

# Rules and Regulations

Federal Register

Vol. 73, No. 201

Thursday, October 16, 2008

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## 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:** Final rule.

**SUMMARY:** In accordance with the Agricultural Bioterrorism Protection Act of 2002, we are amending and republishing 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 implements the findings of the second biennial review of the list.

**DATES:** *Effective Date:* November 17, 2008.

**FOR FURTHER INFORMATION CONTACT:** For information concerning the regulations in 7 CFR part 331, contact Ms. Cassie Armiger, Program Analyst, Select Agent Program, 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, Staff Veterinarian, Animals, Organisms and Vectors, and Select Agents, NCIE, VS, APHIS, 4700 River Road Unit 39, 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). 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. 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. Overlap select agents and toxins—*i.e.*, those determined to have the potential to pose a severe threat to public health and to animal health or animal products—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 determining whether to include an agent or toxin on 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 prophylaxes 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.

On August 28, 2007, in accordance with the Act, we published in the **Federal Register** (72 FR 49231–49236, Docket No. APHIS–2007–0033) a proposal<sup>1</sup> 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.

We solicited comments concerning our proposal for 60 days ending October 29, 2007. We received 41 comments by that date. On November 16, 2007, we published a notice in the **Federal Register** (72 FR 64540) to reopen the comment period for an additional 15 days to allow interested persons additional time to prepare and submit comments. We received an additional 21 comments by the December 3, 2007, close of the reopened comment period, for a total of 62 comments. The comments we received on the proposed rule were from academic institutions, professional associations, corporations, nonprofit organizations, individuals, and representatives of State and Federal Government agencies. The comments are discussed below.

### PPQ Select Agents and Toxins

The list of PPQ select agents and toxins in 7 CFR 331.3 has included entries for *Candidatus Liberobacter asiaticus* and *Candidatus Liberobacter africanus*. In our proposed rule, we proposed to add *Candidatus Liberobacter americanus* to the list and to remove the entry for *Candidatus Liberobacter asiaticus*.

Many commenters supported the proposed delisting of *Candidatus Liberobacter asiaticus*, but opposed the proposed listing of *Candidatus Liberobacter americanus*, arguing that the presence of citrus greening disease in Florida makes both plant pathogens unlikely agents of bioterrorism. A

<sup>1</sup> To view the proposed rule and the comments we received, go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0033>.

majority of those commenters also recommended that that *Candidatus Liberobacter africanus* should also be removed from the list of PPQ select agents and toxins for that same reason. Those commenters pointed out that in the field there are no apparent differences in the biology of the three plant pathogens and that there are few, if any, established polymerase chain reaction primers available to distinguish among them. Only one commenter supported the proposed listing of *Candidatus Liberobacter americanus* based on the assertion that it is more readily transmittable than *Candidatus Liberobacter asiaticus*; however, we are unaware of any evidence to support that specific assertion.

In response to the points raised by these commenters, we have reevaluated the available science. We agree with the commenters that it is difficult to distinguish between the three plant pathogens. In fact, in the Citrus Health Response Program developed by APHIS and Florida regulatory officials in consultation with the Florida citrus industry and other stakeholders, the management responses for the three bacterial species are identical. Further, we agree that the presence of citrus greening disease in Florida makes them unlikely agents of bioterrorism, as does the long latency period of the disease. Therefore, in this final rule, in addition to delisting *Candidatus Liberobacter asiaticus* as proposed, we are also removing *Candidatus Liberobacter africanus* from the list of PPQ select agent and toxins and have decided not to list *Candidatus Liberobacter americanus* as we had originally proposed.

The list of PPQ select agents and toxins has included an entry for *Xanthomonas oryzae* pv. *oryzicola*. In our proposed rule, we proposed to remove the pathovar designation (pv. *oryzicola*) from the currently listed organism and thus regulate both pathovars of *Xanthomonas oryzae* (i.e., both *oryzicola* and *oryzae*).

Several commenters argued that the proposed removal of the pathovar designation from *Xanthomonas oryzae* pv. *oryzicola* is unnecessary because the exposure of *Xanthomonas oryzae* pv. *oryzae* in the United States carries low risk for significant and ongoing damage, and effective management practices and treatments make establishment unlikely. Most of these commenters also recommended that we remove both pathovars from our list.

