

Record of Environmental Consideration supporting this determination is available in the docket.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

**Authority:** 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.4.

- 2. Add § 165.T08–1062 to read as follows:

#### § 165.T08–1062 Safety Zone; Fireworks Display, Lower Mississippi River, Natchez, MS

(a) *Location.* The following area is a safety zone: All navigable waters of the Lower Mississippi River between Mile Markers 363 and 364.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector Lower Mississippi River (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by telephone at (901) 208–0311. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 6 p.m. to 7 p.m. on December 31, 2025.

**Kristi L. Bernstein,**

*CAPT, U.S. Coast Guard, Captain of the Port Sector Lower Mississippi River.*

[FR Doc. 2025–22957 Filed 12–15–25; 8:45 am]

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### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 174

[EPA–HQ–OPP–2025–0212; FRL–13100–01–OCSPP]

#### SpCas9 Protein; Exemption From the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of the SpCas9 protein in or on the food and feed commodities of citrus when used as a plant-incorporated protectant (PIP) in citrus. Soil Culture Solutions LLC (d/b/a Soilcea) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of SpCas9 protein.

**DATES:** This regulation is effective December 16, 2025. Objections and requests for hearings must be received on or before February 17, 2026, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2025–0212, is available at <https://www.regulations.gov>. Additional information about the docket generally, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Shannon Borges, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1400; email address: [BPPDFRNotices@epa.gov](mailto:BPPDFRNotices@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Executive Summary

###### A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers

determine whether this document applies to them:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

###### B. What is EPA's authority for taking this action?

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(c)(2)(A)(i) allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” FFDCA section 408(c)(2)(A)(ii) defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .” Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other things, “available information concerning the cumulative effects of a particular pesticide's residues” and “other substances that have a common mechanism of toxicity.”

###### C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues

resolved in the final rule. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2025-0212 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before February 17, 2026.

EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. See "Revised Order Urging Electronic Filing and Service," dated June 22, 2023, which can be found at <https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf>. Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at [https://yosemite.epa.gov/OA/EAB/EAB-ALJ\\_upload.nsf](https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute. If you wish to include CBI in your request, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

## II. Petitioned for Exemption

In the **Federal Register** of July 3, 2025 (90 FR 29515) (FRL-12474-05-OSCPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 4E9159) by Soil Culture Solutions LLC (d/b/a Soilcea), 3802 Spectrum Blvd., Suite

157, Tampa, FL 33612. The petition requested that 40 CFR part 174 be amended by establishing an exemption from the requirement of a tolerance for residues of the PIP Cas9 protein in citrus. That document referenced a summary of the petition prepared by the petitioner Soilcea, which is available in the docket.

Thirty-six comments were received in response to the notice of filing. All supported the proposed tolerance exemption for SpCas9 protein and urged the Agency to approve the tolerance exemption and associated PIP product registration. No substantive issues were raised in these comments that would affect this tolerance exemption action.

## III. Final Tolerance Actions

### A. EPA's Safety Determination

EPA evaluated the available toxicological and exposure data on Cas9 protein and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which the EPA relied and its risk assessment based on those data can be found within the document entitled "*Product Characterization Review and Human Health Risk Assessment of the Three Plant-Incorporated Protectants for the Loss-Of-Function Edits in Accelerated Cell Death 2 (ACD2); Lethal Leaf Spot 1 (LLS1); and Papain-Like Cysteine Protease (PLCP) and the Genetic Material Necessary for their Production (gRNAs g5, g213, g86) along with the Cas9 Protein, as Expressed in Citrus Rootstock Containing Event CarriCea T1*" (Human Health Risk Assessment). This document, as well as other relevant information, are available in the docket for this action as described under **ADDRESSES**.

The Cas9 protein is an enzyme (endonuclease) that is part of the CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) precision genome editing system. CRISPR is an adaptive immune system in procaryotes and archaea that defends the organism from viral infection by cleaving viral DNA. Specifically, CRISPR is a complex consisting of the Cas9 enzyme and a guide RNA (gRNA) molecule. The gRNA binds to DNA in a sequence-specific manner, while the Cas9 protein makes a double-stranded break at that position. Cas9 alone does not have catalytic activity; instead, the incorrect repair of the DNA cut caused by Cas9 results in the loss of function of the targeted gene.

In citrus, SpCas9 protein (derived from the bacterium *Streptococcus pyogenes*), along with three gRNAs have

been genetically engineered into the Carrizo cultivar ("CarriCea T1" rootstock). Each gRNA is complementary to an endogenous citrus gene and the CRISPR system causes loss of function to those genes. The proteins that would be otherwise produced from the targeted genes are involved in pathways exploited by the bacterium *Candidatus Liberibacter asiaticus* (CLAs), the known causal agent of Huanglongbing disease (also known as citrus greening). The loss of function modifications in these genes disrupt the interactions between the plant proteins and CLAs effector proteins, thus interfering with the bacterium's ability to suppress the plant's immune response and establish infection. As a result, the CarriCea T1 rootstock exhibits resistance to bacterial infection by CLAs.

