

Section	Remove	Add
§ 1.338(i)–1(c)(2)(ii)(B) (Second sentence)	§§ 1.338–11 and 1.338–11T(d)	§ 1.338–11
§ 1.338(i)–1(c)(2)(ii)(B) (Second sentence)	1.197–2T(g)(5)(ii),	
§ 1.338(i)–1(c)(3)(i)	§§ 1.338–11 and 1.338–11T(d)	§ 1.338–11
§ 1.338(i)–1(c)(3)(i)	1.197–2T(g)(5)(ii),	
§ 1.338(i)–1(c)(3)(ii)	§§ 1.338–11 and 1.338–11T(d)	§ 1.338–11
§ 1.338(i)–1(c)(3)(ii)	1.197–2T(g)(5)(ii),	
§ 1.338(i)–1(c)(3)(ii)(B) (First sentence)	§§ 1.338–11 and 1.338–11T(d)	§ 1.338–11
§ 1.338(i)–1(c)(3)(ii)(B) (First sentence)	1.197–2T(g)(5)(ii),	
§ 1.338(i)–1(c)(3)(ii)(B) (Second sentence)	§§ 1.338–11 and 1.338–11T(d)	§ 1.338–11
§ 1.338(i)–1(c)(3)(ii)(B) (Second sentence)	1.197–2T(g)(5)(ii),	
§ 1.1060–1(a)(2)(i)	§§ 1.338–11 and 1.338–11T(d)	§ 1.338–11
§ 1.1060–1(a)(2)(i)	1.197–2T(g)(5)(ii),	
§ 1.1060–1(a)(2)(ii)	§§ 1.338–11 and 1.338–11T(d)	§ 1.338–11
§ 1.1060–1(a)(2)(ii)	1.197–2T(g)(5)(ii),	
§ 1.1060–1(a)(2)(ii)(B)	§§ 1.338–11 and 1.338–11T(d)	§ 1.338–11
§ 1.1060–1(a)(2)(ii)(B)	1.197–2T(g)(5)(ii),	
§ 1.1060–1(a)(2)(iii)	§§ 1.338–11T(d) and 1.338–11T(d)	§ 1.338–11(d)
§ 1.1060–1(a)(2)(iii)	1.197–2T(g)(5)(ii),	
§ 1.1060–1(a)(2)(iii)(B)	§§ 1.338–11 and 1.338–11T(d)	§ 1.338–11
§ 1.1060–1(a)(2)(iii)(B)	1.197–2T(g)(5)(ii),	

PART 602—OMB CONTROL NUMBERS UNDER PAPERWORK REDUCTION ACT

■ **Par. 16.** The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

■ **Par. 17.** In § 602.101, paragraph (b) is amended by removing the entry for § 1.338–11T from the table and adding an entry to the table in numerical order to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * *	* *
1.338–11	1545–1990
* * *	* *

Linda Stiff,

Deputy Commissioner for Services and Enforcement.

Approved: January 9, 2008.

Eric Solomon,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. E8–729 Filed 1–22–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR PART 72

RIN 0920–AA19

Interstate Shipment of Etiologic Agents

AGENCY: Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Final rule.

SUMMARY: HHS is removing Part 72 of Title 42, Code of Federal Regulations, which governs the interstate shipment of etiologic agents, because the U.S. Department of Transportation (DOT) already has in effect a more comprehensive set of regulations applicable to the transport in commerce of infectious substances. DOT harmonizes its transport requirements with international standards adopted by the United Nations (UN) Committee of Experts on the Transport of Dangerous Goods for the classification, packaging, and transport of infectious substances. Rescinding the rule eliminates duplication of the more current DOT regulations that cover intrastate and international, as well as interstate, transport. HHS replaced those sections of Part 72 that deal with select biological agents and toxins with a new set of regulations found in Part 73 of Title 42. Removal of Part 72 alleviates confusion and reduces the regulatory burden with no anticipated adverse impact on public health and safety.

DATES: *Effective Date:* This final rule is effective 30 days after publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Dr. Janet K. Nicholson, National Center for Infectious Diseases/OD, Centers for

Disease Control and Prevention, U.S. Department of Health and Human Services, 1600 Clifton Rd., NE (MS–D10), Atlanta, GA 30333; *telephone:* 404–639–2100; *e-mail* jkn1@cdc.gov.

