DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

[Docket No. CDC–2012–0017]

RIN 0920–AA12

Control of Communicable Diseases: Foreign; Scope and Definitions

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

ACTION: Direct Final Rule and request for comments.

SUMMARY: Through this Direct Final Rule, the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) is updating and reorganizing the Scope and Definitions for foreign quarantine regulations and add a new section to contain definitions for *Importations.* This Direct Final Rule (DFR) will update the scope and definitions to reflect modern terminology and plain language used globally by industry and public health partners. As part of the update, we are updating five existing definitions; adding thirteen new definitions to help clarify existing provisions; creating a new scope and definitions section for *Importations* under a new section by reorganizing existing definitions into this new section; and updating regulations to reflect the language used by the most recent Executive Order regarding quarantinable communicable diseases.

DATES: The direct final rule is effective on February 25, 2013 unless significant adverse comment is received by January 25, 2013. If we receive no significant adverse comments within the specified comment period, we intend to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this DFR ends. If we receive any timely significant adverse comment, we will withdraw this final rule in part or in whole by publication of a document in the **Federal Register** within 30 days after the comment period ends.

ADDRESSES: You may submit comments, identified by ''RIN 0920–AA12'': by any of the following methods:

- *Internet:* Access the Federal e-Rulemaking Portal at *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–03, Atlanta, Georgia 30333, ATTN: Part 71 DFR.

Instructions: All submissions received must include the agency name and docket number or Regulation Identifier Number (RIN) for this rulemaking. All relevant comments will be posted without change to *http://regulations.gov,* including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, please go to *http://www.regulations.gov.* Comments will also be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Standard Time, at 1600 Clifton Road NE., Atlanta, Georgia 30333. Please call ahead to 1–866–694–4867 and ask for a representative in the Division of Global Migration and Quarantine (DGMQ) to schedule your visit. To download an electronic version of the rule, access *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For questions concerning this direct final rule: Ashley A. Marrone, JD, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop E–03, Atlanta, Georgia 30333; telephone 404–498–1600.

SUPPLEMENTARY INFORMATION: HHS/CDC is publishing a direct final rule (DFR) because it does not expect to receive any significant adverse comments and believes that updating scope and definitions to add clarity to the regulations is non-controversial. However, in this **Federal Register,** HHS/CDC is simultaneously publishing a companion notice of proposed rulemaking (NPRM) that proposes identical updates. If HHS/CDC does not receive any significant adverse comments on this DFR within the specified comment period, we will publish a document in the **Federal Register** confirming the effective date of this final rule within 30 days after the comment period on the DFR ends and withdraw the NPRM. If HHS/CDC receives any timely significant adverse comment, we will withdraw the DFR in part or in whole by publication of a document in the **Federal Register** within 30 days after the public comment period ends. If the DFR is withdrawn, we will carefully consider all public comments before proceeding with any subsequent final rule based on the NPRM. A significant adverse comment is one that explains: (1) Why the DFR is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the DFR will be ineffective or unacceptable without a change.

This preamble is organized as follows:

I. Public Participation.

Interested persons are invited to participate in this rulemaking by submitting written views, opinions, recommendations, and data. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you do not wish to be disclosed publicly. Comments are invited on any topic related to this DFR.

II. Authority for These Regulations.

The primary authority supporting this rulemaking is section 361 of the Public Health Service Act (42 U.S.C. 264). Section 361 authorizes the Secretary of HHS to make and enforce regulations as in the Secretary's 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. Regulations that implement federal quarantine authority are currently promulgated in 42 CFR Parts 70 and 71. Part 71 contains regulations to prevent the introduction, transmission, and spread of communicable diseases into the states and possessions of the United States, while Part 70 contains regulations to

prevent the introduction, transmission, or spread of communicable diseases from one state into another. CDC is updating the term ''possession'' to ''territory.'' The U.S. Department of the Interior's Office of Insular Affairs, the lead federal agency on issues involving the territories, no longer uses the term ''possession'' to refer to the insular areas. Therefore, CDC is adopting the predominant term ''territory'' consistent with how other federal agencies use this term. The Secretary has delegated to the Director of the Centers for Disease Control and Prevention the authority for implementing these regulations.

