telephone at (703) 308–5075, or by fax at (703) 308–5077.

SUPPLEMENTARY INFORMATION: A final rule revising certain patent fee amounts for fiscal year 2005 was published as FR Doc. 69–52604 in the **Federal Register** of August 27, 2004 (69 FR 52604). The final rule contains an error for an appeal fee in section 41.20(b)(3). The fee amount for fiscal year 2005 was incorrectly stated as $170.00 for a small entity, and $340.00 for other than a small entity. This correction revises this appeal fee amount.

■ In rule FR Doc. 69–52604 published on August 27, 2004 (69 FR 52604), make the following correction. On page 52606, in the third column, change the appeal fee amount for 41.20(b)(3) to $150.00 for a small entity, and $300.00 for other than a small entity.

Dated: September 8, 2004.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 04–20766 Filed 9–14–04; 8:45 am]

BILLING CODE 3510–16–P

POSTAL SERVICE

39 CFR Part 501

Authorization To Manufacture and Distribute Postage Meters

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: This rule corrects outdated or incorrect information in the text of the cautionary label required to be placed on rented postage meters.

DATES: Effective September 15, 2004.

FOR FURTHER INFORMATION CONTACT: Stanley F. Mires, (202) 268–2958.

SUPPLEMENTARY INFORMATION: Amendment of part 501 is necessary to ensure that the cautionary labels required to be placed on rented postage meters contain current information.

List of Subjects in 39 CFR Part 501

Administrative practice and procedure.

■ For the reasons set forth above, the Postal Service amends 39 CFR part 501 as follows:

PART 501—[AMENDED]

■ 1. The authority citation for part 501 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 410, 2601, 2605; Inspector General Act of 1978, as amended (Pub. L. 95–452, as amended), 5 U.S.C. App. 3.

■ 2. Revise § 501.23(r)(1) to read as follows:

§ 501.23 Distribution controls.

* * * * *

(r) * * *

(1) The cautionary label must be placed on all meters in a conspicuous and highly visible location. Words printed in capital letters should be emphasized, preferably printed in red. The minimum width of the label should be 3.25 inches, and the minimum height should be 1.75 inches. The label should read as follows:

RENTED POSTAGE METER—NOT FOR SALE PROPERTY OF [NAME OF MANUFACTURER]

Use of this meter is permissible only under U.S. Postal Service license. Call [Name of Manufacturer] at (800) ###–#### to relocate/return this meter.

WARNING! METER TAMPERING IS A FEDERAL OFFENSE. IF YOU SUSPECT METER TAMPERING, CALL POSTAL INSPECTORS AT 1–800–654–8896

REWARD UP TO $50,000 for information leading to the conviction of any person who misuses postage meters resulting in the Postal Service not receiving correct postage payments.

* * * * *

Previous versions of the cautionary label are out of date, and should be replaced by the manufacturer when the meter is returned by the licensee for any reason or inspected under § 501.26.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 04–20095 Filed 9–14–04; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0254; FRL–7675–6]

Thiamethoxam; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of thiamethoxam and CGA–322704 in or on cranberries at 0.02 parts per million (ppm). This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on cranberries. This regulation establishes a maximum permissible level for residues of thiamethoxam in this food commodity. The tolerance will expire and is revoked on December 31, 2007.

DATES: This regulation is effective September 15, 2004. Objections and requests for hearings must be received on or before November 15, 2004.

ADDRESSES: To submit a written objection or hearing request, follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0254. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Stacey Milan Groce, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–2505; e-mail address:*milan.stacey@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you a Federal or State Government Agency involved in administration of environmental quality programs (i.e. United States Departments of Agriculture, Environment, etc). Potentially affected entities may include, but are not limited to:

- Federal or State Government Entity (NAICS 9241)

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 and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for combined residues of the insecticide thiamethoxam and CGA–322704, in or on cranberries at 0.02 parts per million (ppm). This tolerance will expire and is revoked on December 31, 2007. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the 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 the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the 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 the 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 the 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 the 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 the 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 the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Thiamethoxam on Cranberries and FFDCA Tolerances

The State of Massachusetts has requested the use of thiamethoxam on cranberries to control cranberry weevil. EPA has authorized under FIFRA section 18 the use of thiamethoxam on cranberries for control of cranberry weevil in Massachusetts. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of thiamethoxam in or on cranberries. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the 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 the FFDCA. Although this tolerance will expire and is revoked on December 31, 2007, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on cranberries 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 thiamethoxam meets EPA's registration requirements for use on cranberries 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 thiamethoxam by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Massachusetts to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for thiamethoxam, 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 the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D) of the 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 thiamethoxam and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for combined residues of thiamethoxam and CGA–322704 in or on cranberries at 0.02 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