SUPPLEMENTARY INFORMATION: On January 3, 2007, HHS published a notice of proposed rulemaking (NPRM) to remove Part 72 of Title 42 of the Code of Federal Regulations. The comment period for the proposed rule closed on March 5, 2007. HHS received no comments on the proposed rule.

With minor modification for clarification, this supplementary information is the same as was in the NPRM.

Part 72 (being removed by this final rule) provides minimal requirements for packaging and shipping materials, including diagnostic specimens and biological products, reasonably believed to contain an etiologic agent. It provides more detailed requirements, including labeling, for materials containing certain etiologic agents, with a list of the biological agents and toxins provided. For agents on the list, the rule requires reporting to HHS/CDC damaged packages and packages not received. The rule also requires sending certain agents on the list by registered mail or an equivalent system.

42 CFR 72, as currently promulgated, is out-of-date, and duplicates more current regulations of DOT. Further, the regulation is inconsistent with the procedures of other transport governing bodies, such as the International Civil Aviation Organization (ICAO) and the International Air Transport Association (IATA), for air, and the U.S. Postal Service for ground.

Section 72.6, a major portion of 42 CFR 72 that dealt with transporting select agents, was superseded by the

issuance of an Interim Final Rule for 42 CFR part 73 on December 13, 2002 (67 FR 76886). Part 73 implements provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 for transporting select agents.

The continued existence of the remaining provisions of the out-of-date HHS/CDC regulation is confusing to the packaging and transport communities. The provisions serve no useful purpose that merits their retention. HHS/CDC will remain available for consultation on and response to public-health issues and emergencies, in accordance with its normal duties in the interest of public health and safety.

Transition From HHS to DOT Regulations

DOT has the primary statutory authority to regulate the safe and secure transportation of all hazardous materials, including infectious materials, shipped in intrastate, interstate, and foreign commerce. The etiologic agents covered by 42 CFR part 72 are considered to be hazardous materials, and, in practice, the DOT regulations, 49 CFR 171–180, have superseded 42 CFR part 72 since DOT began including more specific regulations on infectious substances. The earlier versions of the DOT regulations on etiologic agents were based on and virtually identical to the HHS regulations. These regulations have been modified over time, as necessary, to continue to provide protection for persons who handle shipments with as few impediments as possible to quick shipment. In 1990, DOT authorized the term “infectious substance” as synonymous with “etiologic agent.” In 1991, DOT expanded the definition of “etiologic agent” to include agents listed in 42 CFR part 72, plus others that cause or could cause severe, disabling or fatal human disease, thereby including agents such as human immunodeficiency virus that were not on the HHS list. DOT also issued expanded packaging requirements at that same time. In 1994 and 1995, DOT worked with other Federal agencies (including HHS/CDC, the HHS/Food and Drug Administration, the Occupational Safety and Health Administration, and the Environmental Protection Agency) to minimize differences between the DOT regulations and other Federal regulations on regulated medical waste, and to ease compliance and eliminate gaps to assure safety.

United Nations Recommendations and Model Regulations

The United Nations (UN) publishes its Recommendations on the Transport of Dangerous Goods and Model Regulations, here described as the “UN Model Regulations” or “model regulations,” on a biennial basis. The model regulations are developed by the Committee of Experts on the Transport of Dangerous Goods of the UN Economic and Social Council. Although regulations for transporting infectious substances have existed in all of the editions of the UN Model Regulations, those for infectious medical waste were first adopted in December 1996, in the 10th Revised Edition. The purpose of the Model Regulations is to present a basic scheme of provisions that will allow uniform development of national and international regulations that govern the various modes of transport, thereby facilitating worldwide harmonization.

In 1997, the World Health Organization (WHO) published “Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens,” prepared by the Directors of WHO Collaborating Centers for Biosafety and other advisers to provide practical guidance to facilitate compliance with international standards.

HHS/CDC has a WHO Collaborating Center for Biosafety and Training, and has provided consultation to the WHO Secretariat and to the Committee of Experts on infectious-substance issues and the development of the UN Model Regulations.

DOT has also worked with the Committee of Experts, and over time has harmonized the DOT regulations with the UN Model Regulations.