We agree that there are effective response and recovery plans in development for treatment and management of these pathovars

(*oryzicola* and *oryzae*). However, we do not believe that this alone is a sufficient reason to remove these agents from the list of select agents and toxins at this time. Both pathovars represent a significant risk to U.S. rice production. Until we obtain more scientific information to allow us to better evaluate the potential consequences of removing the pathovars from the list of select agents and toxins, and until we have identified an effective test that can quickly and conclusively distinguish between the pathovars, we intend to regulate all pathovars of *Xanthomonas oryzae* as proposed. As more information becomes available, we will be in a better position to reevaluate the commenters' recommendations.

The list of PPQ select agents and toxins has included an entry for *Peronosclerospora philippinensis*. We proposed to add *Peronosclerospora sacchari* as a synonym of that organism because recent scientific research has shown that these two organisms are the same.

One commenter did not agree with our proposed addition of *Peronosclerospora sacchari* as a synonym and cited evidence that *Peronosclerospora philippinensis* and *Peronosclerospora sacchari* may have differing host ranges to support his position.

The evidence cited by the commenter is not sufficient to convince us that we should not add *Peronosclerospora sacchari* as a synonym of *Peronosclerospora philippinensis*. While we do not believe there is currently sufficient science to confirm the potential speciation pointed to by the commenter, we are open to reconsidering the issue as new data are published.

We proposed to add *Phoma glycinicola* (formerly *Pyrenochaeta glycinis*), which causes red leaf blotch of soybean, to the list of PPQ select agents and toxins.

One commenter was opposed to listing *Phoma glycinicola* as a select agent. The commenter stated that the pathogen is not conducive to widespread movement, effective chemical treatments are available, and the advanced knowledge of plant pathology required to isolate the pathogen makes it unsuitable as a potential weapon of terrorism. However, much of the evidence cited by the commenter was anecdotal and did not provide an adequate basis for not including this aggressive fungus, which is not currently present in the United States, on the list of PPQ select agents and toxins. Therefore, we are adding *Phoma glycinicola* to the list of PPQ

select agents and toxins as proposed. We will review this listing in the future and would consider removing this pathogen from the list of PPQ select agents and toxins should new scientific information become available to support such an action.

We proposed to add *Phytophthora kernoviae* to the list of PPQ select agents and toxins based, in part, on our identification of this pathogen as a serious threat to the nursery industry and woodland areas.

One commenter argued that *Phytophthora kernoviae* should not be listed as a select agent based on evidence that it is primarily a forest pathogen and has not been found in the nursery industry as initially believed; accordingly, the effects of exposure on the production and marketability of plant products would be minimal. Further, the commenter stated that evidence suggests that the current regulatory systems and surveys for *Phytophthora ramorum* could be effectively applied toward the control of *Phytophthora kernoviae*.

We agree with this commenter's point that current regulatory systems and surveys for *Phytophthora ramorum* could be effectively applied toward the surveillance for *Phytophthora kernoviae*. Based on this consideration and due to a clearer understanding of the epidemiology of *Phytophthora kernoviae* that suggests a reduction in the initially determined host range of the pathogen, we have decided that *Phytophthora kernoviae* should not be listed as a select agent. We note that a plant pest permit issued under our regulations in 7 CFR part 330 will still be required for the importation or interstate movement of *Phytophthora kernoviae*, however.

We proposed to add *Rathayibacter toxicus*, a bacterium that causes gumming disease in ryegrass, to the list of PPQ select agents and toxins.

One commenter supported the proposed listing, but recommended that APHIS develop a reliable diagnostic tool to differentiate between *Rathayibacter toxicus* and the related, non-toxic species *Rathayibacter rathayi*. This commenter stated it is critically important to be able to distinguish between the two species for the purposes of cooperative pest surveys and for phytosanitary certification purposes. We agree that it is important to develop a diagnostic tool to distinguish between these two species and note that the USDA's Agricultural Research Service is conducting an ongoing research project focused on the identification, molecular characterization, and detection of

foreign and newly emerging domestic bacteria (including *Rathayibacter toxicus*). However, this is not a basis for not including *Rathayibacter toxicus* on the select agent list.

