



40 CFR Part 180

[EPA-HQ-OPP-2024-0426; FRL-12782-01-OCSP]

Ethyl Formate; 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 ethyl formate in or on citrus (10-10), kiwifruit (fuzzy and hardy), and table grapes when used as a fumigant in accordance with label directions and good agricultural practices. VPTox LLC, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) on behalf of Draslovka Services Pty Ltd, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ethyl formate in or on citrus, crop group 10-10; kiwifruit, fuzzy; kiwifruit, hardy, and grape, table in accordance with the terms of the exemption.

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-2024-0426, 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: Sydnie Vergara, 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)

566-1606; 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.

- 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 proposed 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. 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-2024-0426 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*]**.

The 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 the EPA’s regulations require submission via U.S. Mail or hand delivery, the EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, the 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 November 12, 2024 (89 FR 88948) (FRL-11682-09-OCSP), 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 0F8850) by VPTox LLC, on behalf of Draslovka Services Pty Ltd., 21320 Sweet Clover Place, Ashburn VA 20147. The petitioner requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of ethyl formate. The petition did not specify any limit on the food commodities for the tolerance exemption, and EPA's notice indicated that the petition requested the exemption for all food commodities. The document referenced a summary of the petition prepared by the petitioner, Draslovka Services, which is available in the docket, <https://www.regulations.gov>. Comments were received on the notice of filing. One comment was in support of this regulation and was submitted by the California Citrus Quality Council (CCQC). Three comments were not substantive, and one comment was for a different chemical (submitted to this docket in error).

III. Final Tolerance Actions

A. EPA's Safety Determination

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure to ethyl formate, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with ethyl formate are summarized in this Unit.

B. Toxicological Profile

Ethyl formate is of low acute and subchronic toxicity. All acute toxicity data demonstrate that ethyl formate has low to negligible toxicity. For most routes of exposure (acute dermal, acute inhalation, primary eye irritation, and primary dermal irritation), ethyl formate is classified as Toxicity Category IV. For acute oral toxicity, it is classified as Toxicity Category III. It is not a dermal sensitizer.

All data and information submitted to address the subchronic data requirements (90-day oral, 90-day dermal, 90-day inhalation, genotoxicity, prenatal developmental, and maternal toxicity) are acceptable. For the 90-day oral toxicity, the study indicated the no-observable-adverse-effect-level (NOAEL) is 1000 mg/kg/day (limit dose), and a lowest-observable-adverse-effect-level (LOAEL) is therefore not established. The 90-day dermal toxicity was addressed by scientific rationales since dermal exposure to ethyl formate is not expected. For the 90-day inhalation toxicity, the study indicated the NOAEL is equal or greater than the recommended limit dose of 1.0 mg/L (330 ppm) and no endpoints were identified at this level. For genotoxicity, the Ames test determined there was no concern for genotoxic potential. The maternal toxicity, LOAEL for ethyl formate was not determined and the maternal NOAEL is greater than or equal to 1000 mg/kg/day (limit dose).

For the developmental toxicity, the study indicated the NOAEL is 300 mg/kg/day and the LOAEL is 1,000 mg/kg/day. The adverse effect identified in the database is a 9% fetal body weight reduction (combined sexes) at the extremely high dose (limit dose: 1000 mg/kg/day).

Ethyl formate is not stable, and it quickly breaks down once in contact with water. Ethyl formate has a high volatility (vapor pressure = 200 mmHg), and it is readily vaporized. Because both the NOAEL and LOAEL dose levels are far from achievable in real life, they are not considered relevant to human risk assessment.

C. Toxicological Points of Departure/Levels of Concern

No toxicological endpoints have been identified for ethyl formate since it is of low toxicity, and significant exposure is not expected based on the low application rates and rapid degradation in the environment.

D. Exposure Assessment

1. *Dietary exposure from food, feed uses and drinking water.* As part of its qualitative risk assessment for ethyl formate, the Agency considered the potential for dietary exposure to residues of the chemical. EPA concludes that dietary (food and drinking water) exposures are expected to be negligible. The end-use products (EPs) are used as fumigants in enclosed spaces and drinking water exposure is not expected. Ethyl formate is rapidly hydrolyzed in the fruits, and its residues are not anticipated to be found at levels beyond those occur naturally in the fumigated commodities (citrus crop group 10-10; kiwifruit, fuzzy; kiwifruit, hardy; and grape, table).

2. *Non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). The proposed ethyl formate end-use products are classified as Restricted Use Pesticides, (RUP) based upon the presence of inert ingredients that warrant specific worker protections. These end-use products must be applied by certified applicators. Residential handler exposures are not expected. Because the proposed use pattern only allows for fumigation uses on specific commodities, the product is not expected to be applied in residential areas, so no post-application non-occupational exposure is expected.

3. Cumulative Effects from Substances with a Common Mechanism of Toxicity.

FFDCA section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” EPA has not found ethyl formate to share a common mechanism of toxicity with any other substances, and ethyl formate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that ethyl formate does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <https://www.epa.gov/pesticides/cumulative>.

E. Safety Factor for Infants and Children

FFDCA Section 408(b)(2)(C) provides that EPA shall retain 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. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) safety factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor. An FQPA safety factor is not required at this time for ethyl formate because a qualitative dietary assessment has been conducted based on negligible dietary exposure concerns.

F. Aggregate Risk

In accordance with the FFDCA, EPA must consider and aggregate (add) pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources that have the same toxicological

endpoints are added together and compared to quantitative estimates of hazard, or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, EPA considers both the route and duration of exposure. A quantitative aggregate exposure and risk assessment was not conducted in this review because dietary exposure to pesticidal ethyl formate is considered negligible, there are no residential uses, bystander inhalation exposure is low, and ethyl formate is of low toxicity. No risks of concern have been identified.

A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the May 14, 2024, document entitled “Product Chemistry Review and Human Health Risk Assessment for FIFRA Section 3 Registrations of eFUME Fumigant and eFUME Onsite Fumigant, containing 99.76% Ethyl Formate as the Active Ingredient, and eFUME Pre-mixed Fumigant, Containing 16.7% Ethyl Formate as the Active Ingredient” This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

G. Analytical Enforcement Methodology

An analytical method is not required because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

IV. Determination of Safety for U.S. Population, Infants and Children

Based on the Agency's assessment, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of ethyl formate.

V. Revisions to Petitioned-For Tolerances

The petitioner requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of ethyl formate on all food commodities. After submitting its petition, the petitioner limited its corresponding pesticide registration application to propose use only on citrus, kiwifruit, and table grapes. Consequently, EPA is limiting this exemption from the requirement of a tolerance for residues of ethyl formate in or on citrus

commodities in crop group 10-10; kiwifruit, fuzzy; kiwifruit, hardy; and grape, table when used as a fumigant in accordance with label directions and good agricultural practices.

VI. Conclusion

EPA is establishing an exemption from the requirement of a tolerance for residues of the fumigant ethyl formate in or on the commodities in citrus, crop group 10-10; kiwifruit, fuzzy; kiwifruit, hardy, and grape, table when used in accordance with label directions and good agricultural practice.

VII. 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 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 FFDCIA 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, 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 tolerance actions 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 the pesticide-specific review documents, located in the applicable docket at <https://www.regulations.gov>.

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: July 28, 2025.

Edward Messina,

Director, Office of Pesticide Programs

For the reasons stated in the preamble, EPA is amending 50 CFR chapter I as follows:

PART 180--[AMENDED]

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

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

2. Add § 180.1419 to subpart D to read as follows:

§ 180.1419 Ethyl formate; Exemption from the Requirement of a Tolerance.

An exemption from the requirement of a tolerance is established for residues of the fumigant ethyl formate in or on the commodities in the citrus crop group 10-10; kiwifruit, fuzzy; kiwifruit, hardy; and grape, table when used in accordance with label directions and good agricultural practices.

[FR Doc. 2025-14889 Filed: 8/5/2025 8:45 am; Publication Date: 8/6/2025]