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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Docket No. CDC-2011-0007

42 CFR Part 71

RIN 0920-AA37

**Foreign Quarantine; Import Regulations for Infectious
Biological Agents, Infectious Substances, and Vectors**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Final rule.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) is issuing this final rule amending the regulations regarding the importation of infectious biological agents, infectious substances, and vectors. The amendments improve HHS/CDC's ability to prevent the introduction, transmission, or spread of communicable diseases into the United States.

DATES: The final rule is effective [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION: The preamble is organized as follows:

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I. Background

On October 14, 2011, we published a proposed rule in the Federal Register (76 FR 63891) to clarify regulatory definitions, ensure adequate biosafety measures, increase oversight through inspections, to address permit exemptions and transportation requirements, and to describe an appeal process. The proposed rule provided a 60-day public comment period that ended on December 13, 2011.

This final rule contains provisions that apply to a variety of entities including academic institutions and biomedical centers, commercial manufacturing facilities, federal, state, and local laboratories, including clinical and diagnostic laboratories, research facilities, exhibition facilities, and educational facilities.

II. Statutory Authority

This final rule is issued under the authority of Section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264). This provision authorizes the Health and

Human Services (HHS) Secretary to make and enforce such regulations as in her judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions of the United States and from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the HHS Secretary may authorize a variety of public health measures, including inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be sources of dangerous infection to human beings, and other measures.

The Foreign Quarantine regulations (42 CFR Part 71) set forth provisions to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the United States. Part 71, Subpart F (Importations) contains provisions for importation of etiological agents, hosts, and vectors (42 CFR 71.54), requiring persons to obtain a permit issued by the CDC before importing, or distributing after import, any of these materials.

III. Responses to Public Comment

We received nine comments from academic, private and government facilities. The comments are discussed below.

A. Definitions

Commenters requested clarification about whether the definition of "vector" should (1) include an exemption for animals meant for a zoo, (2) address pelts or other objects meant for museum use or (3) limit the definition to the importation of live animals. Prior to entry into the United States and regardless of the purpose for the importation, a permit will continue to be required for any live animal or animal product (e.g., a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws of an animal) unless (1) the animal or animal product is not known to transfer or to be capable of transferring an infectious biological agent to a human or (2) the animal product has been rendered noninfectious. The documentation may include a statement from a treating veterinarian, statement from a medical facility, medical certificate, or in the case of an animal product, documentary evidence, such as a veterinary or taxidermy certificate, describing how the material had been treated to render it noninfectious. Any live animal or animal

product imported for scientific, educational or exhibition purposes (e.g., bats and bat products) will also continue to require a permit, unless accompanied by documentation indicating that the animal or animal product is not known to transfer or to be capable of transferring an infectious biological agent to a human or the product has been rendered noninfectious.

The terms "educational purpose," "exhibition purpose" and "scientific purpose" are defined in 42 CFR 71.1. "Scientific purpose" means "use for scientific research following a defined protocol and other standards for research projects as normally conducted at the university level. The term also includes the use for safety testing, potency testing, and other activities related to the production of medical products." "Educational purpose" means "use in the teaching of a defined educational program at the university level or equivalent." "Exhibition purpose" means "use as a part of a display in a facility comparable to a zoological park or in a trained animal act. The animal display must be open to the general public at routinely scheduled hours on 5 or more days of each week. The trained animal act must be routinely scheduled for multiple performances each week and open to the general

public except for reasonable vacation and retraining periods.”

One commenter urged HHS/CDC to modify the definition section to include a new definition for the term “infectious substance.” The commenter indicated that defining the term “infectious substance” in the context of applicable transportation standards and requirements for dangerous goods and hazardous materials would clarify HHS/CDC's expectations regarding the packaging and shipping of these materials and help applicants to better understand and address these issues. We agree with the commenter and are replacing the definition of “infectious material” with an “infectious substance” definition, which states “any material that is known or reasonably expected to contain an infectious biological agent.” This definition for “infectious substance” is consistent with the definitions found in the Department of Transportation (DOT) regulations set forth at 49 CFR Part 171-180 (“A material known or suspected to contain a pathogen: - a microorganism (including bacteria, viruses, parasites, fungi) or other agent, that can cause disease in humans or animals”) and World Health Organization (WHO) Transport of Infectious Substances Standard (“For the purposes of transport, infectious substances are defined as substances which are

known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals").