Authority for carrying out most of these functions has been delegated to HHS/CDC's Division of Global Migration and Quarantine (DGMQ). The Secretary's authority to apprehend, examine, detain, and conditionally release individuals is limited to those quarantinable communicable diseases published in an Executive Order of the President. This list currently includes cholera, diphtheria, infectious tuberculosis (TB), plague, smallpox, yellow fever, and viral hemorrhagic fevers, such as Marburg, Ebola, and Crimean-Congo hemorrhagic fever (CCHF), Severe Acute Respiratory Syndrome (SARS), and influenza caused by novel or re-emergent influenza viruses that are causing or have the potential to cause a pandemic (see Executive Order 13295, as amended by Executive Order 13375 on April 1, 2005).

III. Rationale for Direct Final Rule

Through this Direct Final Rule (DFR), HHS/CDC is updating the scope and definitions to part 71 to reflect modern science and current practices. HHS/CDC has chosen to publish a DFR because we view this as a non-controversial action and anticipate no significant adverse comment. This DFR does not create any additional requirements or burden upon the regulated community nor does it alter current HHS/CDC practices.

A significant adverse comment is one that explains: (1) Why the DFR is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the DFR will be ineffective or unacceptable without a change. In determining whether a comment necessitates withdrawal of this DFR, HHS/CDC will consider whether it warrants a substantive response through a notice and comment process. If we receive significant adverse comment on this DFR, we will publish a timely withdrawal in the **Federal Register** informing the public that the amendments in this rule will not take effect. If this DFR is withdrawn, we will carefully consider all public comments before proceeding with any subsequent final rule based on the NPRM which is being published simultaneously in the **Federal Register**.

IV. Updates to 42 CFR 71.1, 71.32(a) and 71.50

Through this DFR, HHS/CDC is updating the Scope and Definitions for 42 CFR Part 71 under section 71.1 and adding a new section 71.50, to reflect modern terminology and plain language commonly used by global private sector industry and public health partners. Specifically, we are updating five existing definitions, adding thirteen new definitions to help clarify existing provisions, and creating a new scope and definitions section within Part 71, under subpart F for Importations, by reorganizing certain existing definitions. In updating the definitions in Part 71, it became evident to us that certain definitions pertain more directly to *Importations* under subpart F than to Part 71 in general; therefore, we decided to reorganize the existing definitions by creating a new section 71.50 for this subpart to better clarify these terms for importers. We are also adding new definitions that have been crafted for section 71.50 to help clarify the intent of certain provisions under subpart F.

Finally, as part of the changes to definitions, we are also updating section 71.32(a) to incorporate the most recent listing of quarantinable communicable diseases under Executive Order 13295, of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005. These changes are not substantive and will not affect current practices.

V. Scope and Definitions for Part 71.1

Section 71.1(a) has been updated to include the current interstate quarantine regulations administered by HHS/CDC found at ''42 CFR part 70'' to the existing cross-reference citing ''21 CFR parts 1240 and 1250.''

On August 16, 2000, the Secretary transferred certain authority for interstate control of communicable disease, including the authority to apprehend, examine, detain, and conditionally release individuals moving from one state into another from HHS/Food and Drug Administration (FDA) to CDC, which became 42 CFR Part 70. As part of this transfer, FDA retained regulatory authority over animals and other products that may transmit or spread communicable disease. These other regulations may be found at 21 CFR parts 1240 and 1250. This rule has no effect upon FDA's regulatory authority. Accordingly, the new scope will read: ''The provisions of this part contain the regulations to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the States or territories (also known as possessions) of the United States. Regulations pertaining to preventing the interstate spread of communicable diseases are contained in 21 CFR parts 1240 and 1250 and *42 CFR part 70.*''

Current section 71.1 (b) *Definitions* contains definitions used in the current CFR. This DFR adds new definitions and updates certain definitions for clarification and to be consistent with current industry and public health principles and practice.

Table 1 list the definitions found in the current 42 CFR part 71, subpart A, and compares them with the updated definitions in this DFR.

TABLE 1—SUBPART A—FOREIGN QUARANTINE DEFINITIONS AND CORRESPONDING CHANGES IN DEFINITIONS IN THE DFR

Existing definitions in 42 CFR 71.1	Corresponding, new or updated definition in DFR
Carrier	No Change. Commander.
Communicable disease	No Change.
Contamination	No Change.
Controlled Free Pratique	No Change.
Deratting Certificate	No Change.
Deratting Exemption Certificate	No Change.
Detention	No Change.
Director	No Change.
Disinfection	No Change.