#### Overlap and VS Select Agents and Toxins

We proposed to remove 10 of the 20 overlap select agents and toxins from the list in 9 CFR 121.4(b). Specifically, we proposed to remove three bacteria (Botulinum neurotoxin producing species of *Clostridium*, *Coxiella burnetii*, and *Francisella tularensis*), a fungus (*Coccidioides immitis*), a virus (Eastern equine encephalitis virus), and five toxins (Botulinum neurotoxins, *Clostridium perfringens* epsilon toxin, shigatoxin, staphylococcal enterotoxin, and T-2 toxin).

One commenter was opposed to the removal of botulinum neurotoxins and botulinum neurotoxin producing species of *Clostridium* from the list of overlap select agents and toxins. The commenter argued that the presence of a select agent in the environment does not minimize the potential for its use as a weapon of bioterrorism, which would result in clear economic and societal consequences.

We do not minimize the fact that botulinum neurotoxins and botulinum neurotoxin producing species of *Clostridium* can present a significant health risk to livestock; indeed, these neurotoxins are some of the most lethal substances known to animals, and could cause the death of many animals in large herds. However, we do not agree that the intentional use of botulinum neurotoxins would have a significant impact on U.S. export trade in animals and animal products, or have a long-term impact on U.S. agriculture. Based on evidence that transmissibility from animal to animal is negligible and that, historically, outbreaks of botulism occur periodically in the United States, we have determined that botulinum neurotoxins are a poor agroterrorism weapon, and we should, therefore, remove botulinum neurotoxins and botulinum neurotoxin producing species of *Clostridium* from the list of overlap select agents in our regulations in § 121.4(b). It should be noted, however, that botulinum neurotoxins and botulinum neurotoxin producing species of *Clostridium* will continue to be regulated by the CDC under its select agent and toxins regulations in 42 CFR part 73 due to their potential threat to human health.

One commenter asked that we clarify which strains of vesicular stomatitis virus (VSV) APHIS considers to be exotic.

Although we did not propose to make any changes in the regulations with respect to VSV, we agree that it would be helpful to clarify which subtypes of VSV we consider to be exotic. Two major serotypes of VSV, New Jersey (VSV-NJ or VSNJV) and Indiana (VSV-IN1 or VSIV), have been reported to cause classical vesicular stomatitis disease in agriculturally significant animals (*i.e.*, cattle, horses, and swine) throughout the Americas. Two subtypes of the Indiana serotype, Cocal (VSIV-IN2 or VSIV-2) and Alagoas (VSV-IN3 or VSIV-3), cause vesicular disease in livestock in Brazil and Argentina. In the United States, VSV has not become established, but domestic outbreaks of VSV caused by VSV-NJ and VSV-IN1 occur sporadically in cycles. Therefore, we have clarified in the regulations that the listed VS select agent “vesicular stomatitis virus (exotic)” refers to Indiana subtypes VSV-IN2 and VSV-IN3.

Two commenters involved in the development of veterinary biological products noted that 4 of the 10 overlap select agents and toxins that APHIS had proposed to remove from its list in § 121.4 were agents that the veterinary biologics industry uses to manufacture licensed veterinary biologics or uses in product research and development. Noting that the veterinary biologics industry has a well-established relationship with APHIS' Center for Veterinary Biologics (CVB), the commenters were concerned about what may happen when APHIS no longer has a role in regulating those agents as select agents or toxins. The commenters suggested that:

- The agents should be removed from the CDC select agent list to mirror their delisting by APHIS;
- CDC should exempt the use of the agents in the manufacture of veterinary biologics by CVB-licensed facilities and their investigation use under CVB supervision;
- APHIS should keep the agents on the overlap list; or
- CDC should utilize APHIS/CVB for oversight and inspection of CVB-licensed firms.