A commenter recommended defining the term "biosafety measures," which is used several times in the proposed regulatory language, to help importers prepare for use of these requirements and to assist in agency review of such measures before the issuance of a permit. The commenter recommended that "biosafety measures" be defined as "standard microbiological practices, special practices, safety equipment (primary and personal protective equipment) and laboratory facilities (secondary barriers) as noted in the current edition of *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) and additional safeguards as provided in the NIH Guidelines for recombinant and synthetic DNA if appropriate for the substance or material for which such measures are implemented." We made no changes based on this comment. While the commenter provided excellent references, we believe that citing only these references is limiting since there are other references that provide useful recommendations for safely working with a variety of human

pathogens (i.e., Occupational Safety and Health Administration (OSHA) regulations, World Health Organization guidance, etc.).

B. Infectious Biological Agent

One commenter noted that she was not aware of any medically important fungal agents that are communicable (transmissible from person to person), with the possible exception of dermatophyte agents (*Epidermophyton*, *Microsporum*, and *Trichophyton*). The commenter argued that the hazardous characteristics of dermatophyte agents are not sufficiently severe to merit regulation of these agents through the import permit mechanism. The commenter suggested that the regulatory text be clarified to list the fungal agents that would be regulated. The commenter further reasoned that *Coccidioides* species, *Histoplasma capsulatum*, and *Blastomyces dermatitidis* should no longer require an import permit since they do not cause communicable disease and are not transmissible from person to person. We made no changes based on this comment. Section 71.1 (Scope and definitions) of Title 42, Code of Federal Regulations defines "communicable disease" as "an illness due to a specific infectious agent or its toxic products which arises through transmission of that agent or

its products from an infected person or animal or a reservoir to a susceptible host, either directly, or indirectly through an intermediate animal host, vector, or the inanimate environment." All examples cited by this commenter meet this definition of the term "infectious biological agents" because each of the fungi cited are capable of causing communicable disease.

C. Biosafety

One commenter was interested in knowing specifically how HHS/CDC will "work with" entities to address safety issues. The commenter questioned if this will entail providing additional financing to bring importers into compliance, or is this "offer to work with" the importer a distinctive part of the permit issuance process. HHS/CDC's statement in the preamble to the proposed rule that it was willing to work with an entity whose biosafety measures were found to be inadequate was neither an offer to provide financial assistance nor a distinctive part of the permit issuance process. It was simply a statement that, rather than simply deny a permit, HHS/CDC would be willing to assist an applicant to achieve compliance with the import regulations. If an importer is unable to address the inadequate biosafety measures identified, the importer

would not receive a permit to import the infectious biological agent, infectious substance, or vector requested.

D. Permit Exemptions

Diagnostic Specimens

One commenter proposed to replace the term "diagnostic specimen" with the phrase, "exempt human specimen or exempt animal specimen", consistent with DOT Hazardous Materials Regulations and the International Air Transport Association Dangerous Goods Standards. We made no changes based on this comment since the proposed replacement language limits the specimens to human and animals and does not include environmental samples.

Another commenter stated that the proposed rule leaves too much speculation about what is potentially infectious material. The commenter suggested that a standard which was more closely aligned with the WHO standard for biological materials and infectious substances would provide more clarity. We agree with the commenter and have replaced the definition for "infectious material" with an "infectious substance" definition that closely aligns with definitions found in the DOT regulations and WHO standards.

Even though we did not receive a comment regarding bats, we clarified that these materials should not be exempted since people become infected with germs either through direct or close contact with bats or their droppings. Specifically, bats are known carriers of germs that cause disease in humans, including internal and external parasites, fungi, bacteria, and viruses. The most significant of these germs are Nipah virus and viruses that cause diseases such as Ebola, Marburg Hemorrhagic Fever, Sudden Acute Severe Respiratory Syndrome (SARS), and rabies.

Genomic Material

One commenter requested that the importation and subsequent transfer of positive stranded viral RNA be considered in this Part. The commenter reasoned that if this material could be used to recover an infectious agent, its importation and subsequent transfer would be, for all intents and purposes, identical to the importation and subsequent transfer of an etiological agent. The commenter also reasoned that if the intent was the extraction of the genetic information only, and the recipient had no intention to retrieve the infectious agent from the nucleic acid preparation, then the need for the permit would seem

not to be warranted. We made no changes based on this comment since positive stranded viral rRNA genomic material would meet our proposed definition as a "component of such microorganism or prion that is capable of causing communicable disease in a human." It should be noted that our proposed rule already contains an exemption for genomic materials certified by the importer to be incapable of producing infectious biological agents.

E. Transportation

One commenter argued that the regulations should place the responsibility for compliance with all applicable laws and regulations concerning the packaging and shipment of infectious substances on the shipper since the only thing related to shipping that could be practically mandated for the recipient would be to open the shipment in a manner consistent with the expected hazard and report any spillage/leakage. The commenter stated that the importer could be required to obtain some type of affirmation from the shipper to the effect that the shipment is done in compliance with applicable regulations. We agree with the commenter insofar as the commenter suggests that the shipper comply with all applicable legal requirements relating to the packaging, labeling, and shipment of

infectious substances, such as those found at 49 CFR part 173 and standards issued by the International Civil Aviation Organization (ICAO). We disagree with the commenter, however, insofar as the commenter suggests that the importer should bear no legal responsibility under these regulations for actions taken by the shipper on the importer's behalf. Accordingly, under these regulations the importer, as the initiator of the Import Permit request, must implement measures to ensure that the shipper will package, label, and ship the requested infectious substance, infectious biological agent, or vector in a manner that is safe and in compliance with all applicable legal requirements.

Another commenter suggested that we amend the statement "The importer is in compliance with all applicable laws concerning the packaging and shipment of infectious substance" to include "and regulations" in the statement. The commenter also recommended that guidance be provided on the HHS/CDC website to clarify HHS/CDC's expectations regarding the packaging and shipping of infectious substances. We agreed with the commenter that the statement should be revised to include all laws and regulations. Therefore, we changed the language to read, "The importer takes measures to help ensure that the

shipper complies with all applicable legal requirements concerning the packaging, labeling, and shipment of infectious substances." To clarify HHS/CDC's expectations regarding the packaging and shipping of infectious substances, we have posted guidance regarding our expectations on the HHS/CDC import permit website at: <http://www.cdc.gov/od/eaipp/faq.htm>.

F. Subsequent Transfer

One commenter requested confirmation that an importer may still seek authorization for subsequent transfers of the items within the United States through the initial permit application. We confirm that an importer may still seek authorization for subsequent transfers of items within the United States in the initial permit application.

G. Miscellaneous

Cost

One commenter believed that there would be a significant cost to implement the HHS/CDC inspection program. The commenter stated it should be an institutional responsibility to ensure that an appropriate biosafety plan is in place. The commenter believed if an institution does not have a biosafety office or plan; it

should not have the permit to import items that may pose any kind of risk. We agree that an entity that does not have a biosafety plan should not have a permit to import items that have the potential to pose a risk to public health and safety.

Since 2009, we have refined the HHS/CDC import permit database to include better descriptions of material being imported, the biosafety level of the laboratory where the work will be performed, and the type of work to be conducted (e.g., diagnostic, research). To estimate the number of facilities that would require a biosafety inspection under this Part; we first identified those facilities that had previously applied to import agents which are capable of causing serious or potentially lethal disease in humans via the aerosol route. From that list, we deleted those facilities already receiving periodic biosafety inspections from either HHS/CDC or the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA/APHIS) under the HHS or USDA Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, or 7 CFR Part 131) and concluded that approximately 25 facilities would need to be inspected per year to verify that they have in place the appropriate biosafety measures. Since we already review documents regarding biosafety and

have a staff of fully trained and experienced biosafety inspectors, and based on our review of recent permitting activity, we believe the projected travel costs to perform these inspections will be less than 1% of the current budget for the HHS/CDC's Division of Select Agents and Toxins. We also plan to coordinate these inspections with those we are already conducting under the Federal Select Agent Inspection Program to recognize greater efficiencies.

Internet Site

One commenter suggested that HHS/CDC maintain on its internet site the current permit preparation guidance text so that permit applicants will have ready access to information regarding their responsibilities under the regulations, separate from the regulations themselves. We agree with this commenter and will review our website content on a regular ongoing basis to ensure that the content is consistent with the regulations and easy to find.

Alternatives Considered

In the proposed rule we discussed the alternative approaches we considered in development of this rulemaking in order to reduce burden for clinical/diagnostic

laboratories or small businesses selling manufactured goods.

First, we noted that, from HHS/CDC's Select Agent inspection program, specific biosafety measure implementation issues were identified in 81 of the 316 entities inspected by CDC since 2003. Some of the biosafety measure implementation issues were serious enough to require the suspension of registration or other restrictions on biological work at these facilities. We noted that USDA/APHIS had identified similar biosafety issues. Because of these issues, we proposed to require specific biosafety measures to be implemented by the applicant.

Second, we considered proposing a requirement that applicants develop and maintain a written biosafety plan commensurate with the hazard posed by the infectious biological agent, infectious material, and/or vector to be imported, and the level of risk given the intended use including what elements of the plan are essential to prevent exposures and dramatically reduce the incidence of laboratory acquired infections and protect the public health and the environment. We acknowledged that most, if not all, importers of etiological agents already have such biosafety plans. We based this on our experience with

import permit submissions that address Section G (Receiving Laboratory Capabilities) of the permit application. We specifically sought comment from the public concerning the cost and burden of requiring a formal a written biosafety plan. We did not receive any comments specifically addressing the cost and burden of requiring a formal written biosafety plan.

Finally, we proposed exemptions to allow importers to import certain material that is already approved or authorized by another Federal agency or material that has been determined not to be an infectious biological agent.

IV. Required Regulatory Analyses under Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule is being treated as "not significant" under EO 12866. It clarifies regulatory

definitions, insures adequate biosafety measures, increases oversight through inspections, addresses permit exemptions and transportation requirements, and describes an appeal process when the permit request is denied. Thus, the rule has not been reviewed by the Office of Management and Budget (OMB).

Based on past experience, we estimate that there will be approximately 2,000 applications for both import and distribution permit requests each year and that the average response time to complete the application is 20 minutes. We believe that the burden has been limited to requesting only essential information on the application, verifying information, when required, by telephone, and mailing information to the appropriate parties.

With regard to the new requirement to have biosafety measures in place, our current experience from reviewing the information submitted for the import permit applications addressing Section G (Receiving Laboratory Capabilities) (e.g., detailed description of any required personal protective equipment (PPE)), and laboratory equipment (i.e., biosafety cabinets, autoclaves) that ensures materials are properly handled and contained indicates that the vast majority of importers of etiological agents already have instituted such biosafety

measures. Based on our review of applications received between March 2011 and January 2012, we estimate that 98% (632 out of 644) of the applicants possess written biosafety plans and already follow standard biosafety practices and procedures.

With regard to whether HHS/CDC will inspect an import facility, as noted above, HHS/CDC will use the following specific criteria to determine which entities are to be inspected: (1) facilities that request to perform research with imported agents that would need to be conducted in a biosafety level (BSL) 3, BSL-4, animal biosafety level (ABSL) 3, ABSL-4 or BSL-3 Agriculture laboratory as described in the BMBL (e.g., *Mycobacterium tuberculosis* used in aerosol studies required at BSL-3), and (2) facilities that have not been inspected by either HHS/CDC or USDA/APHIS under the Federal Select Agent Regulations.

Since 2009, we have refined the HHS/CDC import permit database to include better descriptions of material being imported, the biosafety level of the facility where the work would be performed, and the type of work to be conducted (e.g., diagnostic, research). To estimate the number of facilities that would require a biosafety inspection, we first identified those facilities that applied to import agents to use in research, which may

cause serious or potentially lethal disease after inhalation. From that list, we removed those facilities already subject to periodic biosafety inspections under the Federal Select Agent Regulations. We concluded that approximately 25 facilities would need to be inspected per year to verify that they have in place the appropriate biosafety measures. To minimize additional burdens on inspected facilities, we will be contacting those facilities that received a permit in 2012, and would meet the criteria for requiring an inspection, 3 months prior to the expiration of the facility's import permit to initiate the renewal process. We plan to inspect these facilities once in a two year timeframe, assuming that no significant biosafety problems are identified.

We also anticipate that there will be minimal increased cost to HHS/CDC to implement these changes since we already review documents regarding biosafety and have a staff of fully trained and experienced biosafety inspectors. Based on our review of recent permitting activity, we believe the projected travel costs to perform these inspections will be less than 1% of the current budget for the HHS/CDC's Division of Select Agents and Toxins. We also plan to coordinate these inspections with

those we are already conducting under the Federal Select Agent Inspection Program to recognize greater efficiencies.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) (5 U.S.C. 601 et seq.), agencies must consider the impact of regulations on small entities and analyze regulatory options that would minimize a rule's impacts on these entities. Alternatively, the agency head may certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. The U.S. Small Business Administration defines a small business concern as one that is independently owned and operated, is organized for profit, and is not dominant in its field. Depending on the industry, eligibility for classification as a small business is based on the average number of employees for the preceding twelve months or on sales volume averaged over a three-year period. For example, a business is considered small if its annual revenue ranges between \$2.5 to \$21.5 million for services provided or the number of its employees range from 100 to 500 depending on the particular product being provided. Based on this definition, HHS/CDC does not anticipate that these

regulatory changes will have a significant economic impact on a substantial number of small businesses or other small entities. HHS/CDC estimates that only 100 applications out of the approximately 2000 applications that we receive each year will be from small businesses. We received no comments to the proposed rule concerning the cost and burden of the proposed rule on small businesses.

V. Other Administrative Requirements

A. Paperwork Reduction Act of 1995

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), HHS/CDC has determined that the Paperwork Reduction Act does apply to information collection and recordkeeping requirements included in this rule. We note that the information collection and recordkeeping requirements are already approved by OMB under OMB Control Number 0920-0199, expiration 1/31/2014. There are no new information collection or recordkeeping requirements in this rule.

Since 2003, HHS/CDC has denied 2 applications for permits. HHS/CDC proposes to provide applicants with an opportunity for a written appeal in the event that the HHS/CDC denies a request for a permit to import infectious biological agents, infectious substances, or vectors under

this part. Under the proposal, an applicant who wishes to make such an appeal would have 30 calendar days after receiving the denial to submit the appeal in writing to the HHS/CDC Director. The appeal must state the factual basis for the appeal and provide any supporting documentations to justify the appeal (e.g., documents that demonstrate the facility has the appropriate biosafety measures in place for working safely with requested imported material). HHS/CDC would then issue a written response, which would constitute final agency action. HHS/CDC estimates the time to prepare and submit such a request is four hours. We received no comments regarding this process.

B. Executive Order 12988, Civil Justice Reform and Executive Order 13132, Federalism

This rule has been reviewed under Executive Order 12988, Civil Justice Reform, and Executive Order 13132, Federalism. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

C. Plain Language in Government Writing

Pursuant to Presidential Memorandum of June 1, 1998 Plain Language in Government Writing (63 FR 31885), Executive Departments and Agencies are directed to use plain language in all proposed and final rules. HHS/CDC believes it has used plain language in drafting of this final rule. We received no comments from the public to the proposed rule in this regard.

List of Subjects in 42 CFR Part 71

Airports, Animals, Communicable diseases, Harbors, Imports, Pesticides and pests, Public health, Quarantine, Reporting and recordkeeping requirements.

Dated: January 28, 2013 _____

Kathleen Sebelius,

Secretary,

Department of Health and Human
Services.

For the reasons stated in the preamble, the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, amends 42 CFR Part 71 as follows:

PART 71 - FOREIGN QUARANTINE

1. The authority citation for part 71 continues to read as follows:

Authority: Secs. 215 and 311 of Public Health Service (PHS) Act as amended (42 U.S.C. 216, 243); secs. 361-369, PHS Act, as amended (42 U.S.C. 264-272).

2. Revise § 71.54 to read as follows:

§ 71.54 Import regulations for infectious biological agents, infectious substances, and vectors.

(a) The following definitions apply to this section:

Animal. Any member of the animal kingdom except a human including an animal product (e.g., a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws).

Diagnostic specimen. Specimens of human and animal matter (including tissue, blood, body discharges, fluids, excretions or similar material), or environmental samples.

Genomic material. Deoxyribonucleic acid (DNA) or Ribonucleic acid (RNA) comprising the genome or organism's hereditary information, that may be single-stranded or double-stranded, and in a linear, circular, or segmented configuration and may be positive sense (same polarity as mRNA), negative sense, or ambisense (mixture of the two).

