



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0447; FRL-10014-31]

Methyl Bromide; Pesticide Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of the fumigant methyl bromide, including its metabolites and degradates in or on imported/domestic agricultural commodities in fruit, citrus, group 10-10. This action is in response to EPA's granting a quarantine exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on commodities within fruit, citrus, group 10-10. This regulation establishes a maximum permissible level for residues of methyl bromide in or on these commodities. The time-limited tolerance expires on December 31, 2023.

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-2017-0447, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution

Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@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).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

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

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 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-2017-0447 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*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2017-0447, by one of the following methods:

- *Federal eRulemaking Portal*: <http://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.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6), 21 U.S.C. 346a(e) and 346a (1)(6), is establishing a time-limited tolerance for residues of methyl bromide in or on agricultural commodities in fruit, citrus, group 10-10 at 2 parts per million (ppm). By establishing a tolerance for specific commodities in this citrus fruit crop group, methyl bromide fumigation will be supported for the following crops: Australian desert lime, Australian finger lime, Australian round lime, Brown River finger lime, Calamondin, Citron, Citrus hybrids, Grapefruit, Japanese summer grapefruit, Kumquat, Lemon, Lime, Mediterranean Mandarin, Mount White Lime, New Guinea wild lime, Orange, sour, Orange, sweet, Pummelo, Russell River lime, Satsuma mandarin, Sweet lime, Tachibana orange, Tahiti Lime, Tangelo, Tangerine (Mandarin), Tangor, Trifoliate orange, and cultivars and/or hybrids of Unique fruit and varieties. The time-limited tolerance expires on December 31, 2023.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public

comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCa section 408 and its safety standard to other tolerances and exemptions. Section 408(e) of FFDCa allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of FFDCa allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCa 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. Section 408(b)(2)(C) of FFDCa 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. . . .”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Methyl Bromide on Commodities in Fruit, Citrus, Group 10-10 and FFDCa Tolerance.

The U.S. Department of Agricultural/Animal and Plant Health Inspection Service/Plant Protection and Quarantine (USDA/APHIS/PPQ) Division has requested an amendment to 40

CFR 180.124 to allow methyl bromide fumigation of citrus hybrids from Chile. EPA has previously authorized quarantine exemptions under FIFRA section 18 for the use of methyl bromide on various agricultural commodities for post-harvest control of imported, invasive, non-indigenous, quarantine plant pests in the United States. Methyl bromide fumigation is currently registered for certain individual citrus crops, but not citrus hybrids in citrus fruit group 10-10.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of methyl bromide in or on fruit, citrus, group 10-10 commodities. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the quarantine exemption in order to address an urgent non-routine situation and to ensure that commodities bearing safe levels of residues may be lawfully distributed in commerce. EPA is issuing this tolerance without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although the time-limited tolerance of 2 ppm for fruit, citrus, group 10-10 expires on December 31, 2023, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on citrus hybrid agricultural commodities in citrus, fruit group 10-10 after that date will not be unlawful, provided the pesticide was applied in a manner that is lawful under FIFRA, and the residues do not exceed a level that was authorized by the time-limited tolerance in fruit, citrus, group 10-10 at the time of that application. EPA will take action to revoke the time-limited tolerance of 2 ppm in fruit, citrus, group 10-10 earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because the time-limited tolerance in fruit, citrus, group 10-10 is being approved under

emergency conditions, EPA has not made any decisions about whether methyl bromide meets FIFRA's registration requirements for use on the specified agricultural citrus commodities or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of methyl bromide by a State for special local needs under FIFRA section 24(c). Nor does this time-limited tolerance by itself serve as the authority for any person to make emergency use this pesticide; emergency use on the applicable crops is permitted only as specified in the quarantine exemption issued to the Plant Protection and Quarantine Division of the United States Department of Agriculture and, Animal and Plant Health Inspection Service. For additional information regarding the emergency exemption for methyl bromide, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT.**

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA 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. Section 408(b)(2)(C) of FFDCA 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...."

Consistent with the factors specified in FFDCCA section 408(b)(2)(D), 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 expected as a result of this emergency exemption request and the time-limited tolerance for residues of methyl bromide in or on fruit, citrus, group 10-10 at 2 ppm. EPA's assessment of exposures and risks associated with establishing this time-limited tolerance follows.

In the **Federal Register** on March 1, 2018 (83 FR 8758) (FRL-9971-19), EPA published a final rule establishing tolerances for residues of methyl bromide in or on or various imported/domestic agricultural commodities based on the Agency's determination that aggregate exposure to methyl bromide resulting from the residues subject to those tolerances is safe for the U.S. general population, including infants and children. Because the toxicity profile for methyl bromide has not changed since that last rule was published, EPA is incorporating the discussion of that profile (Unit III.A.) and the identified toxicological endpoints (Unit III.B.) as part of this rulemaking.

EPA's most recent comprehensive risk assessment dated December 17, 2018 remains an up-to-date assessment of the toxicity of, and dietary and aggregate exposures to, methyl bromide resulting from agricultural soil fumigation uses and a variety of non-agricultural uses such as commodity fumigations. Methyl bromide is not registered for any specific residential use patterns. In that December 2018 risk assessment, EPA did not aggregate short-, intermediate-term, or chronic dietary or inhalation exposures to methyl bromide because endpoints for dietary and inhalation exposures for these durations are not based on common toxicological effects. Similarly, no quantitative cancer assessment was conducted or is required for methyl bromide based on the Agency's having classified methyl bromide as of "not likely to be carcinogenic to

humans.” Further information about EPA’s risk assessments and determination of safety supporting the tolerances established in the March 1, 2018 *Federal Register* action, as well as the new methyl bromide time-limited tolerance can be found at <http://www.regulations.gov> in the documents entitled “Methyl Bromide. Human Health Risk Assessment for the Section 18 Emergency Exemption Use on USDA APHIS PPQ Commodities,” dated September 13, 2013, “Methyl Bromide. Section 18 Emergency Quarantine Exemption Use on Commodities Requested by the U.S. Department of Agriculture/Animal and Plant Health Inspection Service/Plant Protection and Quarantine (USDA/ APHIS/PPQ) Division,” dated May 2, 2017, and “Methyl Bromide. Amended Section 18 Emergency Quarantine Exemption for Use on Citrus Fruit Group 10-10 as Requested by the U.S. Department of Agriculture/Animal and Plant Health Inspection Service/Plant Protection and Quarantine (USDA/ APHIS/PPQ) Division,” dated May 7, 2018, respectively. All these documents can be found in docket ID EPA-HQ-OPP-2017-0447.

The acute and chronic dietary risk estimates for methyl bromide are partially refined since they incorporate anticipated residues, assume no methyl bromide residues are present in cooked commodities or in processed commodities subjected to heat, but include no adjustments for percent crop treated (PCT) (*i.e.*, 100 PCT is assumed). The acute and chronic dietary estimates for methyl bromide were found not to be of concern for the U.S. general population and all population subgroups. Acute dietary risks for methyl bromide are below the Agency’s LOC: 3.3% of the aPAD for children 1 to 2 years old, the population group with the highest exposure; and chronic risks are below the Agency’s LOC: 38% of the cPAD for children 1 to 2 years old, the group with the highest exposure level.

There are no residential uses of methyl bromide. Non-occupational and ambient exposures are not typically aggregated with dietary exposures because the former is isolated and

sporadic in nature, and the likelihood of having a significant food exposure occurring concurrently with a significant non-occupational exposure is negligible.

Therefore, the aggregate exposure assessments are equivalent to the dietary risk assessments.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the U.S. general population, or to infants and children, from aggregate exposure to methyl bromide residues. More detailed information on the subject action to establish a tolerance in or on fruit, citrus, group 10-10 can be found at <http://www.regulations.gov> in the document entitled, "Methyl Bromide. Amended Section 18 Emergency Quarantine Exemption for Use on Citrus Fruit Group 10-10 as Requested by the U.S. Department of Agriculture/Animal and Plant Health Inspection Service/Plant Protection and Quarantine (USDA/ APHIS/PPQ) Division." This document can be found in docket ID number EPA-HQ-OPP-2017-0447.

V. Other Considerations

A. Analytical enforcement methodology

An adequate enforcement methodology (King headspace method, J. Agricultural Food Chemistry, Vol 29, No. 5, pp 1003-1005) is available to enforce the tolerance expression. This method is a gas chromatography/electron capture (GC/EC) method that was validated in 1987 in the EPA Environmental Chemistry Laboratory (D168869, L. Cheng, 27-OCT-1992). The headspace procedure for determining methyl bromide has been forwarded to FDA for inclusion in PAM Vol. II. This method is adequate for data collection and for tolerance enforcement on plant and processed food commodities.

B. International residue limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Methyl bromide Codex MRLs have been established for several commodities; however, there are no Codex MRLs for any of the commodities that are the subject of this quarantine action.

VI. Conclusion

Therefore, a time-limited tolerance is established for residues of the fumigant methyl bromide, including its metabolites and degradates for the citrus fruit crop group, 10-10. Compliance with the tolerance level is to be determined by measuring only methyl bromide residues, in or on commodities in fruit, citrus, group 10-10. This tolerance expires on December 31, 2023.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA sections 408(e) and 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735,

October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs”) 82 FR 9339, February 3, 2017. This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in support of a FIFRA section 18 emergency exemption do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, but does not directly regulate 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 (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 (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: September 11, 2020.

Marietta Echeverria,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 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. In §180.124 amend paragraph (b) by:

a. Revising the introductory text and redesignating the table as Table 2 to paragraph (b);

and

b. Amending newly designated Table 2 to paragraph (b) by adding, in alphabetical order, the entry “Fruit, citrus, group 10-10”.

The revision and addition read as follows:

§ 180.124 Methyl Bromide; tolerance for residues.

* * * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the fumigant methyl bromide, including its metabolites and degradates, in or on the specified agricultural commodity in the table below. Compliance with the tolerance level specified below is to be determined by measuring only methyl bromide, in or on the commodities, resulting from use of the pesticide pursuant to Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) section 18 emergency exemptions. The tolerance expires and is revoked on the date specified in the table.

Table 2 to paragraph (b)

Commodity	Parts per million	Expiration date
* * *	* * *	* *

Fruit, citrus, group 10-10	2	12/31/2023
* * *	* * *	* *

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[FR Doc. 2020-21199 Filed: 10/15/2020 8:45 am; Publication Date: 10/16/2020]