

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 7 CFR Part 331

#### 9 CFR Part 121

[Docket No. APHIS–2007–0033]

RIN 0579–AC53

### Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** In accordance with the Agricultural Bioterrorism Protection Act of 2002, we are proposing to amend and republish the list of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The Act requires the biennial review and republication of the list of select agents and toxins and the revision of the list as necessary. This action would implement the findings of the second biennial review of the list.

**DATES:** We will consider all comments that we receive on or before October 29, 2007.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>, select “Animal and Plant Health Inspection Service” from the agency drop-down menu, then click “Submit.” In the Docket ID column, select APHIS–2007–0033 to submit or view public comments and to view supporting and related materials available electronically. Information on using [Regulations.gov](http://www.regulations.gov), including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site’s “User Tips” link.

- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. APHIS–2007–0033, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2007–0033.

*Reading Room:* You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

*Other Information:* Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

**FOR FURTHER INFORMATION CONTACT:** For information concerning the regulations in 7 CFR part 331, contact Ms. Gwendolyn Burnett, Select Agent Program Compliance Manager, PPQ, APHIS, 4700 River Road Unit 2, Riverdale, MD 20737–1231, (301) 734–5960.

For information concerning the regulations in 9 CFR part 121, contact Dr. Frederick D. Doddy, Veterinary Medical Officer, Animals, Organisms and Vectors, and Select Agents, VS, APHIS, 4700 River Road Unit 2, Riverdale, MD 20737–1231, (301) 734–5960.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 provides for the regulation of certain biological agents and toxins that have the potential to pose a severe threat to both human and animal health, to animal health, to plant health, or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) has the primary responsibility for implementing the provisions of the Act within the Department of Agriculture (USDA). Veterinary Services (VS) select agents and toxins are those that have been determined to have the potential to pose a severe threat to animal health or

animal products. Plant Protection and Quarantine (PPQ) select agents and toxins are those that have been determined to have the potential to pose a severe threat to plant health or plant products. Overlap select agents and toxins are those that have been determined to pose a severe threat to both human and animal health or animal products. Overlap select agents are subject to regulation by both APHIS and the Centers for Disease Control and Prevention (CDC), which has the primary responsibility for implementing the provisions of the Act for the Department of Health and Human Services (HHS).

Subtitle B (which is cited as the “Agricultural Bioterrorism Protection Act of 2002” and referred to below as the Act), section 212(a), provides, in part, that the Secretary of Agriculture (the Secretary) must establish by regulation a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products. Paragraph (a)(2) of section 212 requires the Secretary to review and republish the list every 2 years and to revise the list as necessary. In this document, we are proposing to amend and republish the list of select agents and toxins based on the findings of our second biennial review of the list.

In determining whether to include an agent or toxin in the list, the Act requires that the following criteria be considered:

- The effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products;
- The pathogenicity of the agent or the toxin and the methods by which the agent or toxin is transferred to animals or plants;
- The availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin; and
- Any other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products.

We use the term “select agent and/or toxin” throughout the preamble of this proposed rule. Unless otherwise specified, the term “select agent and/or toxin” will refer to all agents or toxins listed by APHIS. When it is necessary to

specify the type of select agent or toxin, we will use the following terms: “PPQ select agent and/or toxin” (for the plant agents and toxins listed in 7 CFR 331.3), “VS select agent and/or toxin” (for the animal agents and toxins listed in 9 CFR 121.3), or “overlap select agent and/or toxin” (for the agents and toxins listed in both 9 CFR 121.4 and 42 CFR 73.4).

#### PPQ Select Agents and Toxins

APHIS’s Plant Protection and Quarantine (PPQ) program convened an interagency working group to review the list of PPQ select agents and toxins and develop recommendations regarding possible changes to that list. Using the four criteria for listing found in the Act, the working group revisited the currently listed PPQ select agents and toxins and evaluated a number of plant pathogens for inclusion on the list. Based on this review, APHIS is proposing several amendments to the list of PPQ select agents and toxins listed in 7 CFR 331.3.

