

# Department of Health and Human Services

## 42 CFR Part 72 | RIN 0905-AE70

### Additional Requirements for Facilities Transferring or Receiving Select Agents

**AGENCY:** Centers for Disease Control and Prevention , HHS.

**ACTION:** Final rule.

#### SUMMARY

On June 10, 1996, the Centers for Disease and Prevention (CDC), the Department of Health and Human Services (HHS), issued a Notice of Proposed Rulemaking (NPRM) to implement Section 511 of Public Law 104-132, "The Antiterrorism and Effective Death Penalty Act of 1996," which requires the Secretary of HHS to regulate the transfer of select agents. CDC requested comments on the NPRM and provided 30 days for individuals to submit their written comments. CDC considered the comments received and is issuing this final regulation in light of those comments. Current regulations specify requirements for the packaging, labeling, and transport of select agents shipped in interstate commerce. This final rule places additional shipping and handling requirements on facilities that transfer or receive select agents listed in the rule that are capable of causing substantial harm to human health.

#### EFFECTIVE DATE

April 15, 1997. Incorporation by reference of certain publications listed in the final rule is approved by the Director of the Federal Register as of **October 24, 1996** . All transfers of select agents must comply with the complete documentation and registration requirements contained in this final rule on or after April 15, 1997. CDC has already begun efforts to inform and educate affected parties about the registration and transfer process for select agents. Within the next 60 days, CDC anticipates providing additional detailed information to interested parties in order to initiate the registration process.

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#### FOR FURTHER INFORMATION CONTACT

Dr. Jonathan Y. Richmond, Director, Office of Health and Safety, Centers for Disease Control and Prevention, 1600 Clifton Road, Mailstop FO5, Atlanta, GA 30333; telephone (404) 639-2453.

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#### SUPPLEMENTARY INFORMATION

This rule finalizes the rule entitled "Additional Requirements for Facilities Transferring or Receiving Select Infectious Agents," which was published in the **Federal Register** on June 10, 1996 (61 FR 29327). It has been retitled, "Additional Requirements for Facilities Transferring or Receiving Select Agents."

Section 511 of Public Law 104-132, enacted on April 24, 1996, stipulated that HHS issue a proposed regulation within 60 days and a final regulation within 120 days. The NPRM was published on June 10 (13 days earlier than required) and provided 30 days for public review and comment. The subject matter, and subsequent comments responding to the NPRM, raised highly- complex issues that demanded careful consideration and significant discussion with numerous other involved Federal agencies. Thus, the publication of this final rule extended beyond 120 days.

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**BACKGROUND ON THE NOTICE OF PROPOSED RULEMAKING AND SUMMARY OF RESPONSES TO PUBLIC COMMENT**

## **Notice of Proposed Rulemaking**

In recent years, the threat of illegitimate use of infectious agents has attracted increasing interest from the perspective of public health, in view of concern that certain select agents could have serious adverse consequences for human health and safety. "The Antiterrorism and Effective Death Penalty Act of 1996," enacted on April 24, 1996, established new provisions to regulate transfer of hazardous

agents, and required HHS to issue rules to implement these provisions. CDC's NPRM proposed new regulations to meet the requirements of this statute.

The NPRM was based on the key principles of ensuring protection of public safety, without encumbering legitimate scientific and medical research. The NPRM also was designed to minimize the need for an additional, expansive federal regulatory implementation structure.

Specifically, the proposed rule was designed to:

- establish a system of safeguards to be followed when specific agents are transported;
- collect and provide information concerning the location where certain potentially- hazardous agents are transferred;
- track the acquisition and transfer of these specific agents; and
- establish a process for alerting appropriate authorities if an unauthorized attempt is made to acquire these agents.

The proposed rule included the following fundamental components:

1. a comprehensive list of select agents;
2. a registration of facilities transferring these agents;
3. transfer requirements;
4. verification procedures including audit, quality control, and accountability mechanisms;
5. agent disposal requirements; and
6. research and clinical exemptions.

## **Public Comment and Department's Response**

During the 30-day comment period that ended on July 10, 1996, CDC received sixty seven written responses. Most of these contained multiple comments, some as many as 10 or more, with the total number of comments exceeding two hundred. Most comments were favorable regarding the proposed rule. In general, these comments focused on specific sections of the regulation, requested clarification of the wording and intended meaning of certain provisions, or suggested additions or deletions to the proposed list of select agents. A small number of the commenters expressed concern that the proposed regulation would not protect against terrorism, would slow or discourage certain areas of research, and/or would add unnecessary additional administrative costs and paperwork burdens. The preamble sections below summarize the NPRM and the comments received, and provide CDC's responses to comments.

## Select Agents List

The NPRM included a proposed list of select agents to be subject to the rule. CDC specifically solicited comments regarding those agents to be added to or deleted from the proposed list. We received a large number of responses to this request. The list of agents subject to the final rule is at Appendix A.

Agents deleted from the list are *Chikungunya virus*, *Japanese encephalitis virus*, *Chlamydia psittaci*, and *Histoplasma capsulatum* (including *var. duboisii*). Infectious agents added to the final list are Equine morbillivirus, and *Coccidioides immitis*. Kyasanur forest disease virus is no longer specifically listed but is included under the broader category of Tick-borne encephalitis complex viruses.

Other changes to the list included: The term "Hantaviruses" was changed to "Viruses causing hantavirus pulmonary syndrome"; "Tick borne encephalitis viruses" was changed to "Tick borne encephalitis complex viruses"; "Encephalitis viruses (Venezuelan, Western, Eastern)" was changed to "Eastern equine encephalitis virus" and "Venezuelan equine encephalitis virus"; "Ebola virus" was changed to "Ebola viruses"; and "Flexal virus" was added to the parenthetical list of "South American haemorrhagic fever viruses."

A large number of responses pertained to the proposed list of select toxins. These commenters recommended additions, deletions, or exemptions based on medical uses. Based on our review of these comments, the following toxins or classes of toxins were deleted from the final list: *Corynebacterium diphtheriae* toxin, cyanoginsins, *Shigella dysenteriae* neurotoxin, tetanus toxin, trichothecene mycotoxins, and verrucologen. The following toxins were added: aflatoxins, conotoxins, diacetoxyscirpenol, and T-2 toxin.

In the NPRM, Section 72.6(a)(6) specified that toxins be handled in accordance with Department of Defense regulations found at 32 CFR 627.17 and in The Biological Defense Safety Program, Technical Safety Requirements (DA Pamphlet 385-69). One commenter correctly pointed out that the proper reference for handling toxins is 29 CFR 1910.1450, "Occupational Exposure to Hazardous Chemicals in Laboratories." This final rule is not intended to preempt, pursuant to Section 4(b)(1) of the Occupational Safety and Health Act of 1970, any other rules designed to protect employees from these agents.

The final rule exempts vaccine strains of viruses, and specifies exemptions for listed agents based on coverage under other federal regulations. Exemptions are listed in Appendix A.

