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July 12, 2002

Part VII

Department of Health and Human Services

Centers for Disease Control and Prevention

Preliminary Guidance for Notification of Possession of Select Agents; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Preliminary Guidance for Notification of Possession of Select Agents

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 preliminary guidance for notification of possession of select agents as mandated in Section 202(a) of Public Law 107–188 ''Public Health Security and Bioterrorism Preparedness and Response Act of 2002.''

FOR FURTHER INFORMATION CONTACT: John R. Moore, Centers for Disease Control and Prevention, Office of Program Planning and Evaluation, 1600 Clifton Road NE, Mailstop D–23, Atlanta, Georgia 30333. Telephone: (404) 639–7070.

SUPPLEMENTARY INFORMATION: On June 12, 2002, President George W. Bush signed Public Law 107–188 ''Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' Section 202(a) of the Act directs the Secretary of the Department of Health and Human Services, within 30 days of enactment, to provide written guidance on how persons in possession of biological agents or toxins shall notify the Secretary of such possession. To meet this requirement, the Centers for Disease Control and Prevention (CDC) has submitted a proposed data collection instrument (see draft form below) and guidance document to the Office for Management and Budget (OMB) for approval under the Paperwork Reduction Act. CDC published a notice in the **Federal Register** on July 2, 2002 inviting public comments on the proposed data collection. Public comments are due by July 16, 2002. Within two weeks of this date, and upon receipt of OMB approval, CDC will publish another notice in the **Federal Register** announcing approval and publication of the data collection instrument. The data collection instrument will contain the list of select agents currently contained in 42 CFR part 72, appendix A.

Each facility should designate a responsible facility official (RFO) to complete this form by September 10, 2002. It is the responsibility of the RFO to ensure management oversight of this notification requirement. The RFO should be either a safety officer, a senior management official of the facility, or both, who has been authorized by the facility to complete and submit the notification form. The RFO should not be an individual who actually possesses, uses, or transfers such agents or toxins. To complete the notification form, the RFO will need to inventory its facility and consult with others (*e.g.*, principal investigators) as necessary to obtain the information required for the notification form. The RFO must review and sign the notification form and will be the point of contact if CDC has questions concerning the form or other matters related to the Act. Many facilities will receive the form via direct mailing, and the form will also be published in the **Federal Register**.

Further guidance, the approved data collection instrument, and location of submission will be announced at a later date.

Dated: July 10, 2002.

Nancy E. Cheal,

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

BILLING CODE 4163–18–P

DRAFT

FORM APPROVED
OMB NO. 0920-XXXX
EXP DATE XX/XX/XXXX

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL CENTER FOR INFECTIOUS DISEASES
LABORATORY REGISTRATION/SELECT AGENT TRANSFER PROGRAM
ATLANTA, GA 30333

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES
NATIONAL CENTER FOR IMPORT-EXPORT, PRODUCTS PROGRAM
RIVERDALE, MD 20737

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

NAME OF FACILITY	NAME OF RESPONSIBLE FACILTIY OFFICAL (RFO) AND ADDRESS, IF DIFFERENT FROM FACILITY
ADDRESS OF FACILITY	TITLE OF RFO
	RFO TELEPHONE NUMBER
	RFO FAX NUMBER

CHECK ("X") FOR EACH AGENT(S) OR TOXIN(S) USED OR POSSESSED BY YOUR FACILITY (CHECK ONE OR MORE CATEGORIES AS APPROPRIATE)	VIABLE	NUCLEIC ACID OR GENETIC ELEMENTS FROM AGENT	VACCINE APPROVED BY USDA OR FDA (modified)	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				
☐ CONOTIXINS				
☐ 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 BURNETTII*				
☐ 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				

DRAFT

CHECK ("X") FOR EACH AGENT(S) OR TOXIN(S) USED OR POSSESSED BY YOUR FACILITY (CHECK ONE OR MORE CATEGORIES AS APPROPRIATE)	VIABLE	NUCLEIC ACID OR GENETIC ELEMENTS FROM AGENT	VACCINE APPROVED BY USDA OR FDA (modified)	REGISTERED WITH HHS SELECT AGENT PROGRAM
USDA HIGH CONSEQUENCE OF LIVESTOCK PATHOGENS AND TOXINS				
☐ AFRICAN HORSE SICKNESS VIRUS				
☐ AFRICAN SWINE FEVER				
☐ AKABANE VIRUS				
☐ AVIAN INFLUENZA VIRUS (HIGHLY PATHOGENIC)				
☐ BLUE TONGUE VIRUS (EXOTIC)				
☐ BOVINE SPONGIFORM ENCEPALOPATHY AGENT				
☐ CAMEL POX VIRUS				
☐ CLASSICAL SWINE FEVER				
☐ *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.*M YCOIDES CAPRI* (CONTAGIOUS CAPRINE PLEUROPNEUMONIA AGENT)				
☐ *MYCOPLASMA MYCOIDES MYCOIDES* (CONTAGIOUS BOVINE PLEUROPNEUMONIA AGENT)				
☐ NEWCASTLE DISEASE VIRUS (EXOTIC)				
☐ PESTE DES PETITS RUMINANTS				
☐ RINDERPEST VIRUS				
☐ SHEEP POX				
☐ SWINE VESICULAR DISEASE VIRUS				
☐ VESICULAR STOMATITIS VIRUS				

TYPE OF FACILITY: ☐ ACADEMIC ☐ GOVERNMENT ☐ COMMERICAL ☐ PRIVATE ☐ OTHER (PLEASE EXPLAIN)

TPYE OF WORK TO BE PERFORMED AT FACILITY *(PROPOSED USE OF MATERIAL AND DERIVATIVES; DIAGNOSTICS, VACCINE DEVELOPMENT, ETC., IF FOR USE IN ANIMALS, SPECIFY SPECIES)*

FOR ANY LISTED AGENTS OR TOXINS POSSESSED BY YOUR FACILIY, LIST U.S. VETERINARY PERMIT FOR IMPORTATION AND TRANSPORTATIONS OF CONTROLLED MATERIALS AND ORGANISMS AND VECTORS NUMBERS (VS Form 16-6A) (if applicable)

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 or up to five years, or both for each violation (18 U.S.C §1001; 1 8 U.S.C § § 3559,3571)

SIGNATURE OF RESPONSIBLE FACILITY OFFICIAL

TYPED NAME AND TITLE | DATE

☐ **DECLARATION OF NON-POSSESSION: THIS FACILITY DOES NOT POSSESS AN 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 §10011 8 U.S.C § § 3559,3571).

SIGNATURE OF RESPONSIBLE FACILITY OFFICIAL

TYPED NAME AND TITLE | 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 or sponsor, and a person in 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:

[LOCATION TO BE DETERMINED]

CDC FORM XXXX
DATE

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BILLING CODE 4163–18–C