First, we are proposing to remove *Candidatus Liberobacter asiaticus*, a bacterium causing Huanglongbing or citrus greening disease, from the list. Citrus greening disease has been introduced into the United States and now *C. Liberobacter asiaticus* would have virtually no impact if used as a weapon of terrorism. The bacterium itself is not harmful to humans but the disease has harmed trees in Asia, Africa, the Arabian Peninsula, and Brazil. The Asian strain of the disease, *C. Liberobacter asiaticus*, was found in south Miami-Dade County Florida in early September, 2005. Since that time, this plant pathogen has spread through much of Southern Florida. The disease is primarily spread by the Asian citrus psyllid and the African citrus psyllid as they feed. The Asian citrus psyllid, *Diaphorina citri*, has been present in Florida since 1998. The exact pathway responsible for introducing citrus greening and the Asian citrus psyllid into the United States is still unknown. Once infected, there is no cure for a tree with citrus greening disease. In areas of the world where citrus greening is endemic, citrus trees decline and die within a few years. In order to protect the U.S. citrus industry, there is an urgent need to facilitate timely research on effective means to manage the disease in the United States. For these reasons, we are removing *C. Liberobacter asiaticus* from list of PPQ select agents and toxins.

We are proposing to regulate all pathovars of *Xanthomonas oryzae*. Currently, *Xanthomonas oryzae* pv. *oryzicola* is listed. However, both pathovars (*oryzicola* and *oryzae*)

represent a significant risk to U.S. rice production. By removing the pathovar designation (pv. *oryzicola*) from the currently listed organism, both pathovars would be covered by the regulations. Originally, we included the pathovar designation because scientific reports indicated the presence of *Xanthomonas oryzae* pv. *oryzae* in the United States. However, current scientific information indicates that this pathovar does not occur in the United States. Entities that currently have possession of *Xanthomonas oryzae* pv. *oryzae* would become regulated as a result of this proposed change to the regulations.

We are also proposing to add *Peronosclerospora sacchari* as a synonym of the listed organism *Peronosclerospora philippinensis* because recent scientific research has shown that these two organisms are the same. Entities that currently have possession of *Peronosclerospora sacchari* would become regulated as a result of this proposed amendment to the regulations.

In addition to the proposed changes to the existing list, the following pathogens would be added to the list:

- *Candidatus Liberobacter americanus*. This bacterial species also causes citrus greening disease and has only been reported in Sao Paulo State, Brazil, where it has been detected in 26 municipalities of Sao Paulo State since its discovery in 2004. The citrus greening disease management plan in place for *C. Liberobacter asiaticus* mentioned above is specific to that one pathogen—not all three. *C. Liberobacter africanus*, which is currently listed, and *C. Liberobacter asiaticus* have different biological characteristics than *C. Liberobacter americanus*, and each of the pathogens has a potential to cause different detrimental effects on citrus production in the United States. There have been no reports of this *Liberobacter* species in the United States although the psyllid insect vector (*Diaphorina citri*) has been reported in both Florida and Texas. Polymerase chain reaction (PCR) assays can distinguish this species from *C. Liberobacter africanus* and *C. Liberobacter asiaticus*. While we use the spelling “*Liberobacter*” in the proposed regulations, some sources use the spelling “*Liberibacter*.” APHIS considers both spellings to be identical for regulatory purposes.

- *Phoma glycinicola* (formerly *Pyrenochaeta glycines*). This fungus causes red leaf blotch of soybean and has been described as very aggressive, having resulted in yield losses up to 75 percent in Ethiopia due to defoliation of some soybean cultivars. The fungus

survives in soil for long periods, and the disease may be spread widely through movement of contaminated seed, soil, or other means. This pathogen is not present in the United States, but it has the potential to be a major foliar disease of soybean if introduced.

- *Phytophthora kernoviae*. This fungus-like organism is a newly reported pathogen of forest trees and shrubs and has only been reported in England, Wales, and New Zealand. The extent of host damage and speed with which disease symptoms arose in rhododendron, beech, and oak prompted England’s Department for Environment, Food and Rural Affairs to identify this pathogen as a serious threat to its woodland areas. Nursery stock shipped to the United States from the European Union must be tested for this pathogen. Pathogen spores are easily spread through airborne mist droplets, rain, wind, or movement of contaminated plant material or soil. *P. kernoviae* is considered more virulent or aggressive in rhododendron than is *P. ramorum*, which causes sudden oak death syndrome. This pathogen could be a highly destructive disease in many common trees and shrubs in the United States if introduced.

- *Rathayibacter toxicus*. This bacterium causes gumming disease in ryegrass and is transported into seed heads by species of *Anguina*, a genus of nematodes widely present in the United States. Additionally, if consumed, a neurotoxin produced by this plant pathogen causes illness or death in mammals. Disease management has been expensive and difficult in areas affected by this pathogen, with heavy reliance on use of herbicides on affected grasses.