TABLE 1—SUBPART A—FOREIGN QUARANTINE—Continued
DEFINITIONS AND CORRESPONDING CHANGES IN DEFINITIONS IN THE DFR

Existing definitions in 42 CFR 71.1	Corresponding, new or updated definition in DFR
Disinfestation	No Change.
Disinsection	No Change.
Educational Purpose	Moved to new 71.50.
Exhibition Purpose	Moved to new 71.50.
Ill person	No Change.
International Health Regulations	Updated.
International voyage	No Change.
Isolation	Updated.
Military Services	No Change.
	Quarantine.
	Quarantinable Communicable disease.
	Possession.
Scientific Purpose	Moved to new 71.50.
Surveillance	Updated.
U.S. port	No Change.
	U.S. Territory.
United States	Updated.
Vector	Updated.

A. Definitions Updated Under Section 71.1

International Health Regulations or IHR. This DFR defines International Health Regulations or IHR as the International Health Regulations of the World Health Organization (WHO), adopted by the 58th World Health Assembly in 2005, as may be further amended, and subject to the United States' reservation and understandings. The DFR updates the current CFR's definition to reflect that the 1969 IHR, as amended in 1973 and 1981 by the World Health Assembly, has been superseded by the 2005 IHR currently in place. This definition also reflects that the United States accepted the IHR with the reservation that it will implement them in line with U.S. principles of federalism. In addition, the United States submitted three understandings, setting forth its views that: (1) Incidents that involve the natural, accidental or deliberate release of chemical, biological or radiological materials are notifiable under the IHR; (2) countries that accept the IHR are obligated to report potential public health emergencies that occur outside their borders to the extent possible; and (3) the IHR do not create any separate private right to legal action against the federal government.

Isolation. The DFR defines the term ''isolation'' as the separation of an individual or group of individuals who are reasonably believed to be infected with a quarantinable communicable disease from others who are healthy in such a manner as to prevent the spread of the quarantinable communicable disease. The current definition of ''isolation,'' when applied to an individual or group of individuals, is stated as ''the separation of that person or group of persons from other persons, except the health staff on duty, in such a manner as to prevent the spread of infection.'' Not only does the updated definition help to clarify the distinction between quarantine and isolation, but it removes the current reference to ''health staff on duty'' to which the separation does not apply. HHS/CDC believes that the reference to ''health staff on duty'' is unnecessary and outmoded because, in practice, a patient may have his or her needs attended to by a variety of individuals. The new definition focuses on the measures used to prevent the spread of infection and not on the types of individuals who may attend to the patient. This is not a substantive change from current practice.

Surveillance. Under this DFR, ''surveillance'' is defined as the temporary supervision by a public health official (or designee) of an individual or group, who may have been exposed to a quarantinable communicable disease, to determine the risk of disease spread. We have updated the term ''surveillance'' to more accurately reflect current practice and to clarify that, just as with quarantine and isolation, this public health measure is applicable to individuals and groups of individuals.

United States. We have updated the definition of ''United States'' to mean the 50 States, the District of Columbia, and the territories (also known as possessions) of the United States, including American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands. We have taken this action to better clarify the authority of provisions within Part 71. The current definition includes the Trust Territory of the Pacific Islands, which have not been administered by the United States since 1986.

Vector. We have updated the term ''vector'' to be defined as any animals (vertebrate or invertebrate) including arthropods or any noninfectious self-replicating system (e.g., plasmids or other molecular vector) or animal products that are known to transfer, or are capable of transferring, an infectious biological agent to a human. To provide further clarity, we have defined the term ''animal products'' in subpart F. This revision more adequately reflects modern science and current practice which are focused on protecting public health.

B. Definitions Added to Section 71.1

Commander. Consistent with current industry practice, this DFR defines ''commander'' as the aircrew member with responsibility for the aircraft's operations and navigation.

Quarantine. ''Quarantine'' is defined as the separation of an individual or group of individuals who are reasonably believed to have been exposed to a quarantinable communicable disease, but who are not yet ill, from others who have not been so exposed, in such a manner as to prevent the possible spread of the quarantinable communicable disease. HHS/CDC is separately defining quarantine, isolation, and surveillance, and is using these terms in a manner that is consistent with public health practice. In current practice, quarantine, isolation, and surveillance may apply either to individuals or groups of individuals. Indeed, the current definition of Isolation in 42 CFR 71.1

applies to ''a person or group of persons.'' HHS/CDC is clarifying that quarantine and surveillance are public health practices that may also be applied to groups of individuals. This is not a substantive change, but rather consistent with CDC's current practice.

