCOIDES CAPRI* (CONTAGIOUS CAPRINE PLEUROPNEUMONIA AGENT)				
☐ *MYCOPLASMA MYCOIDES MYCOIDES* (CONTAGIOUS BOVINE PLEUROPNEUMONIA AGENT)				
☐ NEWCASTLE DISEASE VIRUS (EXOTIC)				
☐ NIPAH VIRUS				
☐ PESTE DES PETITS RUMINANTS				
☐ RINDERPEST VIRUS				
☐ SHEEP POX VIRUS				
☐ SWINE VESICULAR DISEASE VIRUS				
☐ VESICULAR STOMATITIS VIRUS				

8. TYPE OF FACILITY: ☐ ACADEMIC ☐ GOVERNMENT ☐ COMMERCIAL ☐ PRIVATE ☐ OTHER (PLEASE EXPLAIN)

9. TYPE OF WORK PERFORMED AT FACILITY:
☐ DIAGNOSTIC WORK ☐ LARGE-SCALE PRODUCTION
☐ VACCINE DEVELOPMENT ☐ TEACHING
☐ RESEARCH ☐ STORAGE ONLY (NO CURRENT WORK)
☐ USE IN ANIMALS → ANIMAL SIZE: ☐ LIVESTOCK ☐ OTHER ☐ OTHER (PLEASE SPECIFY)

10. LIST ALL USDA VETERINARY PERMIT NUMBERS FOR IMPORTATION AND TRANSPORTATION OF CONTROLLED MATERIALS AND ORGANISMS AND VECTORS NUMBERS (VS Form 16-6A) (If applicable)

11. CDC SELECT AGENT TRANSFER PROGRAM REGISTRATION NUMBER AND EXPIRATION DATE (If applicable)

I hereby certify that I have been designated as the Responsible Facility Official for the institution/organization listed above, that I am authorized to bind the institution/organization, and that the information supplied on this form is to the best of my knowledge accurate and truthful. I understand that a false statement on any part of this form could result in a fine up to $500,000 or imprisonment of up to five years, or both for each violation (18 U.S.C §1001; 1 8 U.S.C § § 3559,3571)

12. SIGNATURE OF RESPONSIBLE FACILITY OFFICIAL

13. TYPED NAME AND TITLE | 14. DATE

15. ☐ **DECLARATION OF NON-POSSESSION: THIS FACILITY DOES NOT POSSESS ANY AGENT ON THIS LIST.**

I hereby certify that I have been designated as the Responsible Facility Official for the institution/organization listed above, that I am authorized to bind the institution/organization, and that the information supplied on this form is to the best of my knowledge accurate and truthful. I understand that a false statement on any part of this form could result in a fine of up to $500,000 or imprisonment or up to five years, or both for each violation (18 U.S.C §1001 8 U.S.C § § 3559,3571).

16. SIGNATURE OF RESPONSIBLE FACILITY OFFICIAL

17. TYPED NAME AND TITLE | 18. DATE

Public reporting burden of this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Clearance Officer, 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-xxxx).

RETURN THIS FORM TO:
Analytical Sciences, Inc.
Attn FSO
P.O. Box 371809
Bethesda, MD 20827

CDC FORM 50.01 Date: 07/2002

[FR Doc. 02–19897 Filed 8–2–02; 11:33 am]

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