

Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: *residuemethods@epa.gov*.

**B. International Residue Limits**

There are no CODEX, Canadian, or Mexican tolerances/Maximum Residue Levels for mesotrione residues for the proposed crops.

**V. Conclusion**

Therefore, the tolerance is established for residues of mesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in or on asparagus at 0.01 ppm; grass, seed screenings at 0.10 ppm; grass, straw at 0.10 ppm; grass, forage at 0.01 ppm; grass, hay at 0.01 ppm; oat, grain at 0.01 ppm; oat, straw at 0.01 ppm; oat, forage at 0.01 ppm; oat, hay at 0.01 ppm; okra at 0.01 ppm; rhubarb at 0.01 ppm; sorghum, grain, forage at 0.01 ppm; sorghum, grain, grain at 0.01 ppm; sorghum, grain, stover at 0.01 ppm; sorghum, sweet at 0.01 ppm and sugarcane, cane at 0.01 ppm.

**VI. Statutory and Executive Order Reviews**

This final rule establishes a tolerance under section 408(d) of FFDCA 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, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *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). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 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 on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. 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 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

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 of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: February 7, 2008.

**Lois Rossi**,  
*Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended 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. Section 180.571 is amended by alphabetically adding the following commodities in the table in paragraph (a) to read as follows:

**§ 180.571 Mesotrione; tolerances for residues.**

\* \* \* \* \*

Commodity	Parts per million
Asparagus .....	0.01
* * * * *	* *
Grass, seed screenings ....	0.10
Grass, straw .....	0.10
Grass, forage .....	0.01
Grass, hay .....	0.01
* * * * *	* *
Oat, grain .....	0.01
Oat, straw .....	0.01
Oat, forage .....	0.01
Oat, hay .....	0.01
Okra .....	0.01
Rhubarb .....	0.01
Sorghum, grain, forage .....	0.01
Sorghum, grain, grain .....	0.01
Sorghum, grain, stover .....	0.01
Sorghum, sweet .....	0.01
Sugarcane, cane .....	0.01

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2006-0916; FRL-8343-6]

**Formetanate Hydrochloride; Pesticide Tolerances for Emergency Exemptions**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for residues of formetanate hydrochloride, *m*-[[[dimethylamino)methylene]amino]phenyl methylcarbamate hydrochloride, in or on dry bulb onions. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on dry bulb onions. This regulation establishes a maximum permissible level for residues of formetanate hydrochloride in this food commodity. The tolerance expires and is revoked on December 31, 2008.

**DATES:** This regulation is effective February 20, 2008. Objections and requests for hearings must be received on or before April 21, 2008, 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:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0916. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,

DC 20460-0001; telephone number: (703) 308-9367; e-mail address: [ertman.andrew@epa.gov](mailto:ertman.andrew@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. Potentially affected entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. 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. How Can I Access Electronic Copies of this Document?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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-2006-0916 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before April 21, 2008.

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 that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2006-0916., by one of the following methods:

• **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

• **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

**II. Background and Statutory Findings**

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of FFDCA, 21 U.S.C. 346a, is establishing a tolerance for residues of the insecticide formetanate hydrochloride, *m*-[[[dimethylamino)methylene]amino]phenyl methylcarbamate hydrochloride, in or on onions, dry bulb at 0.02 parts per million (ppm). This tolerance expires and is revoked on December 31, 2008. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the CFR.

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 section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances

to set binding precedents for the application of section 408 of FFDCA 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." This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

### III. Emergency Exemption for Formetanate Hydrochloride on Dry Bulb Onions and FFDCA Tolerances

The states of Idaho, Oregon, Colorado, Michigan, Ohio, Wisconsin, Texas and New York requested the use of formetanate hydrochloride, formulated as the product Carzol, on dry bulb onions to control thrips. According to these states, the available registered alternatives were not providing adequate control of this pest and without the use of Carzol, growers would suffer significant economic losses. After having reviewed the submissions, EPA concurred that emergency conditions exist and authorized under FIFRA section 18 the use of formetanate hydrochloride on dry bulb onions for control of thrips in Idaho, Oregon, Colorado, Michigan, Ohio, Wisconsin, Texas and New York.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of

formetanate hydrochloride in or on dry bulb onions. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although this tolerance expires and is revoked on December 31, 2008, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on dry bulb onions after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether formetanate hydrochloride meets EPA's registration requirements for use on dry bulb onions or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of formetanate hydrochloride by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for persons in any State other than Idaho, Oregon, Colorado, Michigan, Ohio, Wisconsin, Texas and New York to use this pesticide on this crop under section 18 of FIFRA. For additional information regarding the emergency exemption for formetanate hydrochloride, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

### IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see [\[www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm\]\(http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm\).](http://</a></p>
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Consistent with section 408(b)(2)(D) of FFDCA, 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 formetanate hydrochloride and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a time-limited tolerance for residues of formetanate hydrochloride in or on onions, dry bulb at 0.02 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows. In addition, an Interim Reregistration Eligibility Decision (IRED) Document was published in March 2006. This IRED was proposed to become a final RED in the N-methyl Carbamate Revised Cumulative Risk Assessment that was made available for public comment on September 26, 2007. This IRED/RED provides additional information and more detail on the dietary exposures and risks associated with formetanate hydrochloride. The link for this document on the EPA website is: [http://www.epa.gov/oppsrrd1/REDs/formetanatehcl\\_ired.pdf](http://www.epa.gov/oppsrrd1/REDs/formetanatehcl_ired.pdf).

#### A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute population Adjusted Dose (aPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to

determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q\*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q\* approach assumes that any amount of exposure will lead to some degree of cancer risk.

A Q\* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10<sup>6</sup> or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve.

To estimate risk, a ratio of the point of departure to exposure (MOE<sub>cancer</sub> = point of departure/exposures) is calculated. A summary of the toxicological endpoints for formetanate hydrochloride used for human risk assessment is shown in the following Table. In addition, as noted above in Unit IV., a detailed summary of the toxicological endpoints can be found in the Formetanate Hydrochloride IRED (which, as noted previously, is now proposed to become a final RED) ([http://www.epa.gov/oppsrrd1/REDS/formetanatehcl\\_ired.pdf](http://www.epa.gov/oppsrrd1/REDS/formetanatehcl_ired.pdf)).

TABLE 1.—SUMMARY OF TOXICOLOGICAL ENDPOINTS AND DOSES FOR FORMETANATE HYDROCHLORIDE DIETARY RISK ASSESSMENTS

Exposure Scenario	Dose UF/MOE	Hazard Based FQPA Safety Factor	Endpoint for Risk Assessment
Acute Dietary females 13-50 years of age	Not applicable; the endpoint selected for the general population (see below) based on, and therefore protective of, this population subgroup.		
Acute Dietary general population	BMDL <sub>10</sub> = 0.065 mg/kg UF = 100 (a) aRfD = 0.00065 mg/kg	1X Acute PAD = 0.00065 mg/kg.	BMDL <sub>10</sub> for female pup brain AChE in the Comparative ChE study.
Chronic Dietary	Not applicable; data on formetanate hydrochloride indicate that the magnitude of cholinesterase inhibition (ChEI) does not increase with continued exposure because of the rapid reversibility of ChEI. Therefore, chronic exposure to formetanate hydrochloride may be considered as a series of acute exposures.		
Incidental Oral Short and intermediate terms	Not applicable. There are no current registrations for residential uses.		
Cancer	Group E Carcinogen; Classification: "Not likely."		

### B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.276) for the residues of formetanate hydrochloride, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from formetanate hydrochloride in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. A tier 3, acute probabilistic dietary risk assessment was conducted using the Dietary Exposure Evaluation Model (DEEM-FCID, Version 2.03), which uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. Drinking water exposure was incorporated directly into the dietary exposure analysis. The dietary assessment relies on Pesticide Data Program (PDP) monitoring data from 2001 for oranges, grapefruit and pears. Anticipated residues for apples are

derived using field trial data, since the PDP data reflect the late-season use on apples, which is no longer being supported by the registrant. Field trial residue data were submitted with the exemption request for both peeled and unpeeled onions. Since onions are generally peeled prior to eating, the peeled onion data were used in this assessment. No adjustment was made to account for the percent of onions treated (i.e., 100% crop treated was assumed).

ii. *Chronic exposure.* Cholinesterase inhibition (ChEI) is the only manifestation of exposure to formetanate HCl observed in the variety of toxicity studies conducted to support reregistration of this active ingredient. These formetanate HCl studies indicate that the magnitude of cholinesterase inhibition (ChEI) does not increase with continued exposure because of the rapid reversibility of ChEI. Therefore, chronic exposure to formetanate HCl may be considered as a series of acute exposures, indicating that a chronic dietary exposure assessment is not necessary.

iii. *Cancer.* Formetanate hydrochloride is classified as a group

"E" carcinogen, and therefore a cancer exposure assessment is not required.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to FFDCA section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such data call-ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a

comprehensive dietary exposure analysis and risk assessment for formetanate hydrochloride in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of formetanate hydrochloride. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Tier II screening models, Pesticide Root Zone Model and Exposure Analysis Modeling System (PRZM and EXAMS) with the Index Reservoir and Percent Cropped Area adjustment (IR-PCA PRZM/EXAMS) were used to determine estimated surface water concentrations of formetanate HCL following application to apples in North Carolina, Pennsylvania and Oregon. As noted in previous sections of this document, additional detailed information regarding formetanate hydrochloride, including dietary exposure from drinking water can be found in the March 2006 IRED ([http://www.epa.gov/oppsrrd1/REDS/formetanatehcl\\_ired.pdf](http://www.epa.gov/oppsrrd1/REDS/formetanatehcl_ired.pdf)).

Based on the PRZM/EXAMS model described above, the highest estimated environmental concentration (EEC) of formetanate hydrochloride for acute exposures is estimated to be 7.7 parts per billion (ppb) for surface water based on applications to apples in North Carolina.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID™, Version 2.03). For the acute dietary risk assessment, the entire distribution of estimated daily exposure values from the PRZM-EXAMS run was used probabilistically in the analysis to assess the contribution to drinking water.

3. *Non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Formetanate hydrochloride is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular

pesticide’s residues and “other substances that have a common mechanism of toxicity.”

Formetanate hydrochloride belongs to the *N*-methyl carbamate class of chemicals for which a revised cumulative assessment has recently (72 FR 54656, September 26, 2007) been published by the Agency in the **Federal Register** for comment ([http://www.epa.gov/oppsrrd1/REDS/nmc\\_revised\\_cra.pdf](http://www.epa.gov/oppsrrd1/REDS/nmc_revised_cra.pdf)). This “Revised *N*-Methyl Carbamate Cumulative Risk Assessment” concludes that the cumulative risks from food, water, and residential exposure to *N*-methyl carbamates do not exceed the Agency’s level of concern.

Field trial data for formetanate hydrochloride residues on peeled onion (the value used in dietary risk assessment) are below the LOD of 0.0007 ppm. Field trial data are much more conservative (often 1 to 2 orders of magnitude higher in residue) than the PDP data generally used for registered uses in the cumulative assessment. Using residue values at half the LOQ of 0.002 ppm had negligible impact on dietary risk for formetanate hydrochloride in the *N*-methyl carbamate cumulative assessment. Furthermore, food derived from onion is not a significant contributor to the diet of infants less than 1 year old (the most sensitive subpopulation in the *N*-methyl carbamate cumulative assessment).

If a tolerance were currently in place for formetanate hydrochloride use on onion, it would be among the “Insignificant Contributors” that, in their entirety, account for only 3% of the total risk in the *N*-methyl carbamate “risk cup.” These “Insignificant Contributors” had their tolerances fully reassessed on June 29, 2006 prior to completion of the full *N*-methyl carbamate cumulative assessment. See [http://www.epa.gov/pesticides/cumulative/carbamates\\_commodity.pdf](http://www.epa.gov/pesticides/cumulative/carbamates_commodity.pdf).

In light of these residue findings for formetanate hydrochloride on onion, the Agency does not expect any significant contribution of exposure to the cumulative assessment and therefore, the conclusions from the revised cumulative risk assessment for the *N*-methyl carbamates remain unaffected by this emergency use on onions.

#### C. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold 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 that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* Formetanate HCl did not result in developmental toxicity in either rats or rabbits or in reproductive effects in the multi-generation reproduction study. There was no indication of increased offspring susceptibility in these studies.

3. *Conclusion.* There is a complete toxicity database for formetanate hydrochloride and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency determined that the FQPA Safety Factor can be removed (reduced to 1X) due to lack of concern and no residual uncertainties for prenatal and/or postnatal toxicity. Due to the conservative, health-protective nature of the models and the input parameters, EPA believes exposure via drinking water will not be underestimated. Therefore, the current hazard and exposure data support reducing the FQPA Safety Factor to 1X. Additional information may be found in the March 2006 IRED ([http://www.epa.gov/oppsrrd1/REDS/formetanatehcl\\_ired.pdf](http://www.epa.gov/oppsrrd1/REDS/formetanatehcl_ired.pdf)).

#### D. Aggregate Risks and Determination of Safety

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against estimated drinking water concentrations (EDWCs). The DWLOC values are not regulatory standards for drinking water, but are theoretical upper limits on the concentration of a pesticide in drinking water that can be considered safe in light of total aggregate exposure to a pesticide in food and residential uses. More information on the use of DWLOCs in dietary aggregate risk assessments can be found at <http://www.epa.gov/oppefed1/trac/science/screeningsop.pdf>.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface and ground water EDWCs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic

estimate of exposure because actual body weights and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs. The risk assessment for formetanate hydrochloride used in this tolerance document uses this approach of incorporating water exposure directly into the dietary exposure analysis.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to formetanate hydrochloride will occupy 36% of the aPAD for the U.S. population, 29% of the aPAD for females 13 years and older, 117% of the aPAD for all infants less than 1 year old and 69% of the aPAD for children 1 to 2 years old.

These risk estimates are based on upper-end (99.9th percentile) exposure estimates for each population. The 99.9th percentile is used "in the first instance" in estimating exposure for probabilistic acute dietary exposure assessments which are based on highly refined exposure inputs. EPA evaluates whether to vary from use of the 99.9th percentile in assessing exposure based on considerations primarily related to the conservativeness or lack thereof of the various inputs to the assessment, with particular emphasis on an examination of the conservativeness of those inputs that most greatly influence the risk estimate. There are several inputs to the current assessment that are quite conservative. First, anticipated residue data for apples is based on field trial data as opposed to PDP data; this is likely to substantially overstate residue levels in apples as consumed. Second, EPA assumed that 100% of the onion crop will be treated with formetanate. Actual percent crop treated is likely to be substantially lower than that, if for no other reason than use is only permitted in a few States. Third, and most important, the estimated residue levels in water are very conservative compared to the refined food estimates that generally cause EPA to rely on the 99.9th percentile. This is particularly critical because the estimated dietary exposure from drinking water is the principal driver of the risk assessment, accounting for 106% of the aPAD for infants when considered alone.

The drinking water exposure estimates were based on PRZM-EXAMS surface water modeling results. The

PRZM-EXAMS model is intended to provide upper-end estimates of pesticide residues in surface water. The models use an Index Reservoir based on an actual drinking water reservoir in Illinois (Shipman City Lake) that is known to be vulnerable to pesticide contamination. Pesticide loadings to the water body are modeled using local soils and weather data to reflect crop-specific scenarios around the country. The conservativeness of this model and its tendency to overestimate residues was documented by EPA in an earlier tolerance proceeding. (69 FR 30042, 30060-30063, May 26, 2004). Additionally, there are pesticide-specific factors here that insure that PRZM-EXAMS modeling results will overestimate residue levels in drinking water.

The modeling results were adjusted by a Percent Cropped Area (PCA) factor of 0.87. In other words, the results assume that 87% of the watershed is cropped in apples (or other crops with similar use of formetanate) and that 100% of these crops are treated with formetanate HCl. The PCA factor does not consider the percent of the crop that is actually treated because detailed pesticide usage data (i.e., at the state or watershed level) are generally unavailable or inadequate. In the case of formetanate HCl, however, the national usage estimates suggest that a PCA factor of 0.87 significantly overestimates drinking water concentrations in many areas. Maximum percent crop treated (PCT) estimates for apple, pear, peach, orange and grapefruit are 5% or less, and maximum PCT estimates for lemon/lime and nectarine are 15% and 46%, respectively. Thus, while it is theoretically possible there could be water basins in the United States that are planted almost entirely with crops that may lawfully be treated with formetanate HCl and that all crops in that water basin would be treated with formetanate HCl, the probability of these two unlikely events occurring together is very low.

Accordingly, it is EPA's judgment that use of the 99.9th percentile to estimate exposure significantly overstates exposure and thus the estimated slight exceedance of the aPAD (117%) for infants does not show a risk of concern. This is confirmed by the fact the estimated exposure for this population group declines below the aPAD at the 99.86th percentile level.

2. *Chronic risk.* As noted in Unit IV.B.1.ii. of this preamble, cholinesterase inhibition (ChEI) is the only manifestation of exposure to formetanate hydrochloride observed in the variety of toxicity studies conducted

to support reregistration of this active ingredient. These formetanate hydrochloride studies indicate that the magnitude of cholinesterase inhibition (ChEI) does not increase with continued exposure because of the rapid reversibility of ChEI. Therefore, chronic exposure to formetanate hydrochloride may be considered as a series of acute exposures, indicating that a chronic dietary risk assessment is not necessary. Inasmuch as EPA has concluded that there is no acute risk of concern, chronic risk is also not of concern.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Formetanate hydrochloride is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the chronic risk from food and water, which was previously addressed and is not of concern.

4. *Aggregate cancer risk for U.S. population.* Formetanate hydrochloride is classified as a group "E" carcinogen and is therefore not expected to pose a cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to formetanate hydrochloride residues.

## V. Other Considerations

### A. Analytical Enforcement Methodology

An adequate method is available for enforcement of the currently established plant tolerances Gas Chromatography with Electron Capture Detection (GC/ECD method (Method I); PAM Vol. II). For purposes of the Section 18 emergency exemption, EPA concludes that this method is sufficient to enforce the recommended onion tolerance.

### B. International Residue Limits

There are no CODEX residue limits for residues of formetanate hydrochloride on onions, therefore, harmonization is not an issue.

## VI. Conclusion

Therefore, a time-limited tolerance is established for residues of formetanate hydrochloride; *m*-[[[(dimethylamino)methylene]amino]phenyl methylcarbamate hydrochloride in or on onion, dry bulb at 0.02 ppm. This time-limited tolerance expires and is revoked on December 31, 2008.

**VII. Statutory and Executive Order Reviews**

This final rule establishes a time-limited tolerance under section 408 of FFDCA. 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 rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *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). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 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 on the basis of a FIFRA section 18 exemption under section 408 of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. 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 6, 2000) do not apply to this rule. In addition, this rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded

Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

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 of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

**VIII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: February 6, 2008.

**Lois Rossi,**  
*Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended 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. Section 180.276 is amended by adding text to paragraph (b) to read as follows:

**§ 180.276 Formetanate hydrochloride; tolerances for residues.**

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the insecticide formetanate hydrochloride (*m*-[[dimethylamino]methylene]amino]phenyl methylcarbamate hydrochloride) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances in this paragraph will expire and are revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Onion, dry bulb	0.02	12/31/08

\* \* \* \* \*

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**GENERAL SERVICES ADMINISTRATION**

**41 CFR Part 102-118**

[FMR Amendment 2008-04; FMR Case 2007-102-4; Docket 2008-0001; Sequence 1]

RIN 3090-AI41

**Federal Management Regulation; FMR Case 2007-102-4, Transportation Payment and Audit; Refund of Expired, Unused Tickets**

**AGENCY:** Office of Governmentwide Policy, General Services Administration (GSA).

**ACTION:** Interim final rule.

**SUMMARY:** The General Services Administration is amending the Federal Management Regulation (FMR) pertaining to unused tickets. The section is being deleted that was published without a public comment period.

**DATES:** This final rule is effective on: February 20, 2008.

**FOR FURTHER INFORMATION CONTACT:** For clarification of content, contact Mr. Ted J. Bembenek, Jr., at (202) 208-7629. The Regulatory Secretariat, Room 4035, GS Building, Washington, DC 20405, (202) 501-4755, for information pertaining to status or publication schedules. Please cite FMR Case 2007-102-4, Amendment 2008-04.

**SUPPLEMENTARY INFORMATION:**

**A. Background**

GSA published § 102-118.196 in the **Federal Register** at 69 FR 57619, September 24, 2004, as an addition to part 118 of Title 41 (41 CFR part 118). The amendment was published as a final rule without a comment period and required that Transportation Service Providers (TSPs) refund the value of expired, unused tickets to GSA's Audit Division when a ticket purchasing agency fails to notify the TSP of a cancellation.

Since its publication, GSA has received feedback from sources who wanted to offer comments at the time the rule was originally published. After receipt of contacts from these sources,