ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2025–0176; FRL–13258–01–OCSPP]

Citrus Tristeza Virus (CTV) Strain T36 Expressing Spinach Defensin Proteins SoD2, SoD2-1, and SoD2*; 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 *Citrus tristeza* virus (CTV) strain T36 expressing Spinach Defensin Proteins SoD2, SoD2-1, and SoD2* in or on the food and feed commodities of citrus. Silvec Biologics, Inc 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 CTV strain T36 expressing Spinach Defensin Proteins SoD2, SoD2-1, and SoD2* under FFDCA when used in accordance with this exemption.

DATES: This regulation is effective April 7, 2026. Objections and requests for hearings must be received on or before June 8, 2026, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2025–0176, 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.*

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 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–2025–0176 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 June 8, 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* ''Order Urging Electronic Filing and Service,'' dated December 3, 2025, which can be found at *https://www.epa.gov/system/files/documents/2025-12/2025-12-03-order-urging-electronic-filing-and-service.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.*

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 29516) (FRL–12474–05–OCSPP), 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 4E9114) by Silvec Biologics Inc., 200 Girard

Street, Suite 200, Gaithersburg, MD 20877. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of Spinach Defensin Genes 2 (SoD2, SoD2-1, SoD2*), expressed in CTV strain T36 (CTV-SoD2, CTV-SoD2-1, and CTV-SoD2*) in citrus (Crop Group 10–10). That document referenced a summary of the petition prepared by the petitioner Silvec Biologics Inc, which is available at *https://www.regulations.gov,* docket ID number EPA–HQ–OPP–2025–0176.

Three comments were received on the notice of filing. All comments were supportive of a tolerance exemption for CTV-SoD2, CTV-SoD2-1, and CTV-SoD2* proteins.

III. Final Tolerance Actions

A. EPA's Safety Determination

EPA evaluated the available toxicological and exposure data on CTV strain T36 expressing Spinach Defensin Protein 2 (SoD2), CTV strain T36 expressing Spinach Defensin Protein 2-1 (SoD2-1), and CTV strain T36 expressing Spinach Defensin Protein 2* (SoD2*) (collectively called ''CTV-SoD2 variants'') 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 EPA relied and its risk assessment based on those data can be found in the document, ''Science review of the human health and product characterization data presented for the three active ingredients *Citrus tristeza* virus (CTV) strain T36 expressing Spinach Defensin Proteins (SoD) 2, 2-1 and 2*, and End Use Product Citrus budwood infected with CTV-SoD2, CTV-SoD2-1 and CTV-SoD2*'' (Human Health Risk Assessment). This document, as well as other relevant information, is available at *https://www.regulations.gov,* docket ID number EPA–HQ–OPP–2025–0176.

CTV strain T36 was genetically engineered to create three separate strains expressing spinach defensin genes SoD2, SoD2-1, or SoD2* to help citrus trees resist citrus greening disease. Spinach defensin proteins are derived from a food plant (spinach). The spinach defensin proteins are thought to cause the formation of pores on the outer membrane of the disease-causing bacterium, thus compromising the integrity of the membrane and ultimately killing the bacterium. CTV strain T36, the vector for expression of these defensin proteins, is a single stranded positive sense RNA virus which is commonly found in citrus trees globally. Genetically engineered CTV T36 strains carrying the genes coding for SoD2, SoD2-1, or SoD2* are introduced into the phloem of citrus trees via bark grafting where the viruses express these proteins to control citrus greening.

There is a long history of safe exposure to both CTV and spinach defensins through the consumption of citrus and spinach, respectively. Given this exposure to both CTV and spinach defensins, there is no expectation that genetically engineered CTV strain T36 expressing the three CTV-SoD2 variants are toxic or allergenic to mammals through the dietary route of exposure. In an acute oral toxicity study conducted with a single dose of 5000 mg/kg of microbial-produced SoD2 protein, no evidence of toxic or adverse effects was observed. The estimated acute lethal dose, LD_{50}, was determined to be greater than 5000 mg/kg in female mice (EPA Toxicity Category IV). Due to high amino acid sequence identity, the other two CTV-SoD2 variants (SoD2-1 and SoD*) are likely to show a similar toxicity profile. The potential for all three CTV-SoD2 variants to be allergens is minimal because of experimentally demonstrated rapid digestion of SoD2 in simulated intestinal fluid and no indication of cross-reactivity of any of the three CTV-SoD2 variants to known allergens in *in silico* studies using the internationally recognized Codex Alimentarius guidelines.

Oral exposure to the CTV-SoD2 variants through drinking water is considered unlikely. CTV can only propagate in plant phloem cells and will be rapidly deactivated by environmental conditions outside of a plant or insect vector. CTV-SoD2 variants are proteins expressed in plants. As such, they are susceptible to degradation by environmental conditions and microbial activity. In the unlikely event that CTV-SoD2 variants do enter drinking water, exposure to these proteins would not be expected to result in a human health risk based on the same considerations articulated for food exposure.

Non-occupational and residential exposure is considered to be negligible. CTV can only propagate in plants, where CTV-SoD2 variants would be expressed. As such, CTV-SoD2 variants are contained within the plant cells.

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Here, EPA has determined that there are no such effects due to the lack of toxicity and allergenicity of CTV strain T36 expressing SoD2, SoD2-1, and SoD2* proteins. As a result, an additional margin of safety for the protection of infants and children is unnecessary.

B. Analytical Enforcement Methodology

An analytical method is not required for CTV-SoD2, CTV-SoD2-1, and CTV-SoD2* proteins since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Conclusion

Based upon its evaluation in the Human Health Risk Assessment, EPA concludes that use of CTV strain T36 expressing SoD2, SoD2-1, and SoD2* proteins will not result in unreasonable adverse health effects to humans and 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 the active ingredients. Therefore, an exemption from the requirement of a tolerance is established for residues of CTV strain T36 expressing SoD2, SoD2-1, and SoD2* 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/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 180

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

Dated: March 31, 2026.

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 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. Revise § 180.1337 to read as follows:

§ 180.1337 Citrus tristeza virus (CTV) strain T36 expressing Spinach Defensin Proteins SoD2, SoD2-1, and SoD2*; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Citrus tristeza* virus (CTV) strain T36 expressing Spinach Defensin Proteins SoD2, SoD2-1, and SoD2* in or on the commodities listed in fruit, citrus group 10–10 when used in accordance with label directions and good agricultural practices.

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