We acknowledge that there will be some entities that produce veterinary biologics that will now possess select agents or toxins regulated only by CDC, so the APHIS select agent program will not be part of the inspection process at those facilities unless the facility also possesses VS select agents or toxins. In either case, however, CVB will continue to conduct its own compliance inspections and otherwise exercise oversight of veterinary biologics facilities in keeping with its

responsibilities under the Virus-Serum-Toxin Act (VSTA). The compliance inspections conducted by CVB under the VSTA are separate and distinct from the inspections conducted under the select agent program, and there will be no disruption or change in the way CVB conducts those compliance inspections as a result of the removal of select agents and toxins from the overlap list. As for the select agent program, we note that the regulations administered by APHIS and CDC are entirely consistent with each other, so there will be no change in security requirements, registration procedures, restrictions, exemptions, etc. With respect to inspections and other activities conducted under the select agent program, APHIS and CDC have established procedures that ensure close coordination and consistency in the regulation of select agents and toxins. We do not, therefore, believe that it is necessary to make any of the changes suggested by the commenters in order to ensure the continuing efficiency and consistency of the regulation of select agents and toxins by APHIS and CDC.

#### Other Comments

Several commenters argued that the cost to upgrade security at existing facilities was prohibitive. One commenter stated that the cost of compliance with the regulations at his facility came to almost \$150,000. Other commenters asserted that research facilities that possess, use, or transfer a select agent or toxin would be forced to close due to dramatic increases in the cost of research, or that research programs will be impeded by the regulatory requirements or even terminated because researchers and their institutions will not want to deal with the new regulatory requirements or be liable for violations of the regulations.

In our economic analysis for the proposed rule, we stated that an entity that possesses a newly added agent will have to comply with the regulations, and may therefore incur cost. We also noted that the costs to comply with the security requirements are site-specific and will vary accordingly. In this final rule, we reiterate that compliance with the regulations can be achieved in a wide variety of ways, and while some of these methods can be expensive, the regulations do not specify how the physical security needs (limiting access to the agents) are to be met, only that they are to be commensurate with the threat that the select agent or toxin poses. Therefore, an entity can choose the most cost-effective alternative to meeting those needs. Often an entity's

standard operating procedures for security are sufficient. Accordingly, research facilities that possess, use, or transfer a select agent or toxin may not be forced to close, as one commenter fears, due to an increased cost of research.

We were required by the Act to establish, by regulation, standards and procedures governing the possession, use, and transfer of listed biological agents and toxins in order to protect animal and plant health, and animal and plant products. Those standards and procedures were established in an interim rule published in the **Federal Register** on December 13, 2002, and effective on February 11, 2003. To date, the commenters' concerns about the costs or difficulties of complying with the regulations have failed to materialize.

Several commenters argued that the process of registering an entity is excessively time-consuming and that the regulations entail additional recordkeeping requirements. One commenter claimed that the process of approval (Federal Bureau of Investigation (FBI) checks, security plans, lab and greenhouse modifications, training, and inspection) took more than 1 year.

Registered entities must develop and implement a written security plan that provides graded protection in accordance with the risk of the select agent or toxin, given its intended use, and must develop and implement a written biosafety/biocontainment plan that is commensurate with the risk of the agent or toxin, given its intended use. Registered entities must also develop and implement a written incident response plan that describes the entity's response procedures for releases, theft, or loss of a select agent or toxin, etc. These reporting and recordkeeping requirements have been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act. As for the length of time it took the one commenter's facility to become registered, there are a variety of factors that could have contributed to such a lengthy process, but we are unaware of the particular circumstances of the commenter's experience. We do note that the necessary security risk assessment (SRA) checks are provided free of charge by the FBI and take approximately 45 days to complete, and that APHIS and CDC are committed to ensuring that the registration process is conducted as efficiently as possible.

One commenter stated that we need a mechanism that would allow the timely delisting of a newly detected select

agent if it is found to be widely distributed and ineradicable.

Given that the Administrative Procedure Act provides that an agency may, with a showing of good cause, make a rule effective in less than 30 days and without prior opportunity for public comment, we do not believe it is necessary for us to establish any new mechanism for delisting or otherwise amending the regulations.

We received many comments that recommended we remove specific PPQ, VS, and overlap select agents from the lists in 7 CFR part 331 and 9 CFR part 121. The PPQ select agents specifically mentioned were *Ralstonia solanacearum*, race 3, biovar 2; *Sclerophthora rayssiae* var. *zeae*; *Synchytrium endobioticum*; and *Xylella fastidiosa* (citrus variegated chlorosis strain), and the VS select agents mentioned were the bovine spongiform encephalopathy agent and Venezuelan equine encephalitis virus. These commenters supplied detailed information to support their position that these select agents should be delisted; in most cases, the commenters asserted that the continued listing of specific agents they considered low risks for bioterrorism was prohibitive and impeded timely research. Conversely, another commenter submitted information supporting his contention that the agents that cause scrapie and chronic wasting disease should be added to the list of VS select agents and toxins.

We will take the information provided by the commenters into account as we continue to review our regulations and anticipate that we will be providing an opportunity in the future for affected entities and the general public to offer suggestions for adding or eliminating select agents and toxins to or from the lists in our regulations. We will use the information provided by the commenters as we consider the potential regulatory changes that may be part of our next proposed rule.

#### Miscellaneous Change

We are making one other change in this final rule. In the proposed rule, we included an explanatory footnote to the entry for "virulent Newcastle disease virus" in the proposed list of VS select agents and toxins. This footnote read: "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." We are replacing the word

"having" in the proposed footnote with the word "has." In addition, we are adding a sentence to further clarify the definition: "A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus." This sentence will provide additional guidance to entities in determining whether they possess a virulent strain of Newcastle disease virus.

#### Compliance Dates

We recognize that there may be some entities that are not currently registered under the select agents program, but that possess one of the PPQ select agents being added to the regulations by this final rule. The PPQ select agents we are adding to the regulations in 7 CFR part 331 are:

- *Xanthomonas oryzae* pv. *oryzae*,
- *Peronosclerospora sacchari*,
- *Phoma glycinicola* (formerly *Pyrenochaeta glycinis*), and
- *Rathayibacter toxicus*.

In addition, although it is not likely, the redefinition of Newcastle disease virus (velogenic) to virulent Newcastle disease virus may lead to new registrants, as 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.

Accordingly, entities that currently possess one of those four agents or a strain of Newcastle disease virus that we now define as virulent, if they are not already registered entities, will have to either transfer the organism to a registered entity or become a registered entity themselves as a result of this final rule. Those entities that choose to become registered will need time to come into full compliance with the requirements of the regulations.

This final rule will become effective on November 17, 2008. On and after that date, any individual or entity possessing, using, or transferring any listed agent or toxin must be in compliance with the provisions of each part.

However, to minimize the disruption of research or educational projects (e.g., teaching demonstrations) involving listed select agents or toxins that were underway as of the effective date of these regulations, we provide that any individual or entity possessing such agents or toxins as of the effective date (current possessors) will be afforded additional time to reach full compliance with the regulations in each part. Accordingly, by November 17, 2008, the responsible official at all entities that possess a new agent or toxin must provide notice to APHIS regarding their

possession of the new agent(s) and toxin(s). By April 14, 2008, all previously unregistered entities must be registered.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

#### **Executive Order 12866 and Regulatory Flexibility Act**

This 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 amending and republishing 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 implements 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 extremely 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, the introduction of a VS select agent or toxin 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 75 million acres of soybeans were cultivated in the

United States in 2006, for example), exacerbating difficulties in surveillance and monitoring.<sup>2</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 vital the prevention of the misuse of biological agents and toxins through registration, biosafety, and security measures and the availability of incident response capabilities.

Section 212(a)(2) of the Act requires a biennial review and republication of the select biological agent and toxin list, with revisions as appropriate in accordance with this law. This rule will implement the recommendations of the second biennial review of the list. 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 updates the lists of select agents and toxins contained in the regulations in 7 CFR part 331 and 9 CFR part 121. The regulations require registration, biosafety, incident response, and security measures for the possession, use, and transfer of the listed select agents and toxins. The regulations are intended to prevent the misuse of those select agents and toxins, and therefore reduce the potential for those pathogens to harm 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 would 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 for plants. Industry could also be affected through the imposition of domestic and foreign quarantines that result in a loss of markets. The Federal Government 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 an implicated food product and about the producing country or sector's ability to produce safe food are slow to recover and can have a lasting influence on food demand and global trade.<sup>3</sup> As such, the benefits of the rule are the avoided losses of animals or plants that could be attacked by these organisms or toxic materials (because of the reduced risk of release of the select agents and reduced likelihood of exposure for susceptible animals or plants), the avoided public and private costs of eradication, and the avoided negative effects on products and markets.