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 (acute RfD or chronic RfD) 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 or chronic Population Adjusted Dose (aPAD or cPAD) 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 $x10^{-6}$ 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_{cancer} = point of departure/exposures) is calculated. For a detailed summary of the toxicological endpoints for thiamethoxam used for human risk assessment, refer to Table 1 in the August 27, 2003 **Federal Register** (68 FR 51471, FRL–7320–2) final rule establishing tolerances for the combined residues of thiamethoxam on hops, bean, succulent, and bean, dried.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.565) for the combined residues of thiamethoxam, in or on a variety of raw agricultural commodities. The following crop sites have established tolerances: Barley, canola, cotton, sorghum, wheat, tuberous and corn vegetables crop subgroup, fruiting vegetables crop group, tomato paste, cucurbit vegetables crop group, pome fruits crop group, milk and meat, and meat by products of cattle, goats, horses, and sheep. Risk assessments were conducted by EPA to assess dietary exposures from thiamethoxam 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. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Tolerance level residues and 100% crop treated.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tier 3 analyses that incorporate anticipated residues and percent crop treated (PCT) refinements for most commodities.

iii. *Cancer.* The cancer exposure estimates are based on Tier 3 analyses that incorporate anticipated residues and PCT information for most commodities.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue 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 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. As required by section 408(b)(2)(E) of the FFDCA, EPA will issue a Data Call-In for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: Potatoes, 19%; fruiting vegetables, 15%; cucumbers, 5%; melons, 13%; casabas, 44%; crenshaws, 44%; squash, 44%; pumpkins, 44%; apples, 5%; crabapples, 53%; pears, 9%; quinces, 53%; loquat, 53%; barley, 0.1%; sorghum, 9%; wheat, 2%; canola, 55%; cotton, 20%.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be

exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which thiamethoxam may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for thiamethoxam 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 thiamethoxam.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentrations in Groundwater (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to thiamethoxam they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of thiamethoxam for acute exposures are estimated to be 7.1 parts per billion (ppb) for surface water and 1.94 ppb for ground water. The EECs for chronic exposures are estimated to be 0.43 (non-cancer) and 0.13 ppb (cancer) for surface water and 1.94 ppb for ground water (cancer and non-cancer).

3. *From 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). Thiamethoxam is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the 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.''

EPA does not have, at this time, available data to determine whether thiamethoxam has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, thiamethoxam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that thiamethoxam has 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 the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Safety Factor for Infants and Children

1. *In general*. Section 408 of the 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 data base 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*. The developmental toxicity studies indicated no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetus to in utero exposure based on the fact that the developmental NOAELs are either higher than or equal to the maternal NOAELs. However, the reproductive studies indicate effects in male rats in the form of increased incidence and severity of testicular tubular atrophy. These data are considered to be evidence of increased quantitative susceptibility for male pups when compared to the parents.

3. *Conclusion. Based on*:

i. Effects on endocrine organs observed across species.

ii. The significant decrease in alanine amino transferase levels in the companion animal studies and in the dog studies.

iii. The mode of action of this chemical in insects (interferes with the nicotinic acetyl choline receptors of the insect's nervous system) thus a developmental neurotoxicity study is required.

iv. The transient clinical signs of neurotoxicity in several studies across species.

v. The suggestive evidence of increased quantitative susceptibility in the rat reproduction study, the Agency is retaining the FQPA factor which is l0X.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to thiamethoxam in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of thiamethoxam on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to thiamethoxam will occupy 3% of the aPAD for the U.S. population, 2% of the aPAD for females 13 years and older, 7% of the aPAD for all infants < 1 year old and 9% of the aPAD for children 1–2 years old. In addition, despite the potential for acute dietary exposure to thiamethoxam in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of thiamethoxam in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to thiamethoxam from food will utilize 4% of the cPAD for the U.S. population, 8% of the cPAD for all infants < 1 year old and 12% of the cPAD for children 1–2 years old. There are no residential uses for thiamethoxam that result in chronic residential exposure to thiamethoxam. In addition, despite the potential for chronic dietary exposure to thiamethoxam in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of thiamethoxam in surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

For a detailed discussion of the aggregate risk assessments and determination of safety, refer to the August 27, 2003 (68 FR 51471, FRL–7320–2) final rule establishing tolerances for combined residues of thiamethoxam on hops, bean, succulent, and bean, dried. EPA relies upon that risk assessment and the findings made in the **Federal Register** document in support of this action.