We received several comments regarding some of the terminology used in the NPRM, including pathogenicity, virulence, and less pathogenic. One commenter preferred the term virulence to pathogenicity. CDC views virulence and pathogenicity, which both mean the ability of an organism to cause disease, as synonymous terms. Similarly, avirulent and nonpathogenic are synonymous.

Several comments questioned the use of the term "select infectious agent" to describe all agents subject to the rule, pointing out that toxins are not infectious. In response to these comments, CDC has changed "select infectious agent" to "select agent" and revised the definition to mean "a microorganism (virus, bacterium, fungus, rickettsia) or toxin listed in Appendix A of this part". The term "select agent" in the final rule includes only those select agents listed in Appendix A .

One commenter wanted to know if tissue samples that only contain small amounts of the agent or that may only be suspected of containing a pathogen would be covered by the final rule. All materials that are known or reasonably suspected of containing a select agent, including tissue samples, unless exempted as a human or veterinary clinical specimen, are subject to this regulation.

## **Registration of Facilities Transferring Select Agents**

The NPRM proposed that commercial suppliers of select agents, as well as government agencies, universities, research institutions, individuals, and private companies that transfer or obtain these agents, or that wish to work with these agents, must register with the Secretary of HHS or with an organization authorized by the Secretary. The proposed registration process required that a responsible facility official certify that the facility and its laboratory operations meet the biosafety level 2, 3, and/or 4 requirements for working with agents as described in the Third Edition of " CDC/National Institutes of Health (NIH) Biosafety in Microbiological and Biomedical Laboratories" (BMBL). The NPRM also stipulated that inspection of the facility seeking registration may be required by the Secretary, or an organization authorized by the Secretary, to determine whether the applicant facility meets the appropriate biosafety level requirements. The NPRM proposed that facilities, if approved, would be issued a unique registration number indicating that the facility is registered to work with these select agents at the prescribed biosafety level. The registration number also would be used to help validate all requests for transfer of these agents.

### ***Incorporation of the BMBL***

Some commenters questioned incorporating the BMBL into the regulation because, in their view, the BMBL provides "guidelines" that are vague, and lack specificity and sufficient detail. One commenter recommended that the BMBL be augmented or updated to provide a clear objective standard. Because the BMBL serves as the only nationally and internationally recognized source for biosafety requirements for laboratories, the final rule retains the incorporation of the BMBL. The BMBL provides the minimum requirements for BL-2, 3, and 4 laboratories and animal facilities and is readily applicable to a facility registration and inspection process.

## ***Registration Process***

Some commenters suggested CDC base its registration procedures on models used by other entities. In developing the NPRM, CDC reviewed several models, including a Nuclear Regulatory Commission (NRC) licensing model for the use of radioactive materials; a certification model based on National Committee for Clinical Laboratory Standardization (NCCLS) for hospital certification programs; a model based on the use of an Institutional Biosafety Committee similar to that outlined in the NIH Recombinant DNA Guidelines; the United States Department of Agriculture, Animal Plant and Health Inspection Service (USDA/APHIS) import and transfer program for restricted animal pathogens; the American Association for Accreditation of Laboratory Animal Care (AAALAC) Program; and the CDC import permit program for etiologic agents. CDC found aspects of these models adaptable or partially adaptable to its program. CDC's program includes many elements of these models, such as on-site inspections, registration (user) fees, and registration and transfer requirements.

One commenter suggested providing more detail for the registration process. Another suggested basing the registration process on a "self-audit" where the registering entity would provide self-audit forms.

CDC will provide application forms to be completed by facilities seeking registration. The application will require information regarding laboratory practices, equipment, and other pertinent information. Facilities will submit the completed application to CDC for approval of registration. A facility inspection may or may not be required prior to registration, depending on documentation supplied by the applicant. If CDC approves the registration, a unique registration number will be issued. Those facilities not pre-inspected will be inspected following registration. All registered facilities will be inspected subsequently on a periodic basis.

## ***Appeals***

As proposed in the NPRM, registrations may be denied or withdrawn, subject to appeal. One commenter asked whether the appeals process described in the NPRM would include a hearing. CDC interprets this to mean an oral hearing since courts have construed the term "hearing" to mean the submission of written information as well as oral testimony. Although not explicitly stated, the rule provides flexibility for a variety of forums to ensure that appeals receive due process. This would include an oral hearing if, in the Secretary's discretion, such steps are necessitated by the particular facts presented by any specific situation.

## **Transfer Requirements**

The NPRM proposed that, prior to transferring one of these select agents, both the shipping (transferor) and receiving (requestor) parties complete required sections of the official transfer form. (EA-101). The NPRM proposed that the EA-101 list the restricted agents and require information about the requestor and transferor,

the requesting and transferring facilities, the registration numbers of the transferring and receiving facilities, the name of restricted agent requested, and the proposed use of the agent. The NPRM proposed that the form must accompany the request or purchase order for obtaining these restricted agents, that a copy must be maintained by both the requesting and transferring facility, and that a copy must be sent to a designated central repository which would be available to federal and authorized local law enforcement authorities and other officials authorized by the Secretary. The form could later be used for tracking purposes in case of illegitimate access to these agents. Falsification of this form would be a federal criminal offense. The final rule retains all of these provisions. In addition, the final rule requires requestors to specify on form EA-101 the number of containers and amount per container of the agent(s) being shipped.

As discussed in the NPRM preamble, because these select agents have the potential for causing mass destruction or widespread disease in humans, CDC has determined intrastate transfers of these agents from one geographic site to another also pose a risk of potential interstate transmission of disease; therefore, intrastate transfers of these agents are also subject to the regulation.

### ***Shipping and Transfer Requirements***

Several commenters were concerned about shipping select agents and about acceptable carriers and carrier responsibilities. Nothing in this final rule is intended to preempt other applicable Federal regulations. Select agents included under this final rule are required to be packaged, labeled and shipped in accordance with all applicable federal regulations. CDC believes that compliance with existing federal regulations on packaging, labeling, and shipping select agents, in combination with the transfer requirements of this final rule, provide sufficient safeguards for safe and secure transport.

Other comments expressed concern about emergency response to a transportation incident involving a select agent. Any transportation incident involving a select agent, including a lost or stolen package, or a damaged package, should be reported to CDC through its 24 hour, 7 days-a-week emergency number (1-800-232-0124) by either the shipper, recipient, or package handler. Any unexpected release of these agents may also be covered by the National Oil and Hazardous Substances Pollution Contingency Plan, found in 40 CFR Part 300.

Packages of select agents are required to be packaged as infectious substances, labeled with the infectious substance and etiologic agent label, and shipped in accord with all federal regulations. Both the DOT infectious substance label and the CDC etiologic agent label bear CDC's emergency phone numbers. Also, the packaging requirements for these select agents require that the shipper's name and phone number be on the outer package, to be used in emergencies. Thus, CDC would be able to call the shipper to discuss matters that relate to spill clean-up.