#### VS Select Agents and Toxins

APHIS’ Veterinary Services (VS) program also convened an interagency working group to review the list of VS select agents and toxins and the list of overlap agents and toxins in 9 CFR part 121 in order to update and revise the lists as necessary.

We are proposing to remove 10 of the 20 overlap select agents and toxins from the list set out in § 121.4(b). Specifically, we would remove the following bacteria: *Botulinum neurotoxin* producing species of *Clostridium*, *Coxiella burnetii*, and *Francisella tularensis*; the fungus *Coccidioides immitis*; Eastern equine encephalitis virus; and the following toxins: *Botulinum neurotoxins*, *Clostridium perfringens* epsilon toxin, shigatoxin, staphylococcal enterotoxin, and T-2 toxin.

The interagency working group considered each of the overlap pathogens with respect to the four criteria for listing found in the Act (as listed above, under “Background”), and based on the group’s analysis, APHIS has determined that the 10 overlap select agents and toxins should be removed from the list because they are naturally found in the United States, do not pose a significant impact to animal health, and are not likely candidates for use in an agroterrorism event directed toward animal health. While any one of these considerations alone would not likely be grounds for removing an agent or toxin from the list, the group concluded that all three considerations mentioned above apply to each of the 10 overlap select agents and toxins identified.

Botulinum neurotoxin producing species of *Clostridium* (i.e., *C. botulinum*, *C. butyricum* and *C. baratii*) are widely distributed in soil, sediments of lakes and ponds, and decaying vegetation. The species may be found in any region of the world and some species may occasionally colonize the intestinal tract of birds and mammals under natural conditions. The neurotoxins produced by these agents produce the infectious toxicosis of botulism. There is a well known and established history of infection and toxicosis in agricultural species associated with *C. botulinum* in the United States, and we have concluded that Botulinum neurotoxin producing species do not pose a serious threat to American agriculture.

*Coccidioides immitis* is found naturally and predominantly in the hot, dry regions of the southwestern United States, where winters are relatively mild and the soil is alkaline. The introduction of *Coccidioides immitis* may result in inapparent infection or Coccidioidomycosis.

Coccidioidomycosis, however, is not a contagious disease, nor is it a disease of major agricultural concern. While infections do occur in agricultural species, they appear to be limited.

*Coxiella burnetii* is a ubiquitous organism that occurs commonly in animal reservoirs that include mammals, birds, and arthropods throughout the United States. Infection in ruminants may result in reproductive failures. Inapparent infection or mild illness does occur, but abortion is the most significant clinical presentation.

Eastern equine encephalitis virus has been recognized as an important veterinary pathogen that infects equines and birds during sporadic outbreaks. Infection results in central nervous system dysfunction and may result in

moderate to high morbidity and mortality. The virus is maintained naturally in nature in marshes and swamps in an enzootic bird-mosquito-bird cycle, and is endemic in the United States along the Atlantic and Gulf coasts. Eastern equine encephalitis virus does not play a major role in agricultural species of concern, and equine species are considered a dead-end host of the virus.

Additionally, the working group concluded that because the following overlap select agents and toxins are naturally found in the United States, do not pose a significant impact to animal health, and are not likely candidates for use in an agroterrorism event directed toward animal health, these select agents and toxins would have a limited socio-economic impact on American agriculture, and thus should be removed from the list: Botulinum neurotoxin producing species of *Clostridium*, *Clostridium perfringens* epsilon toxin, *Francisella tularensis*, staphylococcal enterotoxin, shigatoxin, and T-2 toxin.

These select agents and toxins would still be regulated by the CDC under 42 CFR part 73. However, because these select agents and toxins would no longer be subject to regulation under 9 CFR 121.4, they would no longer be overlap select agents and toxins. CDC has initiated rulemaking to revise its regulations to reclassify these select agents and toxins as HHS select agents and toxins.

To reflect recent changes in scientific nomenclature, we would amend the list of VS select agents and toxins in § 121.3(b) by replacing *Cowdria ruminantium* with *Ehrlichia ruminantium*; replacing *Mycoplasma mycoides mycoides* with *Mycoplasma mycoides* subspecies *mycoides* small colony (*MmmSC*); and replacing *Mycoplasma capricolum*/M. F38/*M. mycoides capri* with *Mycoplasma capricolum* subsp. *capripneumoniae*.

The World Organization for Animal Health (OIE) defines reportable Newcastle disease as an infection of birds caused by an avian paramyxovirus 1 virus possessing certain *in vivo* and/or molecular characteristics. To be consistent with OIE’s guideline for reporting an outbreak of Newcastle disease, we would change how we refer to Newcastle disease in the regulations. Specifically, we would replace references to “Newcastle disease virus (velogenic)” in the list in § 121.3(b) and in the text of §§ 121.3(f)(3)(i), 121.5(a)(3)(i), and 121.9(c)(1) with references to “virulent Newcastle disease virus.” Additionally, we would add a footnote to the entry for virulent Newcastle disease virus in § 121.3(b). In

the footnote we would define a virulent Newcastle disease virus as either having an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater, or as having an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus.

In § 121.4(d)(3), we list five overlap toxins that cannot exceed a specified amount while under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor. However, because we are proposing to remove from the overlap select agent list the five overlap toxins listed in this paragraph—specifically, botulinum neurotoxins, *Clostridium perfringens* epsilon toxin, shigatoxin, staphylococcal enterotoxins, and T-2 toxin—the paragraph would no longer be necessary. Therefore, we would remove § 121.4(d)(3) in its entirety.

Section 121.6 deals with the exemptions for overlap select agents and toxins. Two of the overlap select agents and toxins listed in § 121.6(a)(3)(i) are botulinum neurotoxins and *Francisella tularensis*. To reflect our proposed removal of those two select agents and toxins from our list of overlap select agents and toxins, we would also amend § 121.6 by removing botulinum neurotoxins and *Francisella tularensis* from paragraph (a)(3)(i).

Similarly, botulinum neurotoxins and *Francisella tularensis* are included in § 121.9(c)(1), which sets out the reporting requirements for the identification and final disposition of overlap select agents or toxins contained in a specimen presented for diagnosis or verification. We would amend § 121.9 by removing botulinum neurotoxins and *Francisella tularensis* from paragraph (c)(1).

#### Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Agricultural Bioterrorism Protection Act of 2002, we are proposing to amend and republish the list of select agents and toxins that have the potential to pose a severe threat to both human and animal health, to animal or plant health, or to animal or plant products. The Act requires the biennial review and republication of the list of select agents and toxins and the revision of the list as necessary. This

action would implement the findings of the second biennial review of the list.

Certain pathogens or toxins produced by biological organisms that are released intentionally or accidentally can result in disease, wide-ranging and devastating impacts on the economy, disruption to society, diminished confidence in public and private institutions, and large-scale loss of life. People or livestock can be exposed to these agents from inhalation, through the skin, or by the ingestion of contaminated food, feed, or water. Similarly, crops can be exposed to biological pathogens in several ways—at the seed stage, in the field, or after harvest.

Because of its size and complexity, the U.S. food and agriculture system is vulnerable to deliberate attacks, particularly with foreign diseases that do not now occur domestically. The U.S. livestock industry, with revenues of approximately \$150 billion annually, is vulnerable to a host of highly infectious and often contagious biological agents that have been eradicated from the United States, or have never existed here. Many of these animal-targeted agents could simply be point-introduced into herds. Given the increasing concentration and specialization in the livestock industries, this could cause the immediate halt of movement and export of vast quantities of U.S. livestock and livestock products. Crops, too, are vulnerable. They are grown over very large areas (more than 72 million acres of soybeans were cultivated in the United States in 2003), exacerbating difficulties in surveillance and monitoring.<sup>1</sup>

Preparedness for a biological attack against people, crops or livestock is complicated by the large number of potential agents, the long incubation periods of some agents, and the potential for secondary transmission. All of these factors make it vital to prevent the misuse of biological agents and toxins through registration, biosafety, security and incident response measures.

This preliminary regulatory impact analysis addresses expected economic effects of this rule. Expected benefits and costs are examined in accordance with Executive Order 12866. Expected impacts for small entities are also considered, as required by the Regulatory Flexibility Act.