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Thiamethoxam is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Thiamethoxam is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

5. *Aggregate cancer risk for U.S. population*. At the present time, there are no uses of thiamethoxam that will result in non-dietary, non-occupational (i.e., residential) exposures. Therefore, aggregate cancer risk estimates for thiamethoxam address only the food and drinking water pathways of exposure. Estimated environmental concentrations for thiamethoxam for comparison to the DWLOCs is 1.94 µg/L for cancer scenarios. The Agency does not have aggregate risk concerns when the estimated residues in water are less than the DWLOCs.

For cancer risk, which is estimated for the total U.S. population only, the DWLOC is 2.15 µg/L and assumes a negligible risk level of 3×10^{-6}. For risk management purposes, EPA considers a cancer risk to be greater than negligible when it exceeds the range of 1 in 1 million, however the Agency has generally treated cancer risks up to 3 in 1 million as within the range of 1 in 1 million. The DWLOC value indicates that aggregate exposure to thiamethoxam is not likely to exceed the Agency's level of concern.

EPA recognizes that the active ingredient clothianidin is identical to the thiamethoxam metabolite-of-concern CGA–322704, however, clothianidin has not been classified as a carcinogen and therefore, it has been removed from the cancer assessment.

6. *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, and to infants and children from aggregate exposure to thiamethoxam residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology High Performance Liquid Chromatography using ultra violet or mass spectrometry (HPLC/UV or MS) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: *furlow.calvin@epa.gov*.

B. International Residue Limits

There are no CODEX, Canadian, or Mexican maximum residue limits that impact this action.

C. Conditions

Rotational crop restrictions. The thiamethoxam label currently contains the following rotational crop restriction: Immediate rotation to any crop on the label or to cucurbit vegetables, fruiting vegetables, cotton, sorghum, corn, wheat, barley, canola, tuberous and corm vegetables, and tobacco. For all other crops, a 120–day plant back interval must be observed.

VI. Conclusion

Therefore, the tolerance is established for the combined residues of thiamethoxam and CGA–322704, in or on cranberries at 0.02 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the 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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0254 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 November 15, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2.*Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII..A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by the docket ID number OPP–2004–0254, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes a time-limited tolerance under section 408 of the 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 due to its lack of significance, 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the 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. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process

to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that 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.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, 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.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: August 25, 2004.

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 180.565 is amended by alphabetically adding the commodity to the table in paragraph (b) to read as follows:

§ 180.565 Thiamethoxam; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
*	* *	* *
Cranberry	0.02 ppm	12/31/07
*	* *	* *

* * * * *

[FR Doc. 04–20797 Filed 9–14–04; 8:45 am]

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CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

40 CFR Part 1620

Administrative Claims Arising Under the Federal Tort Claims Act

AGENCY: Chemical Safety and Hazard Investigation Board.

ACTION: Final rule.

SUMMARY: The Chemical Safety and Hazard Investigation Board (CSB) adopts the following rule to aid the processing of administrative claims for monetary damages filed under the Federal Tort Claims Act (FTCA). This rule provides information to members of the public who suffer loss or damage of property, personal injury, death, or other damages allegedly caused by the negligence or other wrongful act or omission of CSB officers or employees while acting in the scope of their office or employment. The rule also governs the procedures by which such claims are administratively processed.

DATES: This rule is effective November 15, 2004.

FOR FURTHER INFORMATION CONTACT: Christopher M. Lyon, CSB Office of General Counsel, (202) 261–7600.

SUPPLEMENTARY INFORMATION: The Federal Tort Claims Act (FTCA), 28 U.S.C. 1346(b), 2401(b), 2671–2680, waives the federal government's sovereign immunity to civil suits for damages in certain instances arising out of the negligent or otherwise wrongful acts or omissions committed by federal employees while acting within the scope of their employment. General regulations issued by the U.S. Department of Justice for processing FTCA claims, found at 28 CFR 14.11, authorize federal agencies to issue supplementing regulations. Accordingly, the CSB is adopting this rule to inform the public about the CSB's method of accepting and processing claims arising under the FTCA filed against the agency. This rule provides the public with guidance in presenting a tort claim against the CSB, while also ensuring that the agency has established procedures to receive, investigate and adjudicate such claims. The CSB published a proposed rule on administrative claims arising under the FTCA, and invited public comments on the rule, in the **Federal Register** of June 17, 2004 (69 FR 33879). No comments were received. This final rule is being published unchanged from the proposed version.

Regulatory Impact

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires that a rule that has a significant economic impact on a substantial number of small entities, small businesses, or small organizations must include an initial regulatory flexibility analysis describing the regulation's impact on such small entities. This analysis need not be undertaken if the agency has certified that the regulation will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b). The CSB has considered the impact of this rule under the Regulatory Flexibility Act. The CSB's General Counsel hereby certifies that this rule will not have a significant economic impact on a substantial number of small business entities.

Paperwork Reduction Act

This rule does not contain any information collection requirements that