TABLE 7 TO SUBPART PPPPP OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART PPPPP

Citation	Subject	Brief description	Applies to subpart PPPPP
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§ 63.1(c)(6)	Applicability	Becoming an area source	Yes.
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[FR Doc. E6–22283 Filed 12–29–06; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 72

RIN 0920–AA03

Interstate Shipment of Etiologic Agents

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

ACTION: Notice for proposed rulemaking.

SUMMARY: HHS proposes to remove 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 will eliminate 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. HHS anticipates that removal of Part 72 will alleviate confusion and reduce the regulatory burden with no adverse impact on public health and safety.

DATES: Written comments must be received on or before March 5, 2007. Written comments on the proposed information collection requirements should also be submitted on or before March 5, 2007. Comments received after March 5, 2007 will be considered to the extent practicable.

ADDRESSES: You may submit written comments to the following address: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Infectious Diseases/OD, ATTN: Interstate Shipment of Etiologic Agents Comments, 1600 Clifton Road, NE (C12), Atlanta, GA 30333. Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m. at 1600 Clifton Road, NE, Atlanta, GA. Please call Ruenell Massey at 404–639–945 to schedule your visit. Comments also may be viewed at *http://www.cdc.gov/ncidod/agentshipment/index.htm.* You may submit written comments by fax to 404–639–3039, Attention: Dr. Janet Nicholson, or electronically via the Internet at *http://www.regulations.gov.* To download an electronic version of the rule, you may access *http://www.regulations.gov.* You must include the agency name (Centers for Disease Control and Prevention) and Regulatory Information Number (RIN) on all submissions for this rulemaking.

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–C12), Atlanta GA 30333; telephone: 404–639–3945; e-mail *jkn1@cdc.gov.*

SUPPLEMENTARY INFORMATION: Part 72 of Title 42 of the Code of Federal Regulations 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.

The rule, 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 select agents, was superseded by the issuance of an Interim Final Rule for 42 CFR 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.

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 72 are considered to be hazardous materials, and, in practice, the DOT regulations, 49 CFR 171–178, have superseded 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 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.

UN Recommendations and Model Regulations

The UN publishes Recommendations on the Transport of Dangerous Goods and Model Regulations on a biennial basis. The recommendations are developed by the Committee of Experts on the Transport of Dangerous Goods of the UN Economic and Social Council. Model Regulations were first adopted in December 1996, for 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 Recommendations and 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 the 13th Revised Edition of the UN Model Regulations for Transport of Infectious Substances, published in 2004.

These model regulations recommended a new classification scheme of categories A and B, based on risk during transport, instead of 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. 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.

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 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

Another difference relates to the exemption from regulation of 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. The U.S. Postal Service Domestic Mail Manual (DMM) requires special packaging (not subject to performance requirements as for infectious substances) for liquid diagnostic specimens that would not meet the current definitions for a Category A or B infectious substance. The 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. It is likely these requirements will be revised in time to be entirely consistent with the UN Model Regulations. 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 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 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.

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

Section 72.2 provided 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 DOT detailed 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 classification and shipping as Category A or B a biological product ''known or reasonably expected'' to contain a pathogen that meets the criteria for either category, thereby covering the same substances as 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 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 outmoded 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 has been a partner in that effort.

The list included in the June 2, 2006, DOT final rule differs from the list in the UN Model Regulations in the 14th Revision 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 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 persons who are interested in commenting on the rescission of 42 CFR 72 to read the DOT final rule for a more comprehensive understanding of the new method of categorization, and to review the substances in Category A.

In brief, the UN Committee of Experts on the Transport of Dangerous Goods, with 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 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. The DOT final rule provides a list (not all-inclusive) of Category A agents.

HHS encourages the public to review the current packaging requirements provided in the DOT final rule cited above, as well as the DOT 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)(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 (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, DOT will amend 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.'' DOT will 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 and air shipment. 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 required 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 removal of Part 72, HHS 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. 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 are currently revising the manual, Biosafety in Microbiological and Biomedical Laboratories. The section of the 5th Edition that is related to transport of agents is expected to contain general guidelines for the cleanup of infectious substances. This section will 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.

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 73. 42 CFR 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 (Category A for these agents), including those of 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. 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 agents listed in 72.3(f). As stated above, 42 CFR 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 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 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 would be removed by this notice of proposed rulemaking.

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.

Regulatory Analyses

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 will be beneficial to the regulated community by alleviating confusion and duplication.

HHS does not anticipate the proposed 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.

Paperwork Reduction Act

This notice of proposed rulemaking 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 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.

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 proposed rule have been examined, and the regulatory action has been deemed to be ''not a significant regulatory action'' under the Executive Order because removal of this regulation is not likely to result in a rule that may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Regulatory Flexibility Act

HHS does not anticipate that this notice of proposed rule making will have any economic impact on small businesses and other small entities.

Unfunded Mandates

This notice of proposed rulemaking imposes no mandates, and will not result in any expenditure burden, on State, local, or tribal governments.

Executive Order 12988

This notice of proposed rulemaking includes no provisions that would lead to burden on the court system.

Executive Order 13132

This notice of proposed rulemaking does not propose any regulation that would preempt State, local and Indian tribe requirements, or that would have 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.

Environmental Assessment

This notice of proposed rule making is not a major regulatory action, and will not result in any impact on the environment; transport of infectious substances across State lines is comprehensively covered by existing regulations of other Agencies.

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 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 proposes to amend 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: July 21, 2006.

Julie Louise Gerberding,

Director, Centers for Disease Control and Prevention.

Dated: August 21, 2006.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on December 15, 2006.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[I.D. 110206A]

RIN 0648–AU86

Atlantic Highly Migratory Species (HMS); U.S. Atlantic Swordfish Fishery Management Measures

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

ACTION: Notification of public hearings.

SUMMARY: NMFS published a proposed rule on November 28, 2006, to amend regulations governing the U.S. Atlantic swordfish fishery that would provide a reasonable opportunity for U.S. vessels to more fully harvest the domestic U.S. North Atlantic swordfish quota. This notice announces the dates, locations, and times of seven public hearings to obtain public comment on the proposed rule. Comments received at these hearings will assist NMFS in selecting management measures to more fully utilize the International Commission on the Conservation of Atlantic Tunas (ICCAT)-recommended U.S. North Atlantic swordfish quota in recognition of the improved stock status of North Atlantic swordfish. These public hearings will be combined with scoping meetings on potential shark management measures that require an amendment to the Consolidated Atlantic Highly Migratory Species Fishery Management Plan (HMS FMP). Notice of the shark scoping meetings is published today in a separate **Federal Register** document.

DATES: Public hearings will be held in January 2007. For specific dates and times, see **SUPPLEMENTARY INFORMATION**.