### Benefits and Costs

This rule would update the select agents and toxins listed in 7 CFR part 331 and 9 CFR part 121. Those parts of the CFR require registration, biosafety, incident response and security measures for the possession, use and transfer of the listed select agents and toxins. These parts are intended to prevent the misuse of those select agents and toxins, and therefore reduce the potential for harm to humans, animals, animal products, plants or plant products in the United States. Should any select agent or toxin be intentionally introduced into the United States, the consequences could be significant. Direct losses in agriculture could occur as a result of the exposure, such as death or debility of affected production animals, or yield loss in plants. Industry could also be affected through the imposition of domestic and foreign quarantines and the resulting loss of markets. The Federal and State governments would also incur costs associated with eradication and quarantine enforcement to prevent further spread, and, in the case of intentional introduction, law enforcement. In addition, there is the potential for a disruption in the domestic food supply, whether through contamination, consumer perception, or both. Past food safety incidents have shown that consumer perceptions (both domestic and international) about the safety of an implicated food product and about the producing country or sector's ability to produce safe food can be slow to recover and can have a lasting influence on food demand and global trade.<sup>2</sup> As such, the benefits associated with the rule are the avoided losses to the animals or plants that could be attacked by these organisms, and their products and markets.

The costs associated with outbreaks can be very high, as is demonstrated by natural outbreaks associated with select agents. For example, it has been estimated that the losses to agriculture and the food chain from a recent foot-and-mouth disease (FMD) outbreak in the United Kingdom, including the costs compensated by the government, amounted to about £3.1 billion (\$4.7 billion). In 1999, it was estimated that the potential impacts of an FMD outbreak in California alone would be between \$8.5 billion and \$13.5 billion.<sup>3</sup>

<sup>2</sup> Buzby, J.C. *Effects of food-safety perceptions on food demand and global trade*. Changing Structure of Global Food Consumption and Trade/WRS-01-1. Economic Research Service/USDA.

<sup>3</sup> Ekboir, J.M. *Potential impact of foot-and-mouth disease in California: the role and contribution of animal health surveillance and monitoring services*. Davis, CA: Agricultural Issues Center, Division of

The above-cited consequences relate to natural or accidental introduction. Deliberate introduction greatly increases the probability of a select agent or toxin becoming established and causing wide-ranging and devastating impacts on the economy, disruption to society, diminished confidence in public and private institutions, and possible loss of life.

Any entity that possesses, uses, or transfers listed select agents or toxins is required to comply with the select agent regulations. These entities include research and diagnostic facilities; Federal, State and university laboratories; and private commercial and non-profit enterprises. The regulations include requirements for registering the possession, use, transfer or destruction of select agents or toxins. In addition, the entity is also required to ensure that the facility where the agent or toxin is housed has adequate biosafety and containment measures; ensure that the physical security of the premises are adequate; ensure that all individuals with access to select agents or toxins have the appropriate education, training, and/or experience to handle such agents or toxins; ensure that all individuals with access to select agents or toxins have an approved security risk assessment; and maintain complete records concerning activities related to the select agents or toxins.

While any entity affected by the changes proposed in this rule may incur costs in complying with the select agent regulations, the proposed changes are expected to have minimal impacts. The proposed changes to the PPQ select agent list include the addition of four pathogens to the list, the removal of an organism from the list, and technical changes to the names of organisms currently listed. These changes should only affect a small number of entities. The plant pest permit database maintained by APHIS indicates that very few entities currently possess any of the agents that would be added to the list. In addition, most of the entities that do possess these agents are already registered due to their possession of other listed agents or toxins. The few entities that would be affected by the removal of organisms from the list would no longer be required to comply with the select agent regulations with regard to those removed organisms.

The proposed changes to the VS select agent list include the removal of agents, the redefinition of an agent, and technical changes to the nomenclature used for some agents in the list to be

Agriculture and Natural Resources, University of California, Davis, 1999.

<sup>1</sup> Making the Nation Safer: The Role of Science and Technology in Countering Terrorism. Committee on Science and Technology for Countering Terrorism, Division on Engineering and Physical Sciences, National Research Council. National Academy Press (2002).

consistent with OIE definitions. The agents that are proposed for removal are overlap agents regulated by both USDA and HHS. HHS would continue to regulate these agents as HHS-only agents. Therefore, any entity in possession of these agents would continue to be subject to select agent regulations as administered by HHS. The redefinition of Newcastle disease virus (velogenic) to virulent Newcastle disease virus may lead to new registrants. It is possible that additional entities may be in possession of a virulent strain of Newcastle disease virus that does not fit the current definition. However, these strains have not circulated in the United States since the 1970s. In addition, entities most likely to be in possession of virulent Newcastle disease virus are already in possession of Newcastle disease virus (velogenic) and therefore already registered.