Commenters asked for clarification regarding the relationship between the proposed regulation and federal importation and exportation regulations.

Importers of select agents also are subject to CDC's regulations at 42 CFR Part 71.54, "Importation of Etiologic Agents and Vectors," and are responsible for obtaining an import permit from CDC prior to importing select agents. In such cases, CDC will require the importer to be registered in accordance with this final rule and to supply the registration number before the select agent is imported.

This final rule does not apply to exportation of select agents. Exporters of select agents will continue to follow the Department of Commerce export administration regulations at 15 CFR Parts 742, 744, and 774, "Commerce Control List: Microorganisms and Toxins."

### ***Intrafacility Transfers***

Several commenters believed that the rule should cover intrafacility transfers or at least provide guidelines for intrafacility transfer and tracking, and that the lack of guidelines constituted a weakness in the proposed regulation. While the NPRM proposed that tracking of intrafacility transfers are the responsibility of individual facilities, the final rule has been changed to reflect that a registered facility is not required to follow the transfer and verification requirements listed in the rule, so long as the facility maintains adequate records of intrafacility transfers. Thus, CDC Form EA-101 does not have to be completed when transferring a select agent if the following conditions are met: (1) the transfer is within a single facility at a single geographic site, (2) the intended use of the agent remains consistent with that specified in the most current transfer form, and (3) the facility documents the following information for each intrafacility transfer: the name and location of the recipient; the amount transferred, and date transferred. Recipients are required to comply with all other parts of this final regulation, including the requirements for storage and disposal. Questions concerning the transfer of a select agent meeting the criteria of an intrafacility transfer may be referred to CDC.

### ***Single Geographic Site***

Several commenters also requested clarification on the meaning of a single geographic site. For example, does this mean a building, a complex of buildings, or several sites within a single city? For the purposes of this rule, CDC defines a single geographic site as the complex of buildings and laboratories at a single mailing address. CDC may entertain exceptions on a case-by-case basis at the time of facility registration.

## **Verification Procedures**

To facilitate the shipment of these select agents, the NPRM proposed that each facility shipping or receiving a covered agent must have a "responsible facility official," and that this person be either a biosafety officer, a senior management official of the facility, or both. The NPRM also suggested that the responsible facility official should **not** be the same person as those individuals actually transferring and receiving the agents at the facilities.

The NPRM specified that the requestor's responsible facility official must sign each request, certifying that the individual researcher requesting the agent is officially affiliated with the facility and that the laboratory meets current requirements for working with the requested agent. The NPRM also required the responsible facility official sending the restricted agent to verify that the receiving facility holds a currently valid registration number, indicating that the recipient has the required biosafety level capability. Inability to validate the necessary information could result in immediate notification of the appropriate authorities. The NPRM also specified timeframes for confirmation of select agent transfer and for retention of CDC Form EA-101.

### ***Responsible Facility Official***

Several comments pertained to the designation of a responsible facility official. CDC developed the concept of a responsible facility official to ensure management oversight of the transfer process. CDC envisioned that the responsible facility official either could be a senior management official or a biosafety officer. However, commenters indicated that there are circumstances when a biosafety officer may be inappropriate, such as for facilities that use toxins. As a result of the comments we received, CDC has revised the definition of a Responsible Facility Official to include a senior management official or a "safety officer," the term "safety" being substituted for "biosafety". Although not required in the final rule, a safety officer responsible for select microbial agents or recombinant microorganisms should have a background in microbiology and training and experience in biosafety; a safety officer responsible for select toxins should have a background in chemistry and training and experience in chemical safety.

Another commenter suggested that a biosafety officer should be a Registered Biosafety Professional (RBP). CDC supports the concept of certification of safety professionals in their area of specialty, but has not determined that a specific certification should be required by this final rule.

Several commenters were concerned about the liability of safety officers. CDC believes that these matters rest with facility management, and are beyond the scope of this final rule.

One commenter requested clarification on the meaning of "officially affiliated" as used in section 72.6(e)(1)(ii), Verification Procedures. Personnel may be affiliated with a facility in a variety of ways, such as employee, contractor, consultant, graduate student, postdoctoral fellow, visiting scientist or staff member. Of these affiliations, we believe that "employee" is the affiliation most directly related to the facility. CDC therefore has replaced "officially affiliated" with "employee" in the final rule.

### ***Timeframe for Transfer Confirmation and EA-101 Retention***

A number of commenters thought that the time periods for the requestor acknowledging receipt of the agent to the transferor either electronically or by paper copy were too short. CDC has extended the 24 hour time period for telephonic or electronic notification to 36 hours, but feels that 3 business days is adequate for a paper copy receipt. CDC will accept a facsimile (FAX) transmission receipt as the equivalent of a paper copy receipt. CDC also will accept a facsimile transmission from the transferrer of a completed EA-101.

In addition, the time required for retaining a copy of CDC Form EA-101 after agent consumption or destruction has been extended from 1 year to 5 years in the "Request for Agents" section in the final rule. This time period is consistent with the retention requirement in the "Disposal of Agents" section of the final rule, and is based on the five-year statute of limitations for bringing criminal prosecution under Title 18, United States Code, Section 1001, and under Title 42, United States Code, Section 271.

### **Agent Disposal Requirements**

The NPRM proposed that select agents be stored in accordance with prudent laboratory practices, and stipulated that facilities must have in place procedures for the appropriate disposal of agents.

Several commenters requested more details on suitable location for the storage of agents and the type of security required. Because laboratory structures vary considerably, only broad guidance can be provided beyond what is specified in the final rule. Prudent laboratory practices suggest storing select agents such that unauthorized and unqualified persons cannot gain access to them and such that the responsible person can account for quantities stored. Prudent practice also suggests that storage be secure, including controlled access to the storage area and storage equipment.

Several commenters suggested that the regulation include specific directions on disposal of selected agents. The final rule specifies that disposal of select agents must be at the facility, by known effective methods, and the facility should maintain records as to the quantity destroyed, date of destruction, and method of destruction and persons responsible for destruction. The registering entity must be notified of the disposal or complete consumption of a select agent by completing this section on EA-101. If registration is withdrawn, select agents must be disposed of as required in the regulation. In addition to these rule requirements, it is advisable to retain use and consumption records to account for supplies of toxins, and to maintain records pertaining to storage, consumption and disposal of agents.

Other commenters questioned the need to destroy select agents on-site, pointing out that many microbiology laboratories do not have decontamination autoclaves and they transport their used cultures and stocks off-site for autoclaving or

incineration. Similarly, many laboratories using toxins transport them off site for incineration or other means of destruction. The BMBL specifies that infectious agents removed from BL-3 and BL-4 laboratories be decontaminated on-site, preferably by autoclaving. Toxins can be treated with strong oxidizing agents to inactivate them before removal from laboratories. Thus, the final rule retains the requirement to destroy select agents on-site. Once inactivated, the special agents can be sent to off-site locations for incineration or other ultimate disposal.