In October 2001, the WHO convened a meeting, which included infectious-disease and biosafety experts, to consider guidance needed for the safe transport of infectious substances, and to identify the infectious substances that need to be subject to transport regulation. The meeting developed a consensus document and presented it to the UN Committee of Experts. Subsequent deliberations resulted in development and publication of revised requirements for transporting of infectious substances in the 13th Revised Edition of the UN Model Regulations in 2004.

These model regulations recommended a new classification scheme of categories A and B, based on risk during transport, instead of risk that occurs primarily in the laboratory. The WHO and the Committee of Experts

assessed the risk of infection by pathogens in the transport setting and, with review by HHS/CDC and other public-health experts and scientists, refined the list of Category A agents of concern. This list is not exhaustive. Category A includes “an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals.” Category B includes “an infectious substance which does not meet the criteria for inclusion in Category A.” Packaging requirements were clarified and simplified for each category.

The “Infectious Substances” portion of the 14th Revised Edition of the UN Model Regulations, adopted in December 2004 and published in 2005, is very similar to the 13th Edition. The new edition adds a definition for “patient specimens”; adds “cultures only” to several microorganisms on the infectious-substances list for Category A; clarifies shipping names and labeling; and clarifies exemptions from regulations.

In September 2005, the WHO Secretariat published “Guidance on Regulations for the Transport of Infectious Agents” (WHO/CDS/CSR/LYO/2005.22) which combined into one document the component parts of the 13th and 14th Revised Editions of the UN Model Regulations.

Harmonization of DOT Regulations With UN/WHO Publications

The DOT Notice of Proposed Rulemaking (NPRM), published on January 22, 2001 (66 FR 6941), for public comment, and the final rule, published on August 14, 2002 (67 FR 53118), which became effective on October 1, 2002, revised definitions and adopted packaging requirements consistent with international standards. The DOT final rule incorporated new classification criteria (WHO Risk Groups 1–4 at that time) for infectious substances, diagnostic specimens, biological products, genetically modified organisms and microorganisms, and medical wastes—consistent with the 12th Revision of the UN Model Regulations of 2001. Among other changes, the final rule revised packaging requirements for toxic and infectious substances consistent with the international performance standards. HHS/CDC and other relevant Federal agencies reviewed the DOT proposals before final publication.

The DOT Notice of Proposed Rulemaking (NPRM), published on May 19, 2005 (70 FR 29170), further harmonized the DOT regulations with

the 13th and 14th Revised Editions of the UN Model Regulations. DOT developed a final rule after consideration of comments received from the public, including the affected commercial, research, public-health, medical, and transport communities, and after discussion with other relevant Federal regulating authorities. The final rule was published on June 2, 2006 (71 FR 32244) and became effective on October 1, 2006.

The DOT final rule is almost entirely consistent with the UN Model Regulations. One non-substantive difference is that the final rule retains the definition of “biological products” that is more consistent with the definition used by HHS/FDA and other Federal agencies.

Specimens With Low Likelihood of Pathogens

The DOT final rule also exempts from regulation human and animal specimens for which there is minimal likelihood that pathogens are present. The UN Model Regulations recommend exemption if the specimen is transported in a package (three components) that will prevent any leakage; is of adequate strength for its capacity, mass, and intended use; and is marked as an exempt specimen. The DOT regulations do not specify any packaging requirement for these specimens with minimal likelihood that pathogens are present.

The requirement for triple packaging for these specimens, however, is included in the requirements issued by other transport-governing organizations. For example, the U.S. Postal Service Domestic Mail Manual (DMM) requires special packaging (not subject to performance requirements it prescribes for infectious substances) for liquid diagnostic specimens that would not meet the current definitions for a Category A or B infectious substance. This packaging is consistent with the packaging recommended in the UN Model Regulations, except that for specimens that do not exceed 50 ml. the second leak-proof container may serve as the shipping container if it has enough strength to withstand ordinary postal processing. The ICAO Technical Instructions (ICAO TI) govern virtually all shipments transported internationally by air, and the majority of U.S. domestic air shipments. Addendum No. 2 to ICAO TI (Doc. 9284), issued on June 30, 2005, includes almost verbatim the language from the UN Model Regulations regarding exempt specimens, except that the UN made recommendations for packaging and the ICAO TI requires the packaging

specifications. IATA does the same in Addendum III, posted on July 5, 2005, to the 46th Edition of IATA Dangerous Goods Regulations. Inclusion of the triple-packaging provision by these organizations covers virtually all shipment in commerce of routine patient specimens and biological products for which there is little likelihood of containing an infectious substance.