#### Alternatives Considered

The alternative to this rule would be to leave the regulations unchanged. In this case, the lists of select agents in 7 CFR part 331 and 9 CFR part 121 would remain unchanged. However, APHIS has conducted reviews of these lists and concluded that changes are necessary to ensure that the lists contain those biological agents and toxins that have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. These reviews were conducted in accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which requires a biennial review and republication of the select biological agent and toxin list, with revisions as appropriate. Therefore, this alternative was rejected.

#### Conclusion

This proposed rule would update the PPQ, VS, and overlap select agent and toxin lists. The regulation of select agents and toxins is intended to prevent their misuse and thereby reduce the potential for harm to animals, animal products, plants or plant products in the United States. Should any select agent or toxin be intentionally introduced into the United States, the consequences would be significant. Consequences could include disruption of markets, difficulties in sustaining an adequate food and fiber supply, and the potential spread of disease infestations over large areas. In any animal or plant disease outbreak, the government would incur the costs of eradication or control. Industry would be affected through the imposition of domestic and foreign

quarantines and the resulting loss of markets, and the destruction of infected or exposed animals or plants, or animal products or plant products. Even though compensation may be paid for the destroyed property, repopulating (flocks, herds, fields, etc.) may be time-consuming, with additional losses from idle capital and lost markets. In addition, there is the potential for a disruption in the domestic food supply, whether through contamination, consumer perception, or both. Such a disruption can have a lasting influence on food demand and global trade.

Entities most likely to be affected by this rule are laboratories and other institutions conducting research and related activities that involve the use of the newly added select agents and toxins. The impact of these changes is expected to be minimal, however. Indications are that very few entities currently possess any of the agents or toxins that would be added to the list of select agents and toxins. Entities that would be affected by the removal of agents or toxins from the list would no longer be required to comply with the regulations with regard to those removed agents or toxins. Other changes proposed would not affect what agents or toxins are listed but rather the nomenclature by which those agents and toxins are identified, and therefore would have no economic impact.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

#### Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

#### Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (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.

#### Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### List of Subjects

##### 7 CFR Part 331

Agricultural research, Laboratories, Plant diseases and pests, Reporting and recordkeeping requirements.

##### 9 CFR Part 121

Agricultural research, Animal diseases, Laboratories, Medical research, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 7 CFR part 331 and 9 CFR part 121 as follows:

#### TITLE 7—[AMENDED]

#### PART 331—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

1. The authority citation for part 331 continues to read as follows:

**Authority:** 7 U.S.C. 8401; 7 U.S.C. 2.22, 2.80, and 371.3.

2. In § 331.3, paragraph (b) is revised to read as follows:

##### § 331.3 PPQ select agents and toxins

\* \* \* \* \*

(b) PPQ select agents and toxins:

*Candidatus* *Liberobacter africanus*  
(*Candidatus* *Liberibacter africanus*);  
*Candidatus* *Liberobacter americanus*  
(*Candidatus* *Liberibacter americanus*);  
*Peronosclerospora philippinensis*  
(*Peronosclerospora sacchari*);  
*Phoma glycinicola* (formerly  
*Pyrenochaeta glycines*);  
*Phytophthora kernoviae*;  
*Ralstonia solanacearum*, race 3,  
biovar 2;  
*Rathayibacter toxicus*;  
*Sclerophthora rayssiae* var. *zeae*;  
*Synchytrium endobioticum*;  
*Xanthomonas oryzae*;  
*Xylella fastidiosa* (citrus variegated  
chlorosis strain).

\* \* \* \* \*

#### TITLE 9—[AMENDED]

#### PART 121—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

3. The authority citation for part 121 continues to read as follows:

**Authority:** 7 U.S.C. 8401; 7 U.S.C. 2.22, 2.80, and 371.4.

4. In § 121.3, footnotes 1 and 2 are redesignated as footnotes 2 and 3, respectively, and paragraph (b) is revised to read as follows:

**§ 121.3 VS select agents and toxins**

\* \* \* \* \*

(b) VS select agents and toxins:  
 African horse sickness virus;  
 African swine fever virus;  
 Akabane virus;  
 Avian influenza virus (highly pathogenic);  
 Bluetongue virus (exotic);  
 Bovine spongiform encephalopathy agent;  
 Camel pox virus;  
 Classical swine fever virus;  
*Ehrlichia ruminantium* (Heartwater);  
 Foot-and-mouth disease virus;  
 Goat pox virus;  
 Japanese encephalitis virus;  
 Lumpy skin disease virus;  
 Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1);  
 Menangle virus;  
*Mycoplasma capricolum* subspecies *capripneumoniae* (contagious caprine pleuropneumonia);  
*Mycoplasma mycoides* subspecies *mycoides* small colony (*MmmSC*) (contagious bovine pleuropneumonia);  
 Peste des petits ruminants virus;  
 Rinderpest virus; Sheep pox virus;  
 Swine vesicular disease virus;  
 Vesicular stomatitis virus (exotic).  
 Virulent Newcastle disease virus<sup>4</sup>

\* \* \* \* \*

5. Section 121.4 is amended as follows:  
 a. By revising paragraph (b) to read as set forth below.  
 b. In paragraphs (c) and (d), by redesignating footnotes 3 and 4 as footnotes 4 and 5, respectively.  
 c. By removing paragraph(d)(3).  
 d. In paragraph (f)(3)(i), by removing the words “*Botulinum neurotoxins*,” and “*Francisella tularensis*,”

**§ 121.4 Overlap select agents and toxins.**

\* \* \* \* \*

(b) Overlap select agents and toxins:  
*Bacillus anthracis*;  
*Brucella abortus*;  
*Brucella melitensis*;  
*Brucella suis*;  
*Burkholderia mallei*;  
*Burkholderia pseudomallei*;  
 Hendra virus;  
 Nipah virus;  
 Rift Valley fever virus;  
 Venezuelan equine encephalitis virus.

\* \* \* \* \*

**§ 121.5 [Amended]**

6. In § 121.5, paragraph (a)(3)(i) is amended by removing the words

<sup>4</sup> A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or having an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus.

“Newcastle disease virus (velogenic)” and adding the words “virulent Newcastle disease virus” in their place.

**§ 121.6 [Amended]**

7. Section 121.6, paragraph (a)(3)(i) is amended by removing the words “*Botulinum neurotoxins*,” and “*Francisella tularensis*,”

**§§ 121.7 and 121.8 [Amended]**

8. Sections 121.7 and 121.8 are amended by redesignating footnotes 5, 6, and 7 as footnotes 6, 7, and 8, respectively.

**§ 121.9 [Amended]**

9. In § 121.9, paragraph (c)(1) is amended by removing the words “*Botulinum neurotoxins*,” and “*Francisella tularensis*,” and by removing the words “Newcastle disease virus (velogenic)” and adding the words “virulent Newcastle disease virus” in their place.

**§§ 121.12 through 121.16 [Amended]**

10. Sections 121.12 through 121.16 are amended by redesignating footnotes 8 through 13 as footnotes 9 through 14, respectively.

**§ 121.20 [Amended]**

11. Section 121.20 is amended by redesignating footnote 14 as footnote 15.

Done in Washington, DC, this 22nd day of August 2007.

**Elizabeth E. Gaston,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. E7-17039 Filed 8-27-07; 8:45 am]

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**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2007-28053; Directorate Identifier 2007-NE-18-AD]

RIN 2120-AA64

**Airworthiness Directives; Turbomeca Arrius 2F Turboshift Engines**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) provided by the aviation authority of France to identify and correct an unsafe condition on Turbomeca Arrius 2F

turboshaft engines. The MCAI states the following:

This AD is issued following a case of non-commanded in-flight engine shutdown which occurred on an Arrius 2F turboshaft engine, following the seizing of the gas generator. The result may be an emergency autorotation landing, or, at worst, an accident.

Investigations of this event have revealed that the seizing of the gas generator was caused by the fracture of the separator cage of the gas generator front bearing, due to high-cycle fatigue cracks initiated in the lubrication slots of the separator cage.

We are proposing this AD to prevent uncommanded shutdown of the engine, which could lead to an accident.

**DATES:** We must receive comments on this proposed AD by September 27, 2007.

**ADDRESSES:** You may send comments by any of the following methods:

- **DOT Docket Web Site:** Go to <http://dms.dot.gov> and follow the instructions for sending your comments electronically.

- **Mail:** U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

- **Hand Delivery:** Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- **Fax:** (202) 493-2251.

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

**Examining the AD Docket**

You may examine the AD docket on the Internet at <http://dms.dot.gov>; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:****Comments Invited**

We invite you to send any written relevant data, views, or arguments about