The costs associated with the outbreak of a select agent can be very high, as demonstrated, for example, by the losses to agriculture and the food chain from the foot-and-mouth disease (FMD) outbreak in the United Kingdom (UK) in 2001. Those costs 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 and \$13.5 billion.<sup>4</sup> The bovine spongiform encephalopathy (BSE) crisis in the UK (which has a cattle industry about one-tenth the size of that in the United States) is another example. It has been estimated that the total resource costs to the UK economy as a result of BSE in the first 12 months after the onset of the 1996 crisis were in the range of £740 million to £980 million (\$1.2 to \$1.5 billion), or just over 0.1 percent of the gross domestic product of the United Kingdom.<sup>5</sup> In addition, the UK lost its entire export market for beef.

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

<sup>3</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>4</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 Agriculture and Natural Resources, University of California, Davis, 1999.

<sup>5</sup> DTZ Piedad Consulting. *Economic Impact of BSE on the UK economy*. A report commissioned by the UK Agricultural Departments and HM Treasury.

<sup>2</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), and USDA National Agricultural Statistics Service, *Prospective Plantings*, March 30, 2007, Cr Pr 2-4, <http://www.usda.gov/nass/PUBS/TODAYRPT/pspl0307.txt>.

The entities most likely to be affected by this rule include research and diagnostic facilities, Federal, State, and university laboratories, and private commercial and non-profit enterprises. An entity that possesses, uses, or transfers listed select agents or toxins is required to comply with the select agent regulations. The regulations require registering the possession, 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, that the physical security of the premises is adequate, that all individuals with access to select agents or toxins have appropriate training to handle such agents or toxins, and that complete records concerning activities related to the select agents or toxins are maintained.

The changes to the PPQ select agent list include the addition of four organisms to the list, the removal of two organisms from the list, and technical changes for organisms currently listed. An entity that possesses a newly added agent or toxin will have to comply with the select agent regulations, and may therefore incur costs. These primarily involve becoming registered, maintaining an inventory of the agents and toxins, and limiting access to the agent or toxin to those individuals who are qualified, have a need to have access to a select agent or toxin, and have an SRA conducted by the FBI. This rule does not change the process for obtaining the agents or toxins (*i.e.*, a permit is required regardless of whether an organism is listed as a select agent) or the bio-containment requirements as set forth in the existing permitting process. Necessary SRA checks are performed free of charge by the FBI and take approximately 45 days to complete. Limiting access to the listed agents or toxins can be achieved in a wide variety of ways. Some of these methods can be very expensive. For example, installing new state-of-the-art electronic surveillance equipment can run into the thousands of dollars even for a relatively small space. However, in most instances the physical security needs can be met with far less rigorous methods. Often an entity's standard operating procedures for security are sufficient. Because many entities deal with select agents or toxins in an area that is fully contained within a larger structure, a lack of entry control equipment may not affect the level of graded protection. It should also be noted that only that portion of a given entity affected by select agent or toxin

operations is required to be secured. The select agent regulations do not specify how the physical security needs (limiting access to the agents) are to be met, only that they need to be adequate for the situation. Therefore, an entity can choose the most cost-effective alternative to meet those needs.

The changes should affect only a very small number of entities. The plant pest permit database maintained by APHIS indicates that very few entities currently possess any of the agents that are being added to the PPQ list. It is estimated that less than a total of 10 entities will be affected by changes to the plant list. In addition, most of the entities that do possess the newly added agents are already registered due to their possession of other listed select agents or toxins. After this rule goes into effect, entities will no longer be required to maintain records and security for those agents and toxins that are being removed from the select agent lists by this rule. However, the entities are still required to maintain select agent records for 3 years past the time they were regulated under 7 CFR part 331 or 9 CFR part 121. Additionally, permits are still required under 7 CFR part 330 or 9 CFR part 122 for those agents and toxins that have been removed from the lists. These changes should have little impact.