Other commenters inquired about how the regulatory authority would know when all of an agent previously transferred to a facility was destroyed. It should be noted that this regulation only applies to transfers of agents after the effective date of this final rule. To ensure compliance with this regulation, CDC combined facility management oversight of select agents with facility employee responsibilities and stiff penalties for intentional or willful violations. CDC believes that facility integrity and personal responsibilities combined with these penalties will prove effective in ensuring the controlled safe use, storage, and disposal of select agents.

One commenter expressed concern that the NPRM did not make specific reference to retention requirements for agents which are stored in a culture repository. If a select agent is in a laboratory or institutional culture repository prior to the effective date of this final rule, the regulation requires no action until the select agent is transferred. When the agent is transferred, all requirements of this regulation apply to the transaction.

## **Research and Clinical Exemptions**

In order to provide strains for reference, diagnostic, and research studies at Biosafety Level 2 facilities, the NPRM proposed that less pathogenic strains, such as vaccine strains of restricted viral agents as described in the BMBL or those specifically mentioned on the CDC Form EA- 101, be exempt from the list of select agents. The NPRM also proposed to exempt toxins for medical use, inactivated for use as vaccines, or preparations for biomedical research use at an LD50 for vertebrates of more than 100 nanograms per kilogram of body weight, and to exempt transfer of clinical specimens for diagnostic and verification purposes. However, the NPRM proposed to require that isolates of these agents from clinical specimens must be destroyed after confirmation or sent to an approved repository after diagnostic procedures are complete. Other than for these purposes, such isolates could not be transferred to another site without using the transfer form and approval by the responsible facility officials.

Several commenters recommended that clinical specimens should be subject to the regulation, and expressed the view that exempting clinical specimens provided a "loophole". It should be noted that regulation requires that clinical specimens, in order to be exempt, must be intended for diagnostic, reference and/or verification purposes. Other uses of a clinical specimen containing a select agent, or a select

agent isolated from a clinical specimen, such as for research purposes, will subject the clinical laboratory to this regulation.

Another commenter requested clarification as to when an agent from a clinical specimen becomes subject to the regulation. Subsequent to the isolation and identification of a select agent from a clinical specimen, it must be transferred to a registered facility or destroyed.

Other commenters questioned how clinical labs might receive select agents for proficiency testing or order reference strains. The rule specifically exempts clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, (42 U.S.C. § 263a) (CLIA), that utilize these select agents for diagnostic, reference, verification, or proficiency testing purposes. In addition, the rule provides procedures for facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory. No additional paperwork on behalf of CLIA laboratories is required by this final rule. CDC will accept a CLIA certification number on CDC Form EA-101 in lieu of the required institutional registration number, as stipulated in this final rule.

Another commenter requested clarification of the term "less pathogenic" as a criterion for exemption. CDC has determined that it is premature to issue blanket exemptions of attenuated, avirulent, or less pathogenic strains of agents on the restricted list at this time. Attenuated strains of select agents approved for human vaccination purposes by FDA or other recognized national or international organizations will be exempt. All other attenuated, avirulent, or less pathogenic strains will not be exempt at this time. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents (Appendix A). Individuals seeking additions to the list of exemptions should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future changes to the list of exemptions will be published in the **Federal Register** for review and comment prior to inclusion on Appendix A.

## **Criminal Penalties**

Violations of the final rule are subject to federal criminal penalties. A false, fictitious, or fraudulent statement or representation on the forms required in the regulation for registration of facilities or for transfers of select agents is a violation of Title 18, United States Code, Section 1001. An individual offender is subject to imprisonment for not more than five years, a fine as provided in Section 3571(b) of Title 18, or both. An organization that violates Section 1001 is subject to a fine as provided in Section 3571(c) of Title 18. Other violations of the final rule are subject to criminal penalties as prescribed in Title 42, United States Code, Section 271. A violation of Section 271 subjects an individual offender to imprisonment for not more than one year, a fine as provided in Section 3571(b) of Title 18, or both. An organization that violates Section 271 is subject to a fine as provided in Section 3571(c) of Title 18.

## ***Enforcement***

At least one comment questioned who would constitute "appropriate law enforcement authorities." While the rule is purposely nonspecific on this point to allow flexibility, depending upon individual circumstances, it is anticipated that federal law enforcement authorities, specifically the Federal Bureau of Investigation, and other federal agencies may require access to the records and database for law enforcement purposes. Assistance from state and local authorities may be required on an as-needed basis to aid federal agencies, as dictated by individual situations and as determined necessary by the Secretary and/or the Attorney General.

On the issue of law enforcement, numerous comments were received concerned with the criminal penalties an offender may be subject to for violations of the rule. Most of these comments were concerned that inadvertent or unintentional mistakes could result in criminal punishment. Other commenters suggested adding language to the criminal penalties notices to describe the mental state required for violation of the rule. There are two principal criminal statutes implicated in violations of the rule. Title 18, United States Code, Section 1001 applies to false statements made to the Federal Government in connection with the rule. Such false statements may be made in connection with a facility's application to become a registered entity, completion of CDC Form EA-101 for transfers of select agents, and in other circumstances. To constitute a criminal violation, Section 1001 requires that the false statement be made "knowingly and willfully." Other violations of the rule are covered under Title 42, United States Code, Section 271. This violation is classified as a misdemeanor and requires a "knowing" mental state by the defendant. Thus, both of these criminal statutes subject offenders to punishment for knowing conduct.

## ***Possession***

Several commenters questioned whether the rule was intended to govern possession as well as transfer of the select agents listed in the rule. This final rule and associated criminal penalties apply only to interstate and intrastate transfer of these agents. Possession of these agents is outside the scope of this final rule; however, an individual in possession of a "biological agent or toxin... for use as a weapon" as defined in Title 18 of the U.S. Code, may be subject to separate criminal penalties (18 U.S.C. § 175 et seq.).

## **Publicly Available Information**

Several comments were received regarding the information collections required in Sections 72.6(c)(2)(i) and (ii). Specifically, commenters were concerned with the public availability of the database of registered facilities and repository of transfer forms. While one commenter thought public availability would prove useful to those facilities transferring agents by creating an informal checklist of other registered facilities, the majority of comments suggested that neither the database

nor the registry of transfer forms should be available to the public. Of chief concern was fear that a publicly available list of registered facilities would serve as a "roadmap" to would-be terrorists of facilities possessing these dangerous agents. Another concern was that the database and transfer forms may contain proprietary information.

Taking into consideration these comments, CDC has determined that making this information available through a public database could compromise one of the primary purposes of the proposed rule and its authorizing legislation, i.e., limiting unauthorized access to these select agents. Therefore, CDC will not create publicly available databases of the information referenced in section 72.6 (c)(2)(i) or (ii).

In addition to comments concerned with the public availability of information gathered pursuant to this rule, some commenters suggested adding language to the rule explaining that trade secret and/or confidential commercial or financial information would be exempt from disclosure under the Freedom of Information Act (FOIA).

Currently, CDC exempts from public release trade secret and/or confidential commercial or financial information in accordance with the Freedom of Information Act (5 U.S.C. § 552), Executive Order 12600, and Department of Health and Human Services regulations found at 42 CFR Part 5. In accordance with these authorities, CDC provides a submitter with notice of receiving a third-party request for information whenever the requested records have been designated by the submitter as confidential commercial information or the agency has reason to believe that disclosure of the information could reasonably be expected to cause substantial competitive harm. The submitter is given a reasonable period of time in which the submitter may object to the FOIA disclosure of any specified portion of the information and to state all grounds upon which disclosure is opposed. CDC gives careful consideration to all such specified grounds for nondisclosure prior to making an administrative determination of the issue. In all instances when the agency determines to disclose the requested records, CDC provides the submitter a written statement briefly explaining why the submitter's objections are not sustained. Such a statement shall, to the extent permitted by law, be provided a reasonable number of days prior to a specified disclosure date. If CDC decides to release the information, the submitter may pursue legal action to prevent such release.

Because these existing authorities already explain the policies and procedures utilized by CDC in releasing and/or withholding trade secret and/or confidential commercial or financial information, further explanation is not being included in this final rule.

Proprietary concerns were also raised regarding the provision of transfer forms to state health departments. Some commenters suggested that states generally may benefit by receiving these transfer forms because they could independently track agents arriving and leaving the state. However, disclosure of EA-101 forms may

compromise proprietary interests of the concerned facilities. Additionally, providing a copy of each EA-101 form to the appropriate state health department would constitute an administrative burden on the agency. Further, the Secretary may provide the forms to state law enforcement authorities under appropriate circumstances. For these reasons, CDC has determined that it will not provide state health departments with the transfer forms on a routine basis. Nor is it contemplated that parties to the transfer of select agents will provide a copy of the form to state health departments.

## **Restrictions for Genetic Elements**

The transfer of genetic elements into other cells or organisms offers tremendous possibilities for improving the public health. However the transfer of genetic elements coding for virulence genes, antibiotic resistance, or toxins offers the potential for creating new and deadly pathogens. A large number of comments were received asking for further clarifications of the restrictions placed on genetically modified microorganisms or genetic elements. Commenters stated that "sequences associated with pathogenicity were vague" and questioned what constituted the toxic subunit(s) of a restricted toxin. CDC considers as a select agent, under the definition, and subject to the final rule, genetic elements from a select agent, that contain a nucleic acid sequence(s) which, if inserted into an appropriate host system, are reasonably believed capable of producing disease or toxicosis. Genetic elements from a select agent that contains a nucleic acid sequence(s) which, if inserted into an appropriate host system, do not cause disease or toxicosis are not subject to the final rule.

## **SUMMARY OF CHANGES**

1. The title of the regulation was changed from, "Additional Requirements for Facilities Transferring or Receiving Select Infectious Agents," to "Additional Requirements for Facilities Transferring or Receiving Select Agents," deleting the word, "Infectious." The word, "infectious" was deleted in all instances in the rule and "select agent" is now defined in section 72.6(j) as, "a microorganism, (virus, bacterium, fungus, rickettsia) or toxin listed in Appendix A of this part." The subsequent language dealing with recombinant organisms/molecules was revised and now reads: "The term also includes (1) genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease, and (2) genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins on Appendix A, or their toxic subunits."
2. In section 72.6(a)(1) the word, "laboratory" was deleted. Consistently throughout the final rule, the term "facility" is used to describe regulated entities.
3. The word "minimum" was added to section 72.6(a)(5).

4. In section 72.6(a)(6), the reference to "32 CFR § 627.17 and in The Biological Defense Safety Program, Technical Safety Requirements (DA Pamphlet 385-69), Subpart C--Operational Requirements" was replaced with, "29 CFR § 1910.1450, 'Occupational Exposure to Hazardous Chemicals in Laboratories'."
5. The last sentence of section 72.6(c)(2)(i) regarding the public availability of the databases maintained by registering entities has been deleted.
6. In section 72.6(d)(1), a new section (viii) was added. Section (viii) adds a new provision to CDC Form EA-101 that requires that the quantity of agent being shipped (number of containers and amount per container) be specified on EA-101.
7. In section 72.6(d)(2), the time required for retaining a copy of CDC Form EA-101 after agent consumption or destruction has been extended from 1 year to 5 years to make this section consistent with section 72.6(i)(2). The last two sentences of section 72.6(d)(2) were broken into separate sections, 72.6(d)(3) and 72.6(d)(4).
8. In section 72.6(e)(1)(ii), the term, "employee" was substituted for "officially affiliated."
9. In Section 72.6(e)(2), "and the appropriate law enforcement authorities" was deleted.
10. Grammatical changes were made to Section 72.6(f)(1) to make the section clearer.
11. Twelve (12) hours were added to the time period that the requesting facility's responsible official is allowed to acknowledge receipt of an agent, as required in section 72.6(f)(2). Additional language was also added to sections 72.6(f)(2) and (3) to clearly indicate that a facsimile transmission, in addition to a paper copy, is a sufficient means of transmitting CDC Form EA-101.
12. The reference to the BMBL in section 72.6(h)(1) was deleted as redundant. Specific language was added to this section to clearly indicate that strains exempted from this regulation are found in Appendix A and CDC Form EA-101.
13. Technical language changes were made in sections 72.6(d)(2) and 72.6(i)(2) to accurately describe that the same procedures required when an agent is destroyed also apply once a toxin is consumed. Also, the formal notice of consumption of a toxin or destruction of an agent required by section 72.6(i)(2) must now be specifically noted on the CDC Form EA- 101.
14. Several changes were made to 72.6(h) dealing with exemptions.
  - A. Section 72.6(h)(1) was deleted. The section previously numbered 72.6(h)(2) has been renumbered 72.6(h)(1)(i). Technical changes were also made to make the section clearer and more accurate. This section now reads, "The agent is part of a clinical specimen intended for diagnostic,

reference, or verification purposes. Isolates of covered agents from clinical specimens shall be disposed of in accordance with paragraph (i) of this part after diagnostic, reference, or verification procedures have been completed."

- B. The section previously numbered 72.6(h)(3) has been renumbered 72.6(h)(1)(ii).
  - C. A new section 72.6(h)(1)(iii) clearly indicates that exempted strains are specified in Appendix A. This section now also describes a procedure for applying for an exemption to this rule.
  - D. A new section 72.6(h)(2) was added that exempts from the rule clinical laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. § 263a) (CLIA) that transfer and receive select agents for diagnostic, reference, verification, or proficiency testing purposes.
  - E. Facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory must comply with the provisions of 72.6(h)(3). No additional paperwork is required of CLIA laboratories by this regulation.
15. The definition of "transfer" in section 72.6(j) was expanded to clearly indicate that intrafacility transfers of select agents are not subject to sections 72.6 (d), (e), and (f) so long as (1) the original conditions required in the NPRM are met, and (2) the name and location of the recipient, and the date and amount of agent transferred, are adequately maintained in the registered facility's records.