Section by Section—Comments on Removal

HHS provides a section-by-section rationale for removing the remaining portions of 42 CFR 72.

Section 72.1 Definitions

Current definitions consistent with UN/WHO recommendations are provided in the DOT rule that applies to intra-state and international as well as interstate transport in commerce.

Section 72.2 Transportation of Diagnostic Specimens, Biological Products, and Other Materials; Minimum Packaging Requirements

Section 72.2 provides that diagnostic specimens and biologic products which the shipper “reasonably believes may contain an etiologic agent” must be “packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.” The detailed DOT packaging requirements for Categories A and B have superseded this very general requirement. The term “infectious substance” has replaced “etiologic agent” in the UN Model Regulations, and in the DOT and other applicable regulations. Those regulations define “infectious substance” as a “material known or reasonably expected to contain a pathogen.”

The DOT regulations define pathogens into two categories. Category A is an “infectious substance in a form that is capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs.” Category B is an infectious substance that does not meet the criteria for Category A. The DOT final rule exempts a “material that has a low probability of containing an infectious substance, or where the concentration of the infectious substance is at a level naturally occurring in the environment so it cannot cause disease when exposure to it occurs.” As stated above, leak-proof packaging of adequate strength is required for these materials by the U.S. Postal Service, ICAO, and IATA. The DOT final rule provides for

classifying and shipping as a Category A or B a biological product “known or reasonably expected” to contain a pathogen that meets the criteria for either category, thereby covering, when transported in commerce, those same substances covered by the original intent of section 72.2.

Further, the HHS rule covered the substances only in transport from one State to another or from one State through another State and back to the State of origin. The DOT regulations cover transport in commerce within State, and in international commerce, as well as from State-to-State.

Section 72.3 Transportation of Materials Containing Certain Etiologic Agents; Minimum Packaging Requirements

This section provided a list of specific agents that cannot be shipped in interstate traffic, unless packaged, labeled, and shipped in accordance with the requirements specified in the section. Neither the list of agents, nor the packaging, labeling, and shipping requirements, have been kept up-to-date, and have now become outdated because of the extensive process undertaken biennially by the UN Committee of Experts on the Transport of Dangerous Goods and the harmonization of the DOT regulations with the resultant UN Model Regulations and the WHO “Guidance on the Transport of Infectious Substances.” The HHS/CDC WHO Collaborating Center for Biosafety was a partner in that effort.

The indicative list included in the preamble of the June 2, 2006, DOT final rule differs from the list in the UN Model Regulations in the 14th Revised Edition in only two instances. The DOT list does not include hepatitis B virus (cultures only), and it includes “and other lyssaviruses” as part of the rabies listing. All microorganisms on the DOT list, and other infectious substances that meet the criteria for Category A, are to be packaged and shipped as Category A infectious substances.

A comprehensive discussion of the new method of categorizing substances as Category A or B for purposes of transportation can be found in the previously referenced DOT final rule entitled “Hazardous Materials: Infectious Substances; Harmonization with the United Nations Recommendations; Final Rule” (71 FR 32244, June 2, 2006). HHS/CDC encourages all interested persons to read the DOT final rule for a more comprehensive understanding of the new method of categorizing and defining a Category A material, and to

review the substances it lists in its preamble that meet the Category A definition. The DOT included this list as a guide (not all-inclusive) of infectious substances the WHO and HHS determined are examples of Category A agents.

In brief, the UN Committee of Experts on the Transport of Dangerous Goods, with the input of HHS/CDC, the WHO Secretariat, and others, developed a classification scheme more suited for the risks inherent in transport as opposed to risks in the laboratory. The previous system of four risk groups, with "4" as the highest risk, was developed primarily to protect workers in the laboratory environment. The new Category A includes an infectious substance transported in a form that is capable of causing permanent disability or life-threatening or fatal disease to otherwise healthy humans or animals when exposure to it occurs. It includes substances previously categorized in Risk Group 4 and some in Risk Groups 2 and 3. Category B includes infectious substances (diagnostic or clinical specimens) that do not meet the criteria for Category A.