The 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 consistent with current scientific literature. The agents that will be removed are overlap select agents and toxins regulated by both USDA and HHS. Any entity that is in possession of the overlap select agents and toxins that are to be removed, and that does not possess any other overlap agents or toxins or any of the APHIS select agents or toxins, will subsequently possess HHS-only agents and toxins and will thus continue to be subject to select agent regulations as administered by HHS. In addition, the organisms that will be removed from the lists of select agents and toxins (*Botulinum neurotoxin producing species of Clostridium, Coxiella burnetii, and Francisella tularensis; the fungus Coccidioides immitis; and Eastern equine encephalitis virus*) will continue to be subject to the regulations under 9 CFR part 122. 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 been circulating in the United States since the 1970s. Those entities most likely to be in possession of virulent Newcastle disease virus are those already in possession of Newcastle disease virus (velogenic) and therefore already registered. Therefore, these changes should have little impact.

#### 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 rule will update the PPQ, VS, and overlap select agent lists. The regulation of select agents is intended to prevent their misuse and thereby reduce the potential for those agents and toxins to harm 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. 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 costs of eradication. Industry would be affected through the imposition of domestic and foreign quarantines that result in a loss of markets and the destruction of animals or plants found to be infected with the disease. Even though entities may be compensated for the destroyed property, repopulating (flocks, herds, fields, etc.) can take time, with additional losses incurred due to 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.

The entities most likely to be affected by this rule are those 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 are being added to the list of select agents and toxins. Moreover, after this rule goes into effect, entities will no longer be required to maintain records and security for those agents and toxins that are being removed from the select agent lists by this rule. However, the entities are still required to maintain select agent records for 3 years past the time they were regulated under 7 CFR part 331 or 9 CFR part 121. Additionally, permits are still required under 7 CFR part 330 or 9 CFR part 122 for those agents and toxins that have been removed from the lists. Other changes do not affect what select agents or toxins are listed but rather the nomenclature by which those agents and toxins are identified, and therefore should have no economic impact on holders of those organisms or toxic materials.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will 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 final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### Paperwork Reduction Act

This final 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 are amending 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 CFR 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:

*Peronosclerospora philippinensis*  
(*Peronosclerospora sacchari*);  
*Phoma glycinicola* (formerly  
*Pyrenochaeta glycines*);  
*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 CFR 2.22, 2.80, and 371.4.

■ 4. In part 121, footnotes 1 through 14 are redesignated as footnotes 2 through 15, respectively.

■ 5. In § 121.3, 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);  
Indiana subtypes VSV-IN2, VSV-IN3;  
Virulent Newcastle disease virus<sup>1</sup>

\* \* \* \* \*

■ 6. Section 121.4 is amended as follows:

■ a. By revising paragraph (b) to read as set forth below.

■ b. By removing paragraph (d)(3).

■ c. 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]

■ 7. In § 121.5, paragraph (a)(3)(i) is amended by removing the words “Newcastle disease virus (velogenic)” and adding the words “virulent Newcastle disease virus” in their place.

##### § 121.6 [Amended]

■ 8. In § 121.6, paragraph (a)(3)(i) is amended by removing the words “*Botulinum neurotoxins*,” and “*Francisella tularensis*,”.

<sup>1</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 has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

**§ 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.

Done in Washington, DC, this 3rd day of October 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8-23887 Filed 10-15-08; 8:45 am]

BILLING CODE 3410-34-P

---

**DEPARTMENT OF HOMELAND SECURITY**
**U.S. Citizenship and Immigration Services**
**8 CFR Parts 214 and 248**

[CIS No. 2429-07; DHS Docket No. USCIS-2007-0056]

RIN 1615-AB64

**Period of Admission and Extension of Stay for Canadian and Mexican Citizens Engaged in Professional Business Activities—TN Nonimmigrants**

**AGENCY:** U.S. Citizenship and Immigration Services, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Department of Homeland Security (DHS) is amending its regulations to allow an increased period of admission and extension of stay for Canadian and Mexican citizens who seek temporary entry to the United States as professionals pursuant to the TN classification, as established by the North American Free Trade Agreement (NAFTA or Agreement). This final rule increases the maximum allowable period of admission for TN nonimmigrants from one year to three years, and allows otherwise eligible TN nonimmigrants to be granted an extension of stay in increments of up to three years instead of the current maximum of one year. In addition, this rule grants the same periods of admission or extension to TD nonimmigrants, the spouses and unmarried minor children of TN nonimmigrants to run concurrent. The rule also removes the mention of specific petition filing locations from the TN regulations and replaces the outdated term “TC” (the previous term given to Canadian workers under the

1989 Canada-United States Free Trade Agreement) with “TN.” This rule will reduce the administrative burden of the TN classification on USCIS, and will ease the entry of eligible professionals to the United States.

