



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2023-0217; FRL-12767-01-OCSP]

### **Pepino Mosaic virus, Strain LP, Isolate VX1 and Pepino Mosaic Virus, Strain CH2, Isolate VC1; Exemptions from the Requirement of a Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes exemptions from the requirement of a tolerance for residues of Pepino mosaic virus, strain LP, isolate VX1 and Pepino mosaic virus, strain CH2, isolate VC1 in or on all food commodities when used in accordance with label directions and good agricultural practices. Valto BV submitted a petition to the EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting these exemptions from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of Pepino mosaic virus, strain LP, isolate VX1 and Pepino mosaic virus, strain CH2, isolate VC1 under FFDCA when used in accordance with these exemptions.

**DATES:** This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] 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-2023-0217, is available at <https://www.regulations.gov>. Additional information about dockets 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 (7511M), 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. General Information**

*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. Potentially affected entities may include:

- 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(g), 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 the EPA, you must identify docket ID number EPA-HQ-OPP-2023-0503 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 **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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 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 May 18, 2023 (96 FR 31667) (FRL-10579-04-OCSP), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance exemption petition (PP 2F9022 by Valto BV, Leehove 81, 2678 MB De Lier Zuid-Holland, 2678-MB, Netherlands (c/o SciReg., Inc. 12733 Director's Loop, Woodbridge, VA 22192). The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the virucides Pepino mosaic virus, strain LP, isolate VX1 and Pepino mosaic virus, strain CH2, isolate VC1 in or on all food commodities. That notice referenced a summary of the petition prepared by the petitioner Valto BV and available in the docket via <https://www.regulations.gov>. EPA received a comment on the notice of filing. EPA's response to comment is discussed in Unit III.C.

EPA omitted the descriptor “virucides” from the tolerance exemption. The reasons for this change are explained in Unit III.D.

### **III. Final Tolerance Actions**

#### *A. EPA’s Safety Determination*

EPA evaluated the available toxicological and exposure data on Pepino mosaic virus, strain LP, isolate VX1 and Pepino mosaic virus, strain CH2, isolate VC1 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 within the document entitled “Human Health Risk Assessment of Pepino mosaic virus strain LP isolate VX1 and Pepino mosaic *virus* strain CH2 isolate VC1, New Active Ingredients in (End-use Product) 100361-R V10 Proposed for Registration and an Associated Petition Requesting a Tolerance Exemption” (Pepino mosaic viruses human health risk assessment). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

The active ingredients are naturally occurring isolates of Pepino mosaic virus which have been found to colonize tomato plants without causing disease. These active ingredients are proposed for use in pesticide products to inoculate young tomato plants and elicit cross-protection from other potentially more virulent strains of Pepino mosaic virus. The active ingredients have no demonstrated infectivity to humans and low acute toxicity based on the results of the submitted data and information. In addition, Pepino mosaic viruses are unlikely to cause harm to humans given their host range and inability to grow and replicate within mammalian cells. Exposure to residues on food is expected to be negligible due to the limited use pattern and postharvest processing of food commodities. Drinking water exposure is expected to be negligible since exposure is limited to greenhouse application, and municipal drinking water processing should greatly reduce residues of the active ingredients. Other residential or non-occupational exposure is not expected due to the limited use pattern in

greenhouses. EPA determined that no additional margin of safety is necessary to protect infants and children as part of the qualitative assessment conducted, as data and rationale demonstrated that these active ingredients are not toxic, pathogenic or infective.

Based upon its evaluation in the Pepino mosaic viruses human health risk assessment, which concludes that there are no risks of concern from aggregate exposure to Pepino mosaic virus, strain LP, isolate VX1 and Pepino mosaic virus, strain CH2, isolate VC1, 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 Pepino mosaic virus, strain LP, isolate VX1 and Pepino mosaic virus, strain CH2, isolate VC1.

#### *B. Analytical Enforcement Methodology*

An analytical method is not required for Pepino mosaic virus, strain LP, isolate VX1 and Pepino mosaic virus, strain CH2, isolate VC1 because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

#### *C. Response to Comments*

One anonymous public comment was received and expressed concern with a different active ingredient and was therefore not relevant to this action.

#### *D. Revisions to the Requested Tolerance Exemption*

The Agency is omitting the descriptor, “virucides,” from the tolerance exemption to conform with standard nomenclature and reduce any possible future regulatory burden.

#### *E. Conclusion*

Therefore, exemptions from the requirement of a tolerance are established for residues of Pepino mosaic virus, strain LP, isolate VX1 and Pepino mosaic virus, strain CH2, isolate VC1 in or on all food commodities when used in accordance with label directions 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/laws-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 exemption 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 the 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: June 20, 2025.

**Edward Messina,**

*Director, Office of Pesticide Programs.*

For the reasons stated 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. Add § 180.1480 to Subpart D to read as follows:

**§ 180.1418 Pepino mosaic virus; exemptions from the requirement of a tolerance.**

(a) *Pepino mosaic virus, strain LP, isolate VX1*. An exemption from the requirement of a tolerance is established for residues of *pepino mosaic virus*, strain LP, isolate VX1 in or on all food commodities when used in accordance with label directions and good agricultural practices.

(b) *Pepino mosaic virus, strain CH2, isolate VC1*. An exemption from the requirement of a tolerance is established for residues of Pepino mosaic virus, strain CH2, isolate VC1 in or on all food commodities when used in accordance with label directions and good agricultural practices.

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