## **ANALYSIS OF IMPACTS**

**Review Under Executive Order 12866, Sections 202 and 205 of the Unfunded Mandate Reform Act of 1995 (P.L. 104-4), and by the Regulatory Flexibility Act (5 U.S.C. 603- 605).**

The Department has examined the potential impact of this rule as directed by Executive Order 12866, by sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4), and by the Regulatory Flexibility Act (5 U.S.C. 603-605).

### ***Regulatory Impact Analysis***

Executive Order 12866 directs agencies to assess the costs and benefits of available regulatory alternatives, and, when regulation is necessary, to select regulatory approaches that maximize net benefits. This rule is designed to ensure that select agents are not shipped to parties who are not equipped to handle them appropriately or who otherwise lack proper authorization for their requests. The approach selected decentralizes the oversight process for this purpose, imposes

minimal administrative costs, and prevents possible serious, harmful effects to public safety and health.

The Unfunded Mandates Reform Act of 1995, in sections 202 and 205, requires that agencies prepare several analytic statements for a rule that may result in annual expenditures by State, local and tribal governments, or by the private sector, of \$100 million. Because this final rule would not result in expenditures of this magnitude, such statements are not necessary.

The Regulatory Flexibility Act requires agencies to prepare a regulatory flexibility analysis, describing the impact of the proposed rules on small entities, but permits agency heads to certify that a rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The Secretary hereby has determined that this rule would not have such impact, as it would primarily affect large research institutions.

### ***Review under the Paperwork Reduction Act of 1995***

The final rule contains information collection requirements that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 and assigned control Number 0920-0199. (Persons are not required to respond to a collection of information unless a currently valid OMB control number is evident.) The title, description and respondent description of the information collection are shown below with an estimate of the annual reporting burden. The estimate includes the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

*Title:* Additional Requirements for Facilities Transferring or Receiving Select Agents

*Description:* The Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104- 132) authorizes the Secretary of Health and Human Services (HHS) to regulate the transfer of certain agents harmful to humans. The Centers for Disease Control and Prevention (CDC) is the agency within the Department responsible for promulgating this regulation. This rule is designed to ensure that select agents are not shipped to parties who are not equipped to handle them appropriately, or who otherwise lack proper authorization for their requests, and to implement a system whereby scientists in research institutions may continue transferring and receiving these agents without undue burdens. Respondents include facilities such as those operated by government agencies, universities, research institutions, and commercial entities.

Those facilities requesting select agents listed in the regulation must register with the Secretary of HHS, or with registering entities authorized by the Secretary, as capable and equipped to handle the select agents in accordance with requirements of this regulation.

Once registered, facilities must complete a federally-developed form, CDC Form EA-101, for each transfer of an agent covered by this rule. Information on this form will include the name of the requestor and requesting facility, the name of the transferor and transferring facility, the name of the responsible facility official for the transferor and requestor, the requesting facility's registration number, the transferring facility's registration number, the name of the agent(s) being shipped, the quantities of the agent(s) being transferred (number of containers being transferred and amount per container), and the proposed use of the agent. As a result of the information collection requirements of this regulation, CDC expects that respondents will incur only minimal routine administrative costs, such as those associated with telephone calls, mailing, and facsimile transmission. CDC does not expect that respondents will incur any capital costs, or even significantly increased operating costs.

*Description of Respondents:* Commercial suppliers of these select agents, as well as government agencies, universities, research institutions, and private companies that transfer or obtain these agents, or that wish to work with these agents.

Estimated Annual Reporting Burden					
CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
72.6(a)	1,000	1	1,000	.25	250
72.6(d)	1,000	3	3,000	1.05	3,150
72.6(e)	120	21	2,520	.17	428
72.6(f)	1,000	3	3,000	.11	330
<b>Total</b>					<b>4,158</b>

*Reporting or Disclosures:* The above citations are currently cleared under 30 CFR Part 11 as OMB control Number 0920-0199.

## List of Subjects in 42 CFR Part 72

Biologic, Packaging and containers, Transportation. Incorporation by reference.

Dated:

\_\_\_\_\_  
David Satcher, M.D., Ph.D.  
Director  
Centers for Disease Control and Prevention

Dated:

\_\_\_\_\_  
Donna E. Shalala  
Secretary  
Department of Health and Human Services

For the reasons set out in the preamble, 42 CFR Chapter 1 is amended as set forth below.

## PART 72--Interstate Shipment of Etiologic Agents

1. The authority citation for Part 72 is revised to read as follows:

Authority: 42 U.S.C. 264, 271; 31 U.S.C. 9701; 18 U.S.C. 3559, 3571; 42 U.S.C. 262 note.

2. Sections 72.6 and 72.7 and Appendix A are added to read as follows:

§72.6 Additional requirements for facilities transferring or receiving select agents.

**(a) Registration of facilities.**

(1) Prior to transferring or receiving a select agent listed in Appendix A of this part, a facility shall register with a registering entity authorized by the Secretary (paragraph (c) of this section) or be approved by the Secretary as equipped and capable of handling the covered agent at Biosafety Level (BL) 2, 3, or 4, depending on the agent.

(2) Registration will include:

(i) Sufficient information provided by the responsible facility official indicating that the applicant facility, and its laboratory or laboratories, are equipped and capable of handling the agents at BL 2, 3, or 4, depending upon the agent, and the type of work being performed with the agents;

(ii) Inspection of the applicant facility at the discretion of the Secretary or the registering entity in consultation with the Secretary;

(iii) Issuance by the registering entity of a registration number unique to each facility;

(iv) Collection of a periodic site registration fee by the registering entity or the Secretary. A schedule of fees collected by the Secretary to cover the direct costs (e.g., salaries, equipment, travel) and indirect costs (e.g., rent, telephone service and a proportionate share of management and administration costs) related to administration of this part will be published in the Federal Register and updated annually.

(v) Follow-up inspections of the facility by the registering entity or the Secretary, as appropriate, to ensure the facility continues to meet approved standards and recordkeeping requirements.

(3) Such registration shall remain effective until relinquished by the facility or withdrawn by the Secretary or the registering entity.

(4) The registration may be denied or withdrawn by the registering entity or the Secretary based on:

(i) Evidence that the facility is not or is no longer capable of handling covered agents at the applicable biosafety level;

(ii) Evidence that the facility has handled covered agents in a manner in contravention of the applicable biosafety level requirements;

(iii) Evidence that the facility has or intends to use covered agents in a manner harmful to the

health of humans;

(iv) Evidence that the facility has failed to comply with any provisions of this part or has acted in a manner in contravention of this part; or

(v) Failure to pay any required registration fee.

(5) The requirements for BSL-2, 3, and 4 operations pertaining to this section are contained in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," Third Edition, May 1993 which is hereby incorporated by reference. The Director of the Federal Register has approved under 5 U.S.C. 552(a) and 1 C.F.R. Part 51 the incorporation by reference of the above publication. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington D.C. 20402. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta Georgia, or at the Office of the Federal Register, 800 North Capitol Street N.W., Suite 700, Washington D.C.

(6) Additional specific requirements for handling toxins subject to this part must be met and are found in 29 CFR § 1910.1450, "Occupational Exposure to Hazardous Chemicals in Laboratories."

**(b) Appeals.**

A decision made by the Secretary or a registering entity to deny or withdraw registration of a particular facility may be appealed to the Secretary. An application for appeal must be received by the Secretary no later than 14 days after the appealing party's application for registration was denied or no later than 14 days after the appealing party's registration was withdrawn. The application must clearly identify the issues presented by the appeal and fully explain the appealing party's position with respect to those issues. The Secretary may allow the filing of opposing briefs, informal conferences, or whatever steps the Secretary considers appropriate to fairly resolve the appeal.

**(c) Authorized registering entities.**

(1) The Secretary may authorize a state agency or private entity to register facilities under paragraph (a) of this section, if the Secretary determines that the registering entity's criteria for determining the biosafety standards for facilities handling select agents are consistent with the requirements contained in the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories," Third Edition.

(2) A registering entity shall maintain:

(i) A database of all facilities formerly and currently registered as BL 2, 3, or 4 and capable of working with agents in Appendix A of this part. The database shall include the name and address of the registered facility, the date the facility was registered, the facility's registration number, and the name and phone number of the responsible facility official.

(ii) A copy of each CDC Form EA-101 transmitted by each transferor registered by that registering entity. Such forms shall be made readily accessible to the Secretary and to appropriate federal law enforcement authorities and/or authorized local law

enforcement authorities.

(3) In the event the Secretary authorizes more than one registering entity, or if otherwise necessary, the Secretary may require the establishment of a consolidated database to carry out the provisions of §72.6(c)(2).

**(d) Requests for agents.**

(1) Prior to the transfer of any agent contained in Appendix A of this part, a CDC Form EA-101 must be completed for each transfer sought. As specified in CDC Form EA-101, the information provided must include:

- (i) The name of the requestor and requesting facility;
- (ii) The name of the transferrer and transferring facility;
- (iii) The names of the responsible facility officials for both the transferor and requestor;
- (iv) The requesting facility's registration number;
- (v) The transferring facility's registration number;
- (vi) The name of the agent(s) being shipped;
- (vii) The proposed use of the agent(s); and
- (viii) The quantity (number of containers and amount per container) of the agent(s) being shipped.

(2) The form must be signed by the transferrer and requestor, and the responsible facility officials representing both the transferring and requesting facilities.

(3) A copy of the completed CDC Form EA-101 must be retained by both transferring and requesting facilities for a period of five (5) years after the date of shipment or for five (5) years after the agents are consumed or properly disposed, whichever is longer.

(4) All CDC forms EA-101 must be produced upon request to appropriate federal and authorized local law enforcement authorities, officials authorized by the Secretary, and officials of the registering entity.

**(e) Verification of registration.**

(1) Prior to transferring any agent covered by this part, the transferrer's responsible facility official must verify with the requestor's responsible facility official, and as appropriate, with the registering entity:

- (i) That the requesting facility retains a valid, current registration;
- (ii) That the requestor is an employee of the requesting facility; and
- (iii) That the proposed use of the agent by the requestor is correctly indicated on CDC Form EA-101.

(2) In the event that any party is unable to verify the information required in paragraph (e)(1) of this section, or there is suspicion that the agent may not be used for the requested purpose, then the party shall immediately notify CDC.

**(f) Transfer.**

(1) Upon completion of the CDC Form EA-101 and verification of registration, the transferring facility must comply with the packaging and shipping requirements in

this part or other applicable regulations when transferring the agent.

(2) The requesting facility's responsible official must acknowledge receipt of the agent telephonically or otherwise electronically within 36 hours of receipt and provide a paper copy or facsimile transmission of receipt to the transferee within 3 business days of receipt of the agent.

(3) Upon telephonic acknowledgment of receipt of the agent, the transferor shall provide a completed paper copy or facsimile transmission of CDC Form EA-101 within 24 hours to the registering entity (holding that facility's registration), in accordance with §72.6(c)(2) for filing in a centralized repository.

**(g) Inspections.**

(1) Registering entities or the Secretary may conduct random or for cause inspections of registered facilities to assure compliance with this part. All CDC forms EA-101 and records deemed relevant by inspecting officials must be produced upon request to authorized personnel conducting these inspections. Inspections may also include review of the mechanisms developed by a facility to track intrafacility transfers as well as the facility's agent disposal procedures.

(2) In addition, the Secretary may conduct inspections of registering entities, and/or any consolidated database established in accordance with §72.6(c)(3), to assure compliance with this part.

**(h) Exemptions.**

(1) *Exemptions for certain select agents:* Select agents otherwise covered by this part are exempt from its provisions if:

(i) The agent is part of a clinical specimen intended for diagnostic, reference, or verification purposes. Isolates of covered agents from clinical specimens shall be disposed of in accordance with §72.6(i) after diagnostic, reference, or verification procedures have been completed;

(ii) The agent is a toxin having an LD50 for vertebrates of more than 100 nanograms per kilogram of body weight which is used for legitimate medical purposes or biomedical research or is one of the listed toxins which has been inactivated for use as a vaccine or otherwise detoxified for use in biomedical research procedures; or

(iii) The agent(s) is an exempted strain specified in Appendix A of this part and/or CDC Form EA-101. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents (Appendix A of this part). Individuals seeking additions to the list of exemptions should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future changes to the list of exemptions will be published in the Federal Register for review and comment prior to inclusion on Appendix A of this part.

(2) *Exemption of CLIA certified laboratories:* Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, (42 U.S.C. § 263a) (CLIA), that utilize these select agents for diagnostic, reference, verification, or proficiency testing purposes are exempt from the provisions of 72.6.

(3) *Procedures for facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory:* Facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory must comply with the following provisions. (No additional paperwork on behalf of CLIA laboratories is required by this section.)

(i) Prior to transferring a select agent subject to this part to a CLIA laboratory for diagnostic, reference, verification, or proficiency testing purposes, the *transferrer* must:

(A) Provide the following information on CDC Form EA-101:

- (1) The name of the requestor and requesting facility;
- (2) The name of the transferrer and transferring facility;
- (3) The name of the transferor's responsible facility official;
- (4) The requesting facility's CLIA certification number (which the transferrer must verify as valid and current with the registering entity);
- (5) The transferring facility's registration number;
- (6) The name of the agent(s) being shipped;
- (7) The proposed use of the agent(s); and
- (8) The quantity (number of containers and amount per container) of the agent(s) being shipped.

(B) Verify receipt of the agent with the CLIA laboratory and note such receipt on CDC Form EA-101;

(C) Transmit a copy of the form, signed by the transferrer and the responsible facility official representing the transferring facility, to the registering entity holding the transferring facility's registration; and

(D) Retain a copy of CDC Form EA-101 in accordance with 72.6(d)(3) and §72.6(d)(4).

(ii) Prior to receiving a select agent listed in Appendix A of this part from a CLIA laboratory, the *requestor* must be registered in accordance with 72.6(a) and comply with the following requirements:

(A) Provide the following information on the CDC Form EA-101:

- (1) The name of the requestor and requesting facility;
- (2) The name of the transferrer and transferring facility;
- (3) The name of the requestor's responsible facility official;
- (4) The transferring facility's CLIA certification number;
- (5) The requesting facility's registration number;

- (6) The name of the agent(s) being shipped;
- (7) The proposed use of the agent(s); and
- (8) The quantity (number of containers and amount per container) of the agent(s) being shipped.

(B) Upon receiving the agent, note such receipt on CDC Form EA-101;

(C) Transmit a copy of CDC Form EA-101, signed by the requestor and the responsible facility official representing the requesting facility, to the registering entity holding the requesting facility's registration;

(D) Retain a copy of the CDC Form EA-101 in accordance with 72.6(d)(3) and 72.6(d)(4);

(E) Comply with the disposal requirements of §72.6(i) and all other sections of this part when subsequently transferring the agent.

**(i) Agent disposal.**

(1) Upon termination of the use of the agent, all cultures and stocks of it will be

(i) Securely stored in accordance with prudent laboratory practices,

(ii) Transferred to another registered facility in accordance with this part, or

(iii) Destroyed on-site by autoclaving, incineration, or another recognized sterilization or neutralization process.

(2) When an agent, previously transferred to a facility in accordance with this part, is consumed or destroyed, the responsible facility official must formally notify the registering entity. Formal notification must be noted on CDC Form EA-101 and a copy kept on record by the responsible facility official for a period of five (5) years and is subject to paragraph (g) of this section.

**(j) Definitions.** As used in this section:

*Facility* means any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site that may transfer or receive through any means a select agent subject to this part.

*Registering entity* means an organization or state agency authorized by the Secretary to register facilities as capable of handling select agents at Biosafety Level 2, 3, or 4, depending on the agent, in accordance with the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories."

*Requestor* means any person who receives or seeks to receive through any means a select agent subject to this part from any other person.

*Responsible facility official* means an official authorized to transfer and receive select agents covered by this part on behalf of the transferor's and/or requestor's

facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives an agent at the facility.

*Secretary* means the Secretary of the Department of Health and Human Services or her or his designee.

*Select agent* means a microorganism (virus, bacterium, fungus, rickettsia) or toxin listed in Appendix A of this part. The term also includes:

- (1) Genetically modified microorganisms or genetic elements from organisms on Appendix A of this part, shown to produce or encode for a factor associated with a disease, and
- (2) Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins on Appendix A of this part, or their toxic subunits.

*Single geographic site* means a building or complex of buildings at a single mailing address.

*Transfer* means:

- (1) The conveyance or movement from a point of origination to a point of destination either
  - (i) From one state or territory to another or
  - (ii) Entirely within one contiguous state or territory.
- (2) Intrafacility transfers within a registered facility located at a single geographic site are not covered by the provisions of Section 72.6 (d), (e), and (f) provided that:
  - (i) the intended use of the agent remains consistent with that specified in the most current transfer form and
  - (ii) for each intrafacility transfer, the facility maintains records that include the name and location of the recipient; the amount of agent transferred, and the date transferred. Such records must be maintained for a period of five (5) years after the date of transfer or for five (5) years after the agents are consumed or properly disposed, whichever is longer.

*Transferor* means any person who transfers or seeks to transfer through any means a select agent subject to this part to any other person.

### **§72.7 Penalties.**

Individuals in violation of this part are subject to a fine of no more than \$250,000 or one year in jail, or both. Violations by organizations are subject to a fine of no more than \$500,000 per event. A false, fictitious, or fraudulent statement or representation on the Government forms required in the part for registration of facilities or for transfers of select agents is subject to a fine or imprisonment for not more than five years, or both for an individual; and a fine for an organization.

# Appendix A to Part 72-Select Agents

## Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern Equine Encephalitis virus
3. Ebola viruses
4. Equine Morbillivirus
5. Lassa fever virus
6. Marburg virus
7. Rift Valley fever virus
8. South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
9. Tick-borne encephalitis complex viruses
10. Variola major virus (Smallpox virus)
11. Venezuelan Equine Encephalitis virus
12. Viruses causing hantavirus pulmonary syndrome
13. Yellow fever virus

Exemptions: Vaccine strains of viral agents (Junin Virus strain candid #1, Rift Valley fever virus strain MP-12, Venezuelan Equine encephalitis virus strain TC-83, Yellow fever virus strain 17-D) are exempt.

## Bacteria

1. *Bacillus anthracis*
2. *Brucella abortus*, *B. melitensis*, *B. suis*
3. *Burkholderia (Pseudomonas) mallei*
4. *Burkholderia (Pseudomonas) pseudomallei*
5. *Clostridium botulinum*
6. *Francisella tularensis*
7. *Yersinia pestis*

Exemptions: vaccine strains as described in Title 9 CFR, Part 78.1 are exempt.

## **Rickettsiae**

1. *Coxiella burnetii*
2. *Rickettsia prowazekii*
3. *Rickettsia rickettsii*

## **Fungi**

1. *Coccidioides immitis*

## **Toxins**

1. Abrin
2. Aflatoxins
3. Botulinum toxins
4. *Clostridium perfringens* epsilon toxin
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD50 for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

## **Recombinant organisms/molecules**

1. Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease.
2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Appendix, or their toxic subunits.

## Other restrictions

The deliberate transfer of a drug resistance trait to microorganisms listed in this Appendix that are not known to acquire the trait naturally is prohibited by NIH "Guidelines for Research Involving Recombinant DNA Molecules," if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

## Additional Exemptions

1. Products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. § 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. § 2601 et seq.) are exempt.
2. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents in this Appendix. Individuals seeking an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future exemptions will be published in the Federal Register for review and comment prior to inclusion in this Appendix.

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*Office of Health and Safety, Centers for Disease Control and Prevention,  
1600 Clifton Road N.E., Mail Stop F05 Atlanta, Georgia 30333,  
USA*

*Last Modified: 5/20/97*

<mailto:ohas@cdc.gov>

<http://www.cdc.gov/od/ohs>  
<http://www.cdc.gov/>