Infectious biological agent. A microorganism (including, but not limited to, bacteria (including rickettsiae), viruses, fungi, or protozoa) or prion, whether naturally occurring, bioengineered, or artificial, or a component of such microorganism or prion that is capable of causing communicable disease in a human.

Infectious substance. Any material that is known or reasonably expected to contain an infectious biological agent.

Select agents and toxins. Biological agents and toxins that could pose a severe threat to public health and safety as listed in 42 CFR 73.3 and 73.4.

Vector. Any animals (vertebrate or invertebrate) including arthropods or any noninfectious self-replicating system (e.g., plasmids or other molecular vector) or animal products (e.g., a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws of an animal) that are known to transfer or are capable of transferring an infectious biological agent to a human.

(b) Unless excluded pursuant to paragraph (f) of this section, a person may not import into the United States any infectious biological agent, infectious substance, or vector unless:

(1) It is accompanied by a permit issued by the Centers for Disease Control and Prevention (CDC). The possession of a permit issued by the CDC does not satisfy permitting requirements placed on materials by the U.S. Department of Agriculture that may pose hazards to agriculture or agricultural production in addition to hazards to human health.

(2) The importer is in compliance with all of the permit requirements and conditions that are outlined in the permit issued by the CDC.

(3) The importer has implemented biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector to be imported, and the level of risk given its intended use.

(4) The importer takes measures to help ensure that the shipper complies with all applicable legal requirements concerning the packaging, labeling, and shipment of infectious substances.

(c) If noted as a condition of the issued permit, subsequent transfers of any infectious biological agent, infectious substance or vector within the United States will require an additional permit issued by the CDC.

(d) A permit is valid only for:

(1) The time period and/or term indicated on the permit, and

(2) Only for so long as the permit conditions continue to be met.

(e) A permit can be denied, revoked or suspended if:

(1) The biosafety measures of the permit holder are not commensurate with the hazard posed by the infectious biological agent, infectious substance, or vector, and the level of risk given its intended use; or,

(2) The permit holder fails to comply with all conditions, restrictions, and precautions specified in the permit.

(f) A permit issued under this part is not required for an item if:

(1) It is a biological agent listed in 42 CFR Part 73 as a select agent and its importation has been authorized in accordance with 42 CFR 73.16 or 9 CFR 121.16.

(2) With the exception of bat or nonhuman primate specimens, it is a diagnostic specimen not known by the importer to contain, or suspected by the importer of containing, an infectious biological agent and is accompanied by an importer certification statement confirming that the material is not known to contain or

suspected of containing an infectious biological agent, or has been rendered noninfectious.

(3) With the exception of live bats or bat or nonhuman primate products, it is an animal or animal product being imported for educational, exhibition, or scientific purposes and is accompanied by documentation confirming that the animal or animal product is not known to contain (or suspected of containing) an infectious biological agent or has been rendered noninfectious.

(4) It consists only of nucleic acids that cannot produce infectious forms of any infectious biological agent and the specimen is accompanied by an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent.

(5) It is a product that is cleared, approved, licensed, or otherwise authorized under any of the following laws:

(i) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), or

(ii) Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262), or

(iii) The Virus-Serum-Toxin Act (21 U.S.C. 151-159).

(6) It is an animal or animal product listed in 42 CFR Part 71 and its importation has been authorized in accordance with 42 CFR 71.52, 71.53, or 71.56.

(g) To apply for a permit, an individual must:

(1) Submit a signed, completed CDC Form 0.753 (Application for Permit to Import Biological Agents or Vectors of Human Disease into the United States) to the HHS/CDC Import Permit Program.

(2) Have in place biosafety measures that are commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector to be imported, and the level of risk given its intended use.

(h) Issuance of a permit may be contingent upon an inspection of the importer's facility by the CDC to evaluate whether the importer's biosafety measures (e.g., physical structure and features of the facility, and operational and procedural safeguards) are commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector, and the level of risk given its intended use.

(i) Denial, suspension, or revocation of a permit under this section may be appealed to the CDC Director. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the CDC Director within 30

calendar days of the denial, suspension, or revocation of the permit. HHS/CDC will issue a written response to the appeal, which shall constitute final agency action.

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