The CRISPR/Cas9 system is ubiquitous in bacteria and archaea where it functions by recognizing and removing foreign DNA, serving as a key component of bacterial immune defense. Cas9 proteins are prevalent across a wide range of bacterial groups, highlighting their ubiquitous presence in the environment. Humans are expected to be exposed to natural Cas9 proteins through their interactions with the natural environment. For example, Cas9 is also found in bacteria used in food production, such as *Streptococcus thermophilus*, and in commensal bacteria like *Lactobacillus plantarum* which is found in the human gastrointestinal tract. This widespread presence suggests regular human exposure to Cas9 proteins through environmental and dietary sources. While the amino acid sequences of the various Cas9 proteins vary between species, the endonuclease function remains conserved. This consistent mechanism across bacteria suggests that the function of Cas9 remains the same in pathogenic and non-pathogenic bacteria and therefore indicates a history of safe exposure to Cas9.

In citrus, exposure to SpCas9 protein through the dietary route is expected to be negligible as the SpCas9 protein is expected to remain localized to the rootstock, with no presence identified in the leaves of grafted scions and therefore no expectation of the protein to be present in the fruit of grafted scions. Similarly, exposure via drinking water is considered unlikely due to SpCas9's containment in the rootstock, as well as the protein's susceptibility to degradation by environmental conditions and microbial activity. If exposure were to occur, the risk is expected to be negligible due to (1) the history of safe exposure of humans to

the Cas9 protein due to the ubiquitous presence of Cas9 proteins in the environment, and the SpCas9 protein in CarriCea T1 sharing nearly identical amino acid sequence homology with the naturally occurring SpCas9; (2) a pesticidal mode of action that is not toxic; (3) bioinformatic analyses demonstrating the absence of significant homology between SpCas9 protein and known toxins or allergens; and (4) data showing the rapid digestibility of SpCas9 protein in gastric enzymes and heat lability at 100 °C, which limits the likelihood for allergenic effects.

As a PIP, the SpCas9 protein is contained within the plant cells and as such, non-occupational and residential exposure is considered to be negligible. Further, there are no proposed residential uses for the CarriCea T1 product containing SpCas9 protein; therefore, a residential handler and post-application exposure and risk assessment has not been conducted.

Although FFDCA section 408(b)(2)(C) provides for an additional tenfold margin of safety for infants and children in the case of threshold effects, EPA has determined that there are no such effects due to the lack of toxicity and allergenicity of SpCas9 protein. As a result, an additional margin of safety for the protection of infants and children is unnecessary.

#### *B. Analytical Enforcement Methodology*

EPA has determined that an analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation. Nonetheless, a Western blot method using a monoclonal anti-FLAG antibody was submitted to determine the levels of SpCas9 protein in plant samples. The antibody used to detect SpCas9 protein through its FLAG-tag could also be used to determine SpCas9 presence in citrus, provided no other FLAG-tagged proteins are present at the same time.

#### *C. Conclusion*

Based upon its evaluation in the Human Health Risk Assessment, which concluded that SpCas9 protein residues in or on citrus are not toxic to mammals, the EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of SpCas9 protein. Therefore, an exemption from the requirement of a tolerance is established for residues of SpCas9 protein in or on citrus when used according to the label and good agricultural practices.

### **IV. Statutory and Executive Order Reviews**

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/and-executive-orders>.

#### *A. Executive Order 12866: Regulatory Planning and Review*

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866.

#### *B. Executive Order 14192: Unleashing Prosperity Through Deregulation*

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

#### *C. Paperwork Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA, 44 U.S.C. 3501 *et seq.*, because it does not contain any information collection activities.

#### *D. Regulatory Flexibility Act (RFA)*

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to the APA but is subject to FFDCA section 408(d), which does not require notice and comment rulemaking to take this action in response to a petition.

#### *E. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of \$100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local or Tribal governments or the private sector.

#### *F. Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the

National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

#### *G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

#### *H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866 (See Unit IV.A.), and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

However, EPA's 2021 Policy on Children's Health applies to this action. This rule finalizes an exemption from the requirement of a tolerance under the FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . ." (FFDCA 408(b)(2)(C)). The Agency's consideration is documented in Unit III.A.

#### *I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

#### *J. National Technology Transfer Advancement Act (NTTAA)*

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

#### *K. Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit

a rule report to each House of Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 174

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

Dated: December 4, 2025.

Edward Messina,

Director, Office of Pesticide Programs.

For the reasons set forth in the preamble, EPA is amending 40 CFR chapter I as follows:

#### PART 174—PROCEDURES AND REQUIREMENTS FOR PLANT-INCORPORATED PROTECTANTS

- 1. The authority citation for part 174 continues to read as follows:

**Authority:** 7 U.S.C. 136–136y; 21 U.S.C. 321(q), 346a and 371.

- 2. Add § 174.556 to subpart W to read as follows:

##### § 174.556 SpCas9 Protein; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance for residues of SpCas9 protein in or on the food and feed commodities of Citrus when used as a Plant-Incorporated Protectant in accordance with label directions and good agricultural practices.

[FR Doc. 2025–22927 Filed 12–15–25; 8:45 am]

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#### DEPARTMENT OF COMMERCE

##### National Oceanic and Atmospheric Administration

##### 50 CFR Part 660

[Docket No. 241022–0278]

RIN 0648–BO12

##### Magnuson-Stevens Act Provisions; Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; 2025–2026 Biennial Specifications and Management Measures; Inseason Adjustments

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

**ACTION:** Final rule; inseason adjustments to biennial groundfish management measures.

**SUMMARY:** This final rule announces routine inseason adjustments to management measures in recreational groundfish fisheries. This action is intended to allow recreational fishing vessels to access more abundant groundfish stocks while protecting overfished and depleted stocks.

**DATES:** This final rule is effective December 16, 2025.

**FOR FURTHER INFORMATION CONTACT:** Christopher Biegel, 503–231–6291, [christopher.biegel@noaa.gov](mailto:christopher.biegel@noaa.gov).

#### Electronic Access

This rule is accessible via the internet at the Office of the Federal Register website at <https://www.federalregister.gov>. Background information and documents are available at the Pacific Fishery Management Council's website at <https://www.pcouncil.org/>.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Pacific Coast Groundfish Fishery Management Plan (PCGFMP) and its implementing regulations at title 50 in the Code of Federal Regulations (CFR), part 660, subparts C through G, regulate fishing for over 90 species of groundfish off the coasts of Washington, Oregon, and California. The Pacific Fishery Management Council (Council) develops groundfish harvest specifications and management measures for 2-year periods (*i.e.*, a biennium). NMFS published the final rule to implement harvest specifications and management measures for the 2025–2026 biennium for most species managed under the PCGFMP on December 16, 2024 (89 FR 101514). In general, the management measures set at the start of the biennial harvest specifications cycle help the various sectors of the fishery attain, but not exceed, the catch limits for each stock. The Council, in coordination with Pacific Coast Treaty Indian Tribes and the States of Washington, Oregon, and California, recommends adjustments to the management measures during the fishing year to achieve this goal.

At its September 2025 meeting, the Council recommended an inseason action for the Pacific Coast groundfish fishery. This action involves a canary rockfish sub-bag limit for recreational fishing off the coast of California.

##### California Recreational Canary Rockfish Sub-Bag Limit

In June 2025, the Council's Scientific and Statistical Committee (SSC) adopted a new benchmark assessment for California quillback rockfish. At the

same meeting, the Council adopted an inseason action to relax recreational fishing management measures off the coast of California that were originally implemented to reduce angler interactions with quillback rockfish. The June 2025 action included restoring recreational fishing access to all depths between the California/Oregon border and Point Conception (42° N. lat. to 37°07' N. lat.). In summer 2025, the California Fish and Game Commission (FGC) also took emergency action to implement complementary changes within state regulations to restore recreational fishing access to all depths along that portion of the California coast. In addition, the FGC approved a recreational 2-fish sub-bag limit for the state recreational fishery canary rockfish within the state regulations.

This FGC 2-fish sub-bag limit action was effective on August 28, 2025, and only applies to state jurisdictional waters. Currently, there is no sub-bag limit for canary rockfish in federal regulations for the California recreational fishery, only the 10 fish aggregate bag limit for rockfish, cabezon, and greenlings. The previous changes to allow increased recreational fishing access to depth limits along the California coast allow increased access to the depth range where canary rockfish are commonly encountered in the recreational fishery; thus increasing the likelihood that the California share of the coastwide canary rockfish allocation would be exceeded if additional management measures to address the probability of higher canary rockfish mortality along the California coast were not addressed for the 2025–2026 biennium. Thus, in a September 2025 supplemental California Department of Fish and Wildlife (CDFW) report, CDFW recommended inseason action to implement a recreational 2-fish sub-bag limit for canary rockfish off California within federal regulations. This action is expected to keep canary rockfish mortality off California within limits and accountable to the states' sharing agreements on the percentage of catch to occur off each state, which are contained in the Pacific Coast groundfish fishery Stock Assessment and Fishery Evaluation (SAFE) document available at <https://www.pcouncil.org/documents/2024/08/status-of-the-pacific-coast-groundfish-fishery-stock-assessment-and-fishery-evaluation-july-2025.pdf>. Additionally, this inseason action would establish consistency across state and federal regulations, and thus across jurisdictional boundaries, which would