**DATES:** This final rule is effective October 16, 2008.

**FOR FURTHER INFORMATION CONTACT:** Paola Rodriguez Hale, Adjudications Officer, Business and Trade Services, Office of Service Center Operations, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue, NW., 2nd Floor, Washington, DC 20529, telephone (202) 272-8410.

**SUPPLEMENTARY INFORMATION:**
**I. Background**
*A. NAFTA and the TN Classification*

NAFTA and the NAFTA Implementation Act, Public Law 103-182, redesignated section 214(e) of the Immigration and Nationality Act (INA) to create the “trade NAFTA” (TN) nonimmigrant classification and provide for the temporary entry of qualified business persons from each of the countries that signed the Agreement. The TN nonimmigrant classification permits qualified Canadian and Mexican citizens to seek temporary entry as business persons to engage in professional business activities at a professional level in the United States. 8 CFR 214.6(a). DHS regulations currently require that TN nonimmigrants may be admitted to the United States for a period not to exceed one year. 8 CFR 214.6(e). The regulations further provide that TN professionals may apply for extensions of stay for a maximum period of one year. 8 CFR 214.6(h)(1).

*B. Proposed Rule*

On May 9, 2008, DHS published a notice of proposed rulemaking in the **Federal Register** at 73 FR 26340 proposing a change in the period of admission and extension of stay granted to TN nonimmigrants from Canada and Mexico engaged in professional business activities. The notice also proposed granting the same period of admission or extension of stay to TN dependents (TD nonimmigrants), removing outdated references to specific filing locations and prior requirements, and replacing the outdated term TC with the current TN term. Written comments to the proposed rule were due on or before June 9, 2008.

In this final rule, DHS is adopting the proposed rule with no changes. The proposed rule was, and this final rule is, intended to improve the administration

of the TN program and make it more flexible and attractive to Canadian and Mexican professionals and to employers in the United States. Currently, DHS regulations require TN nonimmigrants, to either seek readmission in TN status or apply for extensions of stay annually if they wish to remain in the United States beyond the period of their initial admission. 8 CFR 214.6(h). This requirement involves the annual submission of documentation and payment of filing fees. By removing these types of administrative requirements on TN employees and their U.S. employers, DHS will further the intent of NAFTA to facilitate the entry of eligible professionals into the United States.

**II. Comments Received in Response to the Proposed Rule**

DHS received 80 comments in response to the proposed rule. The majority of commenters (76) supported this rulemaking. Many of these 76 commenters suggested additional changes or enhancements to the TN classification regulations which were not part of the proposed rule. Two commenters opposed the proposed rule. One of these two commenters asked questions about lawful permanent residence and educational opportunities for aliens in the TN classification, but did not express an opinion on the proposed rule. The second of these two commenters simply complained about a perceived slight to U.S. workers contained in another public comment. Many of the received comments raised issues that are beyond the scope of this rulemaking but will be mentioned briefly as part of this disposition of the comments.

*A. Increase to Three Years for Admissions and Extensions of Stay*

*Comments on period of admission:* The overwhelming majority of the commenters supported increasing the period of admission and extensions of stay granted to TN nonimmigrants from one to three years. Only two commenters opposed this proposal because they thought that jobs should be offered to U.S. workers rather than to foreign nationals. One commenter stated that the U.S. economy is suffering and jobs should thus be reserved for U.S. workers. The other commenter stated that the United States is presently flooded with immigrants and the TN program should be shut down while the country sorts out the problems with illegal immigrants present in the United States, and also made additional comments about aliens, politicians and the U.S. government in general.