HHS also encourages the public to review the current packaging requirements provided in the 2006 DOT final rule cited above, as well as those published in the DOT's final rule entitled "Revisions to Standards for Infectious Substances" published in the **Federal Register** (67 FR 53118, August 14, 2002). The requirements are consistent with the requirements adopted by the UN, and have been refined over time to be more specific than the older HHS requirements, with some liquid-volume changes from those specified in 72.2(a) and (b). Another example of refinement is that the DOT regulations require the outer packaging to release carbon dioxide gas when dry ice (72.2(c)) is used, while maintaining structural integrity of the package.

72.3(d) describes a label that is required on the outer shipping container for etiologic agents transported in interstate traffic. The UN Model Regulations have also described a label that can be recognized for transport of these agents anywhere in the world. With harmonization of the DOT regulations with the international regulations, the label required in this section of the HHS regulation is duplicative, and no longer necessary.

72.3(e) required reporting of damaged packages to HHS. The label mentioned above included the statement: "In case of damage or leakage, notify Director CDC," and a telephone number was provided. Reporting over the years has been sporadic, and has served little

direct purpose. The attention to the importance of preventing leakage and preventing exposure has resulted in the benefit that most carriers have cleanup procedures in place, and most reports are made after the persons involved have followed the company procedures for cleanup. Having procedures in place, such as the U.S. Postal Service has, is preferable to relying on a call to HHS to obtain directions. Moreover, the DOT regulations (at 49 CFR 171.15 and 171.16) require carriers to report transportation incidents that involve infectious substances. Immediate reporting by telephone is required for incidents where fire, breakage, spillage, or suspected contamination occurs that involves the shipment of infectious substances (see 49 CFR 171.15(a) (3)). In addition, a written report is required for any unintentional release of hazardous materials from a packaging during transportation; including those covered under 49 CFR 171.15 (see 49 CFR 171.16(a)). Additional reporting of incidents to HHS is redundant and unnecessary. The DOT regulations permit a carrier to provide telephoned incident reports to HHS instead of DOT. For consistency, we will ask the DOT to consider amending this provision of its regulations after rescission of Part 72.

DOT regulations require packages that contain infectious substances to be labeled to indicate the infectious hazard (see 49 CFR 172.434 for a depiction of the required label). The label currently includes this statement: "In case of damage or leakage immediately notify public health authority. In USA, notify Director—CDC; Atlanta, GA; 1-800-232-0124." We will also ask the DOT to consider revising the INFECTIOUS SUBSTANCE label after rescission of Part 72.

The WHO "Guidance on Regulations for the Transport of Infectious Substances," September 2005, provides specific recommended procedures for spill cleanup. This Guidance is available to the agencies that govern land, vessel, and air shipments. The recommended procedures reflect those contained in the WHO Laboratory Biosafety Manual, Third Edition, 2004. As discussed below, the DOT regulations provide criteria for incident reporting. The HHS regulation requires reporting of "damaged packages" without additional criteria for reporting. Nothing will be lost by withdrawing this requirement for immediate and routine reporting of damaged packages.

Although routine reporting to HHS will not be required by regulation after the effective date of this final rule to remove Part 72, HHS will remain available for consultation on and in

response to public-health issues and emergencies, in accordance with its normal duties in the interest of public health and safety. As part of this support, HHS will maintain the current reporting telephone number on a 7 day/24 hour basis in order to assist DOT with the management of suspected exposures.

HHS/CDC and the HHS/National Institutes of Health revised the manual "Biosafety in Microbiological and Biomedical Laboratories" in 2007. Although Annex B of this 5th Edition is concerned with decontamination and disinfection primarily in the laboratory environment, it could be useful to organizations responsible for transporting packages. Having clean-up procedures in place is the most important element of response to a damaged package. The WHO publishes a "Laboratory Biosafety Manual" that includes a simpler list of procedures for spill clean-up in the section on transport of infectious substances.

