

Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 4, 2023.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR part 180 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.1404 to subpart D to read as follows:

§ 180.1404 (2S)-5-Oxopyrrolidine-2-carboxylic Acid (L-PCA); exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the pesticide, (2S)-5-Oxopyrrolidine-2-carboxylic Acid (L-PCA) in or on all food commodities when used as a plant growth regulator in accordance with label directions and good agricultural practices.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

Select Agent Determination Concerning *Coxiella burnetii* Phase II, Nine Mile Strain, Plaque Purified Clone 4 With Reversion to Wildtype *cbu0533*

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

ACTION: Determination.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), has determined that an excluded attenuated strain, *Coxiella burnetii* Phase II, Nine Mile Strain, plaque purified clone 4, has, in one instance, been shown to spontaneously mutate when passaged *in vivo*. The resulting mutant, *C. burnetii* Phase II, Nine Mile Strain, plaque purified clone 4 with reversion to wildtype *cbu0533*, has enhanced pathogenicity and virulence. Therefore, *C. burnetii* Phase II, Nine Mile Strain, plaque purified clone 4 with reversion to wildtype *cbu0533* is not an excluded strain but is a select agent and subject to the HHS select agent and toxin regulations.

DATES: This determination is effective August 10, 2023.

FOR FURTHER INFORMATION CONTACT:

Samuel S. Edwin Ph.D., Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–4, Atlanta, Georgia 30329, Telephone: (404) 718–2000.

SUPPLEMENTARY INFORMATION: *Coxiella burnetii* is a select agent that is regulated pursuant to the HHS select agent and toxin regulations (42 CFR part 73). *C. burnetii* is a gram-negative intracellular bacterium that causes Q Fever. Q Fever is a zoonotic disease that causes flu-like symptoms in humans, including fever, chills, fatigue, and muscle pain. Humans become infected when they are in close contact with infected animal fluids and products.

The HHS select agent regulations (42 CFR part 73) established a process by which an attenuated strain of a select biological agent that does not have the potential to pose a severe threat to public health and safety may be excluded from the requirements of the regulations. On October 15, 2003, *C. burnetii* Phase II, Nine Mile Strain, plaque purified clone 4 was excluded from HHS select agent regulations as it does not pose a significant threat to public health and safety (<https://selectagents.gov/sat/exclusions/hhs.htm>).

As set forth under 42 CFR 73.4(e)(2), if an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting select agent will be subject to the requirements of the regulations. On March 20, 2023, an entity informed CDC of a reversion whereby *C. burnetii* Phase II, Nine Mile Strain, plaque purified clone 4 spontaneously mutated. The *C. burnetii* Phase II, Nine Mile Strain, plaque purified clone 4 with reversion to wildtype *cbu0533* displayed increased pathogenicity and virulence. The entity stated that after the excluded strain was injected into guinea pigs, a spontaneous reversion occurred that resulted in a mutant strain of the agent and the guinea pigs subsequently exhibited elevated fever and weight loss. The genetic mutation that led to the mutant strain was the reversion and restoration of a deletion in the *cbu0533* gene. CDC subject matter experts have determined that this reversion in *cbu0533* restored virulence and pathogenicity. Therefore, *C. burnetii* Phase II, Nine Mile Strain, plaque purified clone 4 with reversion to wildtype *cbu0533* is determined to be a select agent and subject to 42 CFR part 73.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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