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

<table>
<thead>
<tr>
<th>NAME OF FACILITY</th>
<th>NAME OF RESPONSIBLE FACILITY OFFICIAL (RFO) AND ADDRESS, IF DIFFERENT FROM FACILITY</th>
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<tbody>
<tr>
<td>ADDRESS OF FACILITY</td>
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<tr>
<td>TITLE OF RFO</td>
<td>RFO TELEPHONE NUMBER</td>
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CHECK ("x") FOR EACH AGENT(S) OR TOXIN(S) USED OR POSSESSED BY YOUR FACILITY (CHECK ONE OR MORE CATEGORIES AS APPROPRIATE)

<table>
<thead>
<tr>
<th>Viable</th>
<th>Nucleic Acid or Genetic Elements From Agent</th>
<th>Vaccine Approved by USDA or FDA (modified)</th>
<th>Registered with HHS Select Agent Program</th>
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### HHS SELECT AGENTS

- CRIMEAN-CONGO HAEMORRHAGIC FEVER VIRUS
- EBOLA VIRUSES
- LASSA FEVER VIRUS
- MARBURG VIRUS
- RICKETTSIA PROWAZEKII
- RICKETTSIA RICKETTSI
- SOUTH AMERICAN HAEMORRHAGIC FEVER VIRUSES
- TICK-BORNE ENCEPHALITIS COMPLEX VIRUSES
- VARICELA MAJOR VIRUS (SMALLPOX VIRUS)
- VIRUSES CAUSING HANTAVIRUS PULMONARY SYNDROME
- YELLOW FEVER VIRUS
- YERSINIA PESTIS
- ABRIN
- CONOTOXINS
- DIACETOXYCIRRENOL
- RICIN
- SAXITOXIN
- TETROTOXIN

### USDA-HHS OVERLAP AGENTS

- BACILLUS ANTHRACIS
- BRUCELLA ABORTUS
- BRUCELLA MELITENIS
- BRUCELLA SUIS
- BURKHOLDERIA (PSEUDOMONAS) MALLEI
- BURKHOLDERIA (PSEUDOMONAS) PSEUDOMALLEI
- CLOSTRIDIUM BOTULINUM
- COCCIDIOIDES IMMITIS
- COXIELLA BURNETTI
- EASTERN EQUINE ENCEPHALITIS VIRUS
- EQUINE MORBILLI VIRUS (HENDRA VIRUS)/NIPAH VIRUS
- FRANCISELLA TULARENSIS
- RIFT VALLEY FEVER VIRUS
- VENEZUELAN EQUINE ENCEPHALITIS VIRUS
- AFTATOXINS
- BOTULINUM TOXINS
- CLOSTRIDIUM PERFRINGENS EPSILON TOXIN
- SHIGATOXIN
- STAPHYLOCOCCAL ENTEROTOXIN
- T-2 TOXIN
# DRAFT

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<thead>
<tr>
<th>CHECK [ ] FOR EACH AGENT(S) OR TOXINS USED OR POSSESSED BY YOUR FACILITY (CHECK ONE OR MORE CATEGORIES AS APPROPRIATE)</th>
<th>VIABLE</th>
<th>NUCLEIC ACID OR GENETIC ELEMENTS FROM AGENT</th>
<th>VACCINE APPROVED BY USDA OR FDA (modified)</th>
<th>REGISTERED WITH HHS SELECT AGENT PROGRAM</th>
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<tr>
<td>AFRICAN HORSE SICKNESS VIRUS</td>
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<td>AFRICAN SWINE FEVER</td>
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<td>AKABANE VIRUS</td>
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<td>AVIAN INFLUENZA VIRUS (HIGHLY PATHOGENIC)</td>
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<tr>
<td>BLUE TONGUE VIRUS (EXOTIC)</td>
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<td>BOVINE SPONGIFORM ENCEPHALOPATHY AGENT</td>
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<td>CAMEL POX VIRUS</td>
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<td>CLASSICAL SWINE FEVER</td>
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<td>COWDRA RUMINANTVITUB BACTERIUM (HEARTWATER)</td>
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<td>FOOT AND MOUTH DISEASE VIRUS</td>
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<td>GOAT POX VIRUS</td>
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<td>JAPANESE ENCEPHALITIS VIRUS</td>
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<td>LUMPY SKIN DISEASE VIRUS</td>
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<td>MALIGNANT CATARRHAL FEVER</td>
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<td>MENANGLE VIRUS</td>
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<td>MYCOPLASMA CAPRICOLUM/MMF 36/M M YCOCIDES CAPRI</td>
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<td>(CONTAGIOUS CAPRINE PLEUROPNEUMONIA AGENT)</td>
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<td>MYCOPLASMA MYCOCIDES MYCOCIDES (CONTAGIOUS BOVINE PLEUROPNEUMONIA AGENT)</td>
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<td>NEWCASTLE DISEASE VIRUS (EXOTIC)</td>
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<td>PESTE DES PETITS RUMINANTS</td>
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<td>Rinderpest virus</td>
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<td>SHEEP POX</td>
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<td>SWINE VESICULAR DISEASE VIRUS</td>
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<td>VESICULAR STOMATITIS VIRUS</td>
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<td>USDA HIGH CONSEQUENCE OF LIVESTOCK PATHOGENS AND TOXINS</td>
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**TYPE OF FACILITY:**
- [ ] Academic
- [ ] Government
- [ ] Commercial
- [ ] Private
- [ ] Other (please explain)

**TYPE 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 FACILITY, 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; 18 U.S.C. § 3556.501).

SIGNATURE OF RESPONSIBLE FACILITY OFFICIAL

**TYPE NAME AND TITLE**

**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 up to $500,000 or imprisonment or up to five years, or both for each violation (18 U.S.C. §1001; 18 U.S.C. § 3556.501).

SIGNATURE OF RESPONSIBLE FACILITY OFFICIAL

**TYPE NAME AND TITLE**

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 CDCATSDR Information Clearance Officer: 1600 Clifton Road NE, MS-D-24, Atlanta, Georgia 30333. ATTN: PRA (0920-0042). (888) 871-9499.

**RETURN THIS FORM TO:**

[LOCATION TO BE DETERMINED]

[CDC FORM XXXX]

DATE

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