72.3(f) Registered mail or an equivalent system. This section lists several agents that are required to be shipped by registered mail or an equivalent system, with required notification of receipt. All but one of these agents (*Histoplasma capsulatum*) is included on the list of select agents and toxins covered by 42 CFR part 73. 42 CFR part 73 establishes more strict requirements for transfer of these agents. The sender and recipient must have a certificate of registration for the agent. A form is submitted to HHS for approval of the transfer. Packaging and shipping must comply with all applicable requirements for Category A agents, including those of the DOT. The recipient must notify the sender and HHS of receipt within 2 business days or of non-receipt within 48 hours after expected time of receipt. As a result of these requirements, the requirement for registered mail for these agents is no longer applicable.

Section 72.4 Notice of Delivery; Failure To Receive

This section required notification of the Director of HHS of non-delivery within five days of expected delivery of the select agents or toxins listed in 72.3(f). As stated above, 42 CFR part 73 provides more strict notification requirements for these agents. Notification is required of non-delivery within 48 hours of expected delivery time; also submission of a form confirming receipt is required within two business days of receipt of a select agent or toxin.

The amendment published on March 18, 2005 (70 FR 13316), which

conformed this section to the new 42 CFR part 73, is no longer necessary, and is removed.

Section 72.5 Requirements; Variations

This section allowed the Director of HHS to approve variations in requirements if protection remains equivalent. No variations have been approved that DOT has not also approved. Removal of the rule eliminates the basis of necessity for the Director of HHS to have such authority.

Section 72.6 Additional Requirements for Facilities Transferring or Receiving Select Agents

This entire section, 72.6(a)–(j), was replaced or amended by publication by HHS in the **Federal Register** of 42 CFR part 73, “Possession, Use, and Transfer of Select Agents and Toxins,” as Interim Final Rules on December 13, 2002 (67 FR 76886), and November 3, 2003 (68 FR 62245), and as a Final Rule on March 18, 2005 (70 CFR 13294), with an effective date of April 18, 2005.

These rulemakings also replaced the list of agents at “Appendix A to Part 72—Select Agents,” as well as the “Exemptions” section following the Appendix.

The amendments published on March 18, 2005 (70 FR 13316), which conformed section 72.6(h) and Appendix A to 42 CFR 73, are no longer needed, and are removed by this final rule.

Section 72.7 Penalties

Penalties were specified for violations of this part, with stronger penalties for violations related to select agents. Similar penalties for violations of provisions of part 73 related to select agents have been specified by revision to 42 CFR part 1003—Civil Money Penalties, Assessments and Exclusions. The DOT regulations provide for penalty for non-compliance, as do ICAO and other entities with instructions or regulations regarding transport of infectious substances.

Authority

The HHS regulation of the interstate transfer of etiologic agents is based on the general authority found in Section 264 of Title 42, United States Code, Regulations to Control Communicable Diseases, in Part G, Quarantine and Inspection. The HHS considers the intrastate, interstate, and international regulations of the DOT and UN Model Regulations for transporting infectious substances to include the majority of the HHS’s etiologic agents covered under its authority.

Regulatory Analysis

Rescinding Part 72 reduces the regulatory burden on affected entities. The DOT Hazardous Materials Transportation regulations and the HHS Select Agent regulations already apply, and shippers are following them. DOT and HHS have completed the required analyses for rules that supersede the rule being removed, and which are already in effect. Eliminating this Federal regulation is beneficial to the regulated community by alleviating confusion and duplication.

HHS does not anticipate the removal to have any impact on other Federal programs involved in transport of materials that are reasonably believed to contain infectious substances, such as the HHS/CDC Import Permit Program; the HHS/CDC Clinical Laboratories Improvement Program; the HHS/CDC Select Agent Program; and various research programs of HHS/NIH and HHS/FDA and other Agencies. Agencies will need to review and update references in their guidance and regulating documents to reflect changes brought about by this final rule.

Paperwork Reduction Act

This final rule does not impose any new information-collection requirements, and does not invoke any issues that make it subject to the Paperwork Reduction Act.

The only impact of removal of 42 CFR part 72 is to reduce burden. It eliminates specification for a second label to be attached to the outer shipping container. This label is no longer needed since it duplicates the label recommended by the UN Model Regulations, and adopted by DOT and other organizations (such as ICAO, IATA, and the U.S. Postal Service) that govern shipments of infectious substances.

Impact of paperwork previously involved with sections that dealt with notice of delivery or failure to receive (72.4) is insignificant because HHS has rarely received such paperwork.

Consequently, the removal of 42 CFR part 72 will eliminate the need for the duplicative labeling requirements and the collection of data associated with the notice of delivery or failure to receive packages. However, the removal of 42 CFR 72 does not eliminate the provisions set forth in Subpart F (Importations) of the Foreign Quarantine Regulations (42 CFR part 71), which contains provisions for importation of etiologic agents, hosts, and vectors (See 42 CFR 71.54). Specifically, this provision requires persons that import or distribute after importation these materials to obtain a permit issued by

the CDC (OMB Control Number 0920–0199).

Executive Order 12866 and Regulatory Flexibility Act

Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Executive Order classifies a “significant regulatory action,” requiring review by the Office of Management and Budget unless OMB waives such review, as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

The economic, interagency, budgetary, legal, and policy implications of this final rule have been examined, and the regulatory action has been deemed to be “a significant regulatory action” under the Executive Order because removal of this regulation will eliminate confusing and potentially contradictory regulatory requirements which should benefit the regulated community.

Regulatory Flexibility Act

The HHS Secretary hereby certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

Executive Order 13132

This final rule does not include any regulation that preempts State, local and Indian tribe requirements, or that has any substantial direct effects on the States, relationship between the

national government and the States, or the distribution of power and responsibilities among the various levels of government.

List of Subjects in 42 CFR Part 72

Biologics, Hazardous materials transportation, Packaging and containers, Penalties, Transportation.

■ For the reasons set forth in the preamble and under the authority of 42 U.S.C. 264, 271; 31 U.S.C. 9701; 18 U.S.C. 3559, 3571, and 42 U.S.C. 262 note, the Department of Health and Human Services amends title 42 (Public Health) of the Code of Federal Regulations by removing part 72 (Interstate Shipment of Etiologic Agents).

PART 72—[REMOVED AND RESERVED]

Dated: August 15, 2007.

Julie Louise Gerberding,
Director, Centers for Disease Control and Prevention.

Dated: October 11, 2007.

Michael O. Leavitt,
Secretary.

[FR Doc. E8–1050 Filed 1–22–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 070213033–7033–01]

RIN 0648–XF14

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Processors Using Pot Gear in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by pot catcher processors in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the A season allowance of the 2008 Pacific cod allowable catch (TAC) specified for pot catcher processors in the BSAI.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), January 20, 2008, though 1200 hrs, A.l.t., June 10, 2008.

FOR FURTHER INFORMATION CONTACT:

Jennifer Hogan, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The A season directed fishing allowance of the 2008 Pacific cod TAC allocated to pot catcher processors in the BSAI is 862 metric tons as established by the 2007 and 2008 final harvest specifications for groundfish in the BSAI (72 FR 9451, March 2, 2007) and revision (72 FR 71802, December 19, 2007). See § 679.20(c)(3)(iii), § 679.20(c)(5), and § 679.20(a)(7)(ii).

In accordance with § 679.20(d)(1)(iii), the Administrator, Alaska Region, NMFS, has determined that the A season allowance of the 2008 Pacific cod TAC allocated to pot catcher processors in the BSAI has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by pot catcher processors in the BSAI.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of Pacific cod by pot catcher processors in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of January 16, 2008.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of

prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: January 16, 2008.

Emily H. Menashes,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 070213033–7033–01]

RIN 0648–XF06

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Greater Than or Equal to 60 Feet (18.3 Meters) Length Overall and Using Pot Gear in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by pot catcher vessels greater than or equal to 60 feet (≥ 18.3 meters (m)) length overall (LOA) in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the A season allowance of the 2008 Pacific cod allowable catch (TAC) specified for pot catcher vessels ≥ 60 feet (18.3 m) LOA in the BSAI.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), January 18, 2008, though 1200 hrs, A.l.t., June 10, 2008.

FOR FURTHER INFORMATION CONTACT: Jennifer Hogan, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The A season allowance of the 2008 Pacific cod TAC allocated to pot catcher