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 9, 2000) do not apply to this final rule. In addition, this final 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).

X. 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: March 20, 2009.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention 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 180.1128 is revised to read as follows:

§ 180.1128 *Bacillus subtilis* MBI 600; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biofungicide *Bacillus subtilis* MBI 600 in or on all food commodities, including residues resulting from post-harvest uses, when applied or used in accordance with good agricultural practices.

[FR Doc. E9–7172 Filed 4–7–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0167; FRL–8407–8]

Thiamethoxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of thiamethoxam and its metabolite CGA-322704 in or on citrus fruits, citrus pulp, tree nuts, almond hulls, and pistachios. Syngenta Crop Protection, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 8, 2009. Objections and requests for hearings must be received on or before June 8, 2009, 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–2008–0167. All documents in the docket are listed in the docket index available at *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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open 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: Julie Chao, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8735; e-mail address: *chao.julie@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 those engaged in the following activities:

- 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 to provide 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 electronically available documents 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0167 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 as required by 40 CFR part 178 on or before June 8, 2009.

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 this copy, identified by docket ID number EPA–HQ–OPP–2008–0167, 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., N.W., 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 Facility'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. Petition for Tolerance

In the **Federal Register** of April 16, 2008 (73 FR 20632) (FRL–8359–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F7293) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419–8300. The petition requested that 40 CFR 180.565 be amended by establishing tolerances for combined residues of the insecticide thiamethoxam [3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-*N*-nitro-4*H*-1,3,5-oxadiazin-4-imine] and its metabolite CGA-322704 [*N*-(2-chloro-thiazol-5-ylmethyl)-*N*'-methyl-*N*'-nitro-guanidine], in or on fruit, citrus (crop group 10) at 0.3 parts per million (ppm); almond, nut, tree (crop group 14) including pistachio at 0.02 ppm; and almond hulls at 1.2 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has determined that the tolerance level for citrus (crop group 10) needs to be raised, and that separate tolerances need to be established for pistachios and citrus, dried pulp. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 and to make a determination on aggregate exposure for the petitioned-for tolerances for combined residues of thiamethoxam and its metabolite CGA-322704 on nut, tree (crop group 14) at 0.02 ppm; almond, hulls at 1.2 ppm; fruit, citrus (crop group 10) at 0.40 ppm; citrus, dried pulp at 0.60 ppm; pistachio at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Thiamethoxam shows toxicological effects primarily in the liver, kidney, testes, and hematopoietic system. In addition, developmental neurological effects were observed in rats. This developmental effect is being used to assess risks associated with acute exposures to thiamethoxam, and the liver and testicular effects are the bases for assessing longer term exposures. Although thiamethoxam causes liver tumors in mice, the Agency has classified thiamethoxam as ''not likely to be carcinogenic to humans'' based on convincing evidence that a non-genotoxic mode of action for liver tumors was established in the mouse and that the carcinogenic effects are a result of a mode of action dependent on sufficient amounts of a hepatotoxic metabolite produced persistently. The non-cancer (chronic) assessment is sufficiently protective of the key events (perturbation of liver metabolism, hepatotoxicity/regenerative proliferation) in the animal mode of action for cancer published in the **Federal Register** of June 22, 2007 (72 FR 34401 (FRL–8133–6). Thiamethoxam produces a metabolite known as CGA-322704 (referred to in the remainder of this rule as clothianidin). Clothianidin is also registered as a pesticide. While some of the toxic effects observed following testing with the thiamethoxam and clothianidin are similar, the available information indicates that thiamethoxam and clothianidin have different toxicological effects in mammals and should be assessed separately. A separate risk assessment of clothianidin has been completed in conjunction with the registration of clothianidin. The most recent assessment, which provides details regarding the toxicology of clothianidin are discussed in the final rule published in the **Federal Register** of February 6, 2008 (FRL–8346–9) at (*http://www.epa.gov/fedrgstr/EPA-*

PEST/2008/February/Day-06/p1784.htm).

Specific information on the studies received and the nature of the adverse effects caused by thiamethoxam as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of June 22, 2007.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account 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. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for thiamethoxam used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of June 22, 2007.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to thiamethoxam, EPA considered exposure under the petitioned-for tolerances as well as all existing thiamethoxam tolerances in (40 CFR 180.565). EPA assessed dietary exposures from thiamethoxam in food as follows:

For both acute and chronic exposure assessments for thiamethoxam, EPA combined residues of clothianidin coming from thiamethoxam with residues of thiamethoxam *per se*. As discussed in this unit, thiamethoxam's major metabolite is CGA-322704, which is also the registered active ingredient clothianidin. Available information indicates that thiamethoxam and clothianidin have different toxicological effects in mammals and should be assessed separately, however, these exposure assessments for this action incorporated the total residue of thiamethoxam and clothianidin from use of thiamethoxam because the total residue for each commodity for which thiamethoxam has a tolerance has not been separated between thiamethoxam and its clothianidin metabolite. The combining of these residues, as was done in this assessment, results in highly conservative estimates of dietary exposure and risk. A separate assessment was done for clothianidin. The clothianidin assessment included clothianidin residues from use of clothianidin as a pesticide and clothianidin residues from use of thiamethoxam on those commodities for which the pesticide clothianidin does not have a tolerance. As to these commodities, EPA has separated total residues between thiamethoxam and clothianidin.

i. *Acute exposure*. Quantitative acute dietary exposure and 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 1–day or single exposure.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed maximum residues of thiamethoxam and clothianidin observed in the thiamethoxam field trials. It was also assumed that 100% of crops with registered or requested uses of thiamethoxam and 100% of crops with registered or requested uses of clothianidin are treated.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed maximum residues of thiamethoxam and clothianidin observed in the thiamethoxam field trials. It was also assumed that 100% of crops with registered or requested uses of thiamethoxam and 100% of crops with registered or requested uses of clothianidin are treated.

A complete listing of the inputs used in these assessments can be found in the following documents: *Thiamethoxam Acute and Chronic Aggregate Dietary and Drinking Water Exposure and Risk Assessments for FIFRA Section 3 Registration on Citrus and Tree Nut Crops; Clothianidin. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Section 3 Registration of Thiamethoxam on Citrus and Tree Nut Crop Groups*. These documents are available in the docket EPA–HQ–OPP–2008–0167, at *http:///www.regulations.gov*.

iii. *Cancer*. A quantitative cancer exposure assessment is not necessary because EPA concluded that thiamethoxam is ''not likely to be carcinogenic to humans'' based on convincing evidence that a non-genotoxic mode of action for liver tumors was established in the mouse, and that the carcinogenic effects are a result of a mode of action dependent on sufficient amounts of a hepatotoxic metabolite produced persistently. The non-cancer (chronic) assessment is sufficiently protective of the key events (perturbation of liver metabolism, hepatotoxicity/regenerative proliferation) in the animal mode of action for cancer and thus a separate exposure assessment pertaining to cancer risk is not necessary. Because clothianidin is not expected to pose a cancer risk, a quantitative dietary exposure assessment for the purposes of assessing cancer risk was not conducted.

iv. *Anticipated residue information*. EPA did not use percent crop treated (PCT) information in the dietary assessments for thiamethoxam or clothianidin. Maximum field trial residues and 100 PCT were assumed for all food commodities.

Section 408(b)(2)(E) of 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 residues

that have been measured in food. If EPA relies on such information, EPA must require pursuant to section 408(f)(1) of FFDCA 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. For the present action, EPA will issue such data Call-Ins as are required by section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* Thiamethoxam is expected to be persistent and mobile in terrestrial and aquatic environments. These fate properties suggest that thiamethoxam has a potential to move into surface water and shallow ground water. The Agency lacks sufficient monitoring 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, the Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for thiamethoxam in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of thiamethoxam. 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*.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Groundwater (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of thiamethoxam for acute exposures are 12.26 parts per billion (ppb) for surface water and 7.94 ppb for ground water. The EDWCs for chronic exposures for non-cancer assessments are 1.29 ppb for surface water and 7.94 ppb for ground water.

The registrant has conducted small-scale prospective ground water studies in several locations in the United States to investigate the mobility of thiamethoxam in a vulnerable hydrogeological setting. A review of those data shows that generally residues of thiamethoxam, as well as CGA-322704, are below the limit of quantification (0.05 ppb). When quantifiable residues are found, they are sporadic and at low levels. The maximum observed residue levels from any monitoring well were 1.0 ppb for thiamethoxam and 0.73 ppb for CGA-322704. These values are well below the modeled estimates summarized in this unit, indicating that the modeled estimates are, in fact, protective of what actual exposures are likely to be.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For both acute and chronic dietary risk assessments for thiamethoxam, the upper-bound EDWC value of 12.26 ppb was used to assess the contribution to drinking water.

Clothianidin is not a significant degradate of thiamethoxam in surface or ground water sources of drinking water. Clothianidin drinking water residues only result from uses of clothianidin. The acute EDWC value of 7.3 ppb for clothianidin was incorporated into the acute dietary assessment and the chronic EDWC value of 5.9 ppb for clothianidin was incorporated into the chronic dietary assessment.

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 currently registered for the following uses that could result in residential exposures: Turfgrass on golf courses, residential lawns, commercial grounds, parks, playgrounds, athletic fields, landscapes, interiorscapes and sod farms. EPA assessed residential exposure using the following assumptions:

Thiamethoxam is registered for use on turfgrass on golf courses, residential lawns, commercial grounds, parks, playgrounds, athletic fields, landscapes, interiorscapes and sod farms. Thiamethoxam is applied by commercial applicators only. Therefore, exposures resulting from homeowner applications were not assessed. However, entering areas previously treated with thiamethoxam could lead to exposures for adults and children. As a result, risk assessments have been completed for postapplication scenarios. Short-term exposures (1 to 30 days of continuous exposure) may occur as a result of activities on treated turf. There are no use patterns for thiamethoxam that indicate intermediate-term (1 to 6 months of continuous exposure) or chronic non-dietary exposures are likely to occur.

Dermal exposures were assessed for adults and children. Oral non-dietary ingestion exposures (i.e. soil ingestion, and hand-/object-to-mouth) were assessed for children as well. Since all postapplication scenarios occur outdoors the potential for inhalation exposure is negligible and therefore does not require an inhalation exposure assessment. For purposes of this assessment, exposure from residential lawns is used to represent the worst case scenario for both dermal and oral postapplication exposure.

Postapplication dermal exposure resulting from contact with treated turf was assessed using the EPA's Standard Operating Procedures for Residential Exposure and a chemical-specific turf transfer residue study.

Thiamethoxam use on turf does not result in significant residues of clothianidin. In addition, clothianidin residential and aggregate risks are not of concern. Refer to the final rule published in the **Federal Register** of February 6, 2008 (*http://www.epa.gov/fedrgstr/EPA-PEST/2008/February/Day-06/p1784.htm*).

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.''

Thiamethoxam is a member of the neonicotinoid class of pesticides and produces, as a metabolite, another neonicotinoid, clothianidin. Structural similarities or common effects do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same sequence of major biochemical events (EPA, 2002). Although clothianidin and thiamethoxam bind selectively to insect nicotinic acetylcholine receptors (nAChR), the specific binding site(s)/receptor(s) for clothianidin, thiamethoxam, and the other neonicotinoids are unknown at this time. Additionally, the commonality of the binding activity itself is uncertain, as preliminary evidence suggests that clothianidin operates by direct competitive inhibition, while thiamethoxam is a non-competitive inhibitor. Furthermore, even if future research shows that neonicotinoids share a common binding activity to a specific site on insect nicotinic acetylcholine receptors, there is not necessarily a relationship between this pesticidal action and a mechanism of toxicity in mammals. Structural variations between the insect and mammalian nAChRs produce quantitative differences in the binding affinity of the neonicotinoids towards these receptors, which, in turn, confers the notably greater selective toxicity of

this class towards insects, including aphids and leafhoppers, compared to mammals. While the insecticidal action of the neonicotinoids is neurotoxic, the most sensitive regulatory endpoint for thiamethoxam is based on unrelated effects in mammals, including effects on the liver, kidney, testes, and hematopoietic system. Additionally, the most sensitive toxicological effect in mammals differs across the neonicotinoids (e.g., testicular tubular atrophy with thiamethoxam; mineralized particles in thyroid colloid with imidacloprid).

Thus, EPA has not found thiamethoxam or clothianidin to share a common mechanism of toxicity with any other substances. For the purposes of this tolerance action, therefore, EPA has assumed that thiamethoxam and clothianidin do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. In the developmental studies, there is no evidence of increased quantitative or qualitative susceptibility of rat or rabbit fetuses to *in utero* exposure to thiamethoxam. The developmental NOAELs are either higher than or equal to the maternal NOAELs. The toxicological effects in fetuses do not appear to be any more severe than those in the dams or does. In the rat developmental neurotoxicity study, there was no quantitative evidence of increased susceptibility.

There is evidence of increased quantitative susceptibility for male pups in two 2–generation reproductive studies. In one study, there are no toxicological effects in the dams whereas for the pups, reduced bodyweights are observed at the highest dose level, starting on day 14 of lactation. This contributes to an overall decrease in bodyweight gain during the entire lactation period. Additionally, reproductive effects in males appear in the F1 generation 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 (increased incidence of testicular tubular atrophy at 1.8 milligrams/kilogram/day (mg/kg/day) when compared to the parents (hyaline changes in renal tubules at 61 mg/kg/day; NOAEL is 1.8 mg/kg/day).

In a more recent 2–generation reproduction study, the most sensitive effect was sperm abnormalities at 3 mg/kg/day (the NOAEL is 1.2 mg/kg/day) in the F1 males. This study also indicates increased susceptibility for the offspring for this effect.

Although there is evidence of increased quantitative susceptibility for male pups in both reproductive studies, NOAELs and LOAELs were established in these studies and the Agency selected the NOAEL for testicular effects in F1 pups as the basis for risk assessment. The Agency has confidence that the NOAEL selected for risk assessment is protective of the most sensitive effect (testicular effects) for the most sensitive subgroup (pups) observed in the toxicological database.

Due to the finding of quantitative sensitivity in the reproduction studies, the EPA conducted a degree of concern analysis to assess the residual uncertainties for prenatal and/or postnatal susceptibility. The Agency concluded that there is low concern for an increased susceptibility in the young given:

i. There was no increased sensitivity (qualitative or quantitative) in the rat developmental, rabbit developmental and rat developmental neurotoxicity studies;

ii. There was a clear NOAEL identified for the effects in pups in the rat reproduction studies where sensitivity was seen; and

iii. The Agency selected this NOAEL as the basis for risk assessment.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for thiamethoxam is largely complete, including acceptable/guideline developmental toxicity, 2–generation reproduction, and developmental neurotoxicity studies designed to detect adverse effects on the developing organism, which could result from the mechanism that may have produced the decreased alanine amino transferase levels.

The registrant must submit, as a condition of registration, an immunotoxicity study. This study is now required under 40 CFR part 158. The available data for thiamethoxam show the potential for immunotoxic effects, which are described in more detail below:

a. *Subchronic Dog - Leukopenia*. In the subchronic dog study, leukopenia (decreased white blood cells) was observed in females only, at the highest dose tested (HDT) of 50 mg/kg/day; the NOAEL for this effect was 34 mg/kg/day. The overall study NOAEL was 9.3 mg/kg/day in females (8.2 mg/kg/day in males) based on hematology and other clinical chemistry findings at the LOAEL of 34 mg/kg/day (32 mg/kg/day in males).

b. *Subchronic Mouse – Spleen weight changes*. In the subchronic mouse study, decreased spleen weights were observed in females at 626 mg/kg/day; the NOAEL for this effect was the next lowest dose of 231 mg/kg/day. The overall study NOAEL was 1.4 mg/kg/day (males) based on increased hepatocyte hypertrophy observed at the LOAEL of 14.3 mg/kg/day. The decreased absolute spleen weights were considered to be treatment related, but were not statistically significant at 626 mg/kg/day or at the HDT of 1,163 mg/kg/day. Since spleen weights were not decreased relative to body weights, the absolute decreases may have been related to the decreases in body weight gain observed at higher doses.

Overall, the Agency has a low concern for the potential