Quarantinable communicable disease. ''Quarantinable communicable disease'' is defined as any of the communicable diseases listed in an Executive Order, as provided under section 361 of the Public Health Service Act (42 U.S.C. 264). Executive Order 13295, of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005, contains the current revised list of quarantinable communicable diseases, and may be obtained at *http://www.cdc.gov* and *http://www.archives.gov/federal_register.* If this Order is amended, HHS will enforce that amended order immediately and update the appropriate Web site. A new definition for ''quarantinable communicable disease'' is being added to part 71 through this DFR to incorporate the most recent Executive Order. The addition of this new definition will also be reflected in section 71.32(a), *Persons, carriers and things.*

Possession. To best add clarity to part 71 and to align this part with 42 CFR part 70, we have updated the term ''possession'' to mean ''U.S. territory'' and defined U.S. territory to include American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands. Currently, only Puerto Rico and the Virgin Islands are explicitly listed in the definition. Thus, CDC is updating this provision to explicitly list the other U.S. jurisdictions to which this part applies.

U.S. territory. Under this DFR, ''U.S. territory'' means any territory (also known as possessions) of the United States including American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands. The Department of the Interior's Office of Insular Affairs, the federal government's lead agency for U.S. territories, no longer uses the term ''possession'' to refer to these jurisdictions. Consequently, HHS/CDC is adding a new definition for U.S. territory consistent with current federal usage.

VI. Update of Section 71.32(a)

In 2003, in response to the emergence of Severe Acute Respiratory Syndrome (SARS), HHS amended 42 CFR 70.6 and 71.32 to incorporate by reference the Executive Order listing the quarantinable communicable diseases subject to detention, isolation, quarantine, or conditional release, thereby eliminating the administrative delay involved in separately publishing the list of diseases through rulemaking.

Section 71.32(a), *Persons, carriers, and things,* contains the general authority for the Director to take measures to protect public health against ''any of the communicable diseases listed in an Executive Order, as provided under section 361(b) of the Public Health Service Act.'' The current § 71.32(a) lists Executive Order (E.O.) 13295, of April 4, 2003. The subpart states that ''If this Order is amended, HHS will enforce that amended order.''

On April 1, 2005, the existing Executive Order was amended by Executive Order 13375. Therefore, as part of the non-controversial changes in this DFR, we are also updating section 71.32(a) to reflect the most recent Executive Order that lists the ''Quarantinable Communicable Diseases,'' which we have also defined. These changes are not substantive and will not affect current practices.

VII. Scope and Definitions for Section 71.50

This DFR moves certain definitions from section 71.1 to new section 71.50, because these definitions only apply to the regulations found in subpart F, *Importations.* Subpart F, *Importations,* contains the restrictions on importations of nonhuman primates; certain kinds of animals; etiological agents, hosts, and vectors; and dead bodies. The addition of § 71.50 Scope and Definitions is not a substantive change. To clarify the regulations for the reader, the terms used only in subpart A through subpart G are found in § 71.1, while the terms used only in subpart F, have been moved to new § 71.50. We have also separated definitions for quarantine and isolation to reflect current practices as they apply to individuals (§ 71.1) and animals (§ 71.50).

Section 71.50(a) *Scope* under subpart F—*Importations,* clarifies that HHS/CDC also has the statutory authority to prevent the introduction, transmission, and spread of communicable human diseases resulting from importations of various animal hosts, product, vectors, or other etiological agents that pose a threat to human health.

Section 71.50(b) *Definitions* contains updated definitions used in the current CFR. The DFR promulgates new and updated definitions to be consistent with current medical and public health principles and practice.

Table 2 lists the definitions found in the 42 CFR part 71, subpart A, prior to the DFR and the definitions retained in this final rule.

TABLE 2—SUBPART F—*Importations*
DEFINITIONS AND CORRESPONDING CHANGES IN DEFINITIONS IN THE DFR

Existing definitions in 42 CFR 71.1	Corresponding, new and modified definition in DFR § 71.50
	Animal product or Product.
Educational purpose	No Change.
Exhibition purpose	No Change.
	In transit.
	Isolation, when applied to animals.
	Licensed Veterinarian.
	Person.
	Quarantine, when applied to animals.
	Rendered Noninfectious.
Scientific purpose	No Change.
	You or Your.

A. Definitions Added to Section 71.50

Animal Product or Product. We have defined the term ''animal product'' or ''product'' to describe those items that are known to transfer, or are capable of transferring, an infectious biological agent to a human and that are prohibited from entering the United States unless accompanied by a permit

or rendered noninfectious. For the purposes of this DFR, ''animal product'' or ''product'' means the hide, hair, skull, teeth, bones, claws, blood, tissue, or other biological samples from an animal, including trophies, mounts, rugs, or other display items. We have added this definition, which is used in subpart F, to best describe the current prohibition on animal products that are known to transfer, or are capable of transferring, an infectious biological agent to a human and that as a condition of entry into the United States must be accompanied by a permit or rendered noninfectious.

In transit. In this DFR, we have defined ''in transit'' as animals that are located within the United States, including animals whose presence is anticipated, scheduled, or otherwise, as part of the movement of those animals between a foreign country of departure and foreign country of final destination without clearing customs and officially entering the United States. As part of modern global trade and travel practices, animals commonly pass through the United States without being formally admitted into this country. These animals pose a potential risk to U.S. public health where the improper handling of these shipments during exchange of cargo could introduce zoonotic diseases into the United States. We note that the term ''in-transit'' is currently only found in section 71.51 relating to the importation of dogs and cats and we believe it is useful to add clarity to this section by defining what is meant by this term.

Isolation, when applied to animals. To distinguish the concept of isolation for individuals from isolation of animals, we have defined ''isolation'' under this subpart to mean the separation of an ill animal or ill group of animals from individuals, other animals, or vectors of disease in such a manner as to prevent the spread of infection.

Licensed Veterinarian. We have defined ''licensed veterinarian'' to mean an individual who has obtained both an advanced degree and a valid license to practice animal medicine. This new definition best describes the intent of provisions of this subpart.

Person. We have defined ''person'' to mean any individual or partnership, firm, company, corporation, association, organization, or similar legal entity, including those that are not-for-profit. With the exception of 42 C.F.R. section 71.55, which refers to the imported remains of a natural person, this definition is intended to clarify the relevant import prohibitions applicable to individuals and organizations under this subpart.

Quarantine, when applied to animals. We have defined ''quarantine'' as it applies to animals as the practice of separating live animals that are reasonably believed to have been exposed to a communicable disease, but are not yet ill, in a setting where the animal can be observed for evidence of disease, and where measures are in place to prevent transmission of infection to humans or animals. This new definition best clarifies the current public health measure of quarantining animals, and it distinguishes it from public health practice of isolation when applied to animals.

Render Noninfectious. For purposes of this DFR, to ''render noninfectious'' means ''treating an animal product (e.g., by boiling, irradiating, soaking, formalin fixation, or salting) in such a manner that renders the product incapable of transferring an infectious biological agent to a human.''

Acceptable methods of rendering a product noninfectious typically include the following:

(1) Boiling in water to ensure that any matter other than bone, horns, hooves, claws, antlers, or teeth is removed,

(2) Irradiating with gamma irradiation at a dose of at least 20 kilogray at room temperature (20° C or higher),

(3) Soaking, with agitation, in a 4 percent (weight/volume) solution of washing soda (sodium carbonate, Na_2CO_3) maintained at pH 11.5 or above for at least 48 hours,

(4) Soaking, with agitation, in a formic acid solution (100 kg salt [sodium chloride, NaCl] and 12 kg formic acid per 1,000 liters water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added.

(5) In the case of raw hides, salting for at least 28 days with sea salt containing 2 percent washing soda (sodium carbonate, Na_2CO_3).

(6) Formalin fixation.

(7) Another method approved by HHS/CDC.

Through this definition within the DFR, HHS/CDC is better clarifying and explaining existing practices that limit the importation of animal products that are known to transfer, or are capable of transferring, an infectious biological agent to a human. Such products must be accompanied by an HHS/CDC import permit or rendered noninfectious as a condition of entry into the United States. Items that have been rendered noninfectious, as described in this subpart, may be imported without an HHS/CDC permit.

You or *your.* To best identify and assign responsibilities under this subpart, we have defined the terms ''you'' or ''your'' to mean an importer, owner, or an applicant.

VIII. Alternatives Considered

Under Executive Order 13563 agencies are asked to consider all feasible alternatives to current practice and the rulemaking. HHS/CDC notes that the main impact of the DFR is to clarify the current practices and intent of HHS/CDC by updating and defining terms used in the existing 42 CFR Part 71. As explained in Section III. ''Rationale for Updates to 42 CFR 71.1, 71.32(a) and 71.50,'' through this DFR, HHS/CDC is also updating the Scope and Definitions for 42 CFR Part 71 under sections 71.1 and add new section 71.50, to reflect modern terminology and plain language commonly used by global private sector industry and public health partners. By clarifying and explaining the provisions within part 71, HHS/CDC hopes to assist the regulated community in complying with the provisions to best protect public health. HHS/CDC believes that this rulemaking complies with the spirit of the Executive Order; updating definition and clarifying language provides good alternatives to the current regulation.

IX. Required Regulatory Analyses

A. Required Regulatory Analyses under Executive Orders 12866 and 13563

Under Executive Order 12866 (EO 12866), Regulatory Planning and Review (58 FR 51735, October 4, 1993) CDC is required to determine whether this regulatory action would be ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Orders. This order defines ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may:

- 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;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients; or,
- Raise novel legal or policy issues arising out of legal mandates, the

President's priorities, or the principles set forth in EO 12866.

Executive Order 13563 (EO 13563), Improving Regulation and Regulatory Review, (76 FR 3821, January 21, 2011), updates some of the provisions of EO 12866 in order to promote more streamlined regulatory actions. This EO charges, in part, that, while protecting ''public health, welfare, safety, and our environment'' that regulations must also ''promote predictability and reduce uncertainty'' in order to promote economic growth. Further, regulations must be written in common language and be easy to understand. In the spirit of EO 13563, this DFR enhances definitions related to control of communicable diseases and adds more recent medical information where appropriate. CDC has determined that this DFR is an update of definitions and compliant with the spirit of EO 13563. Further, CDC has determined that this DFR is not a significant regulatory action as defined in EO 12866 because the DFR is definitional and does not change the baseline costs for any of the primary stakeholders.

B. Regulatory Flexibility Act

We have examined the impacts of the rule under the Regulatory Flexibility Act (5 U.S.C. 601–612). Unless we certify that the rule is not expected to have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. We certify that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

C. Small Business Regulatory Enforcement Fairness Act of 1996

This regulatory action is not a major rule as defined by Sec. 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

D. The Paperwork Reduction Act of 1995

HHS/CDC has determined that the Paperwork Reduction Act does apply to the date collection and record keeping requirements of 42 CFR Part 71 and has obtained approval by the Office of Management and Budget (OMB) under OMB Control No. 0920–0134, expiration 07/31/2015. The updates in this rule do not impact the data collection and record keeping requirements already approved by OMB.

E. National Environmental Policy Act (NEPA)

Pursuant to 48 FR 9374 (list of HHS/CDC program actions that are categorically excluded from the NEPA environmental review process), HHS/CDC has determined that this action does not qualify for a categorical exclusion. In the absence of an applicable categorical exclusion, the Director, HHS/CDC, has determined that provisions amending 42 CFR Part 71 will not have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

F. Civil Justice Reform (Executive Order 12988)

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

G. Executive Order 13132 (Federalism)

HHS/CDC has reviewed this rule in accordance with Executive Order 13132 regarding Federalism, and has determined that it does not have ''federalism implications.'' The rule does not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

H. Plain Language Act of 2010

Under Public Law 111–274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS/CDC has attempted to use plain language in promulgating this rule consistent with the Federal Plain Writing Act and requests public comment on this effort.

List of Subjects in 42 CFR Part 71

Communicable diseases, Isolation, In transit, Public health, Quarantine, Quarantinable communicable disease, Render noninfectious.

Amended Text

For the reasons discussed in the preamble, the Centers for Disease Control and Prevention 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. Amend § 71.1 as follows:
■ a. Revise paragraph (a).
■ b. In paragraph (b), add in alphabetical order definitions of Commander, Quarantine, Quarantinable communicable disease, and U.S. territory.
■ c. In paragraph (b), revise definitions of International Health Regulations, Isolation, Surveillance, United States, and Vector.

The revisions and additions read as follows:

§ 71.1 Scope and definitions.

* * * * *

(a) The provisions of this part contain the regulations to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the States or territories (also known as possessions) of the United States. Regulations pertaining to preventing the interstate spread of communicable diseases are contained in 21 CFR parts 1240 and 1250 and 42 CFR part 70.

(b) * * *

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Commander means the aircrew member with responsibility for the aircraft's operations and navigation.

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International Health Regulations or *IHR* means the International Health Regulations of the World Health Organization, adopted by the Fifty-Eighth World Health Assembly in 2005, as may be further amended, and subject to the United States' reservation and understandings.

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Isolation means the separation of an individual or group who is reasonably believed to be infected with a quarantinable communicable disease

from those who are healthy to prevent the spread of the quarantinable communicable disease.

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Possession means U.S. territory.

Quarantine means the separation of an individual or group reasonably believed to have been exposed to a quarantinable communicable disease, but who is not yet ill, from others who have not been so exposed, to prevent the possible spread of the quarantinable communicable disease.

Quarantinable communicable disease means any of the communicable diseases listed in an Executive Order, as provided under § 361 of the Public Health Service Act (42 U.S.C. § 264). Executive Order 13295, of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005, contains the current revised list of quarantinable communicable diseases, and may be obtained at *http://www.cdc.gov* and *http://www.archives.gov/federal_register.* If this Order is amended, HHS will enforce that amended order immediately and update that Web site.

Surveillance means the temporary supervision by a public health official (or designee) of an individual or group, who may have been exposed to a quarantinable communicable disease, to determine the risk of disease spread.

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U.S. territory means any territory (also known as possessions) of the United States, including American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands.

United States means the 50 States, District of Columbia, and the territories (also known as possessions) of the United States, including American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands.

Vector means any animals (vertebrate or invertebrate) including arthropods or any noninfectious self-replicating system (e.g., plasmids or other molecular vector) or animal products that are known to transfer, or are capable of transferring, an infectious biological agent to a human.

■ 3. Revise § 71.32(a) to read as follows:

§ 71.32 Persons, carriers, and things.

(a) Whenever the Director has reason to believe that any arriving person is infected with or has been exposed to any of the communicable diseases listed in an Executive Order, as provided under section 361(b) of the Public Health Service Act, he/she may isolate, quarantine, or place the person under surveillance and may order disinfection or disinfestation, fumigation, as he/she considers necessary to prevent the introduction, transmission or spread of the listed communicable diseases. Executive Order 13295, of April 4, 2003, as provided under section 361 of the Public Health Service Act (42 U.S.C. 264), and as amended by Executive Order 13375 of April 1, 2005, contains the current revised list of quarantinable communicable diseases, and may be obtained at *http://www.cdc.gov* and *http://www.archives.gov/federal-register.* If this Order is amended, HHS will enforce that amended order immediately and update this reference.

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■ 4. Add § 71.50 to subpart F to read as follows:

§ 71.50—Scope and definitions.

(a) The purpose of this subpart is to prevent the introduction, transmission, and spread of communicable human disease resulting from importations of various animal hosts or vectors or other etiological agents from foreign countries into the United States.

(b) In addition to terms in § 71.1, the terms below, as used in this subpart, shall have the following meanings:

Animal product or *Product* means the hide, hair, skull, teeth, bones, claws, blood, tissue, or other biological samples from an animal, including trophies, mounts, rugs, or other display items.

Educational purpose means use in the teaching of a defined educational program at the university level or equivalent.

Exhibition purpose means use as 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 schedule for multiple performances each week and open to the general public except for reasonable vacation and retraining periods.

In transit means animals that are located within the United States, whether their presence is anticipated, scheduled, or not, as part of the movement of those animals between a foreign country of departure and foreign country of final destination without clearing customs and officially entering the United States.

Isolation when applied to animals means the separation of an ill animal or ill group of animals from individuals, or other animals, or vectors of disease in such a manner as to prevent the spread of infection.

Licensed veterinarian means an individual who has obtained both an advanced degree and valid license to practice animal medicine.

Person means any individual or partnership, firm, company, corporation, association, organization, or similar legal entity, including those that are not-for-profit.

Quarantine when applied to animals means the practice of separating live animals that are reasonably believed to have been exposed to a communicable disease, but are not yet ill, in a setting where the animal can be observed for evidence of disease, and where measures are in place to prevent transmission of infection to humans or animals.

Render noninfectious means treating an animal product (e.g., by boiling, irradiating, soaking, formalin fixation, or salting) in such a manner that renders the product incapable of transferring an infectious biological agent to a human.

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.

You or *your* means an importer, owner, or an applicant.

Dated: December 13, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2012–0003; Internal Agency Docket No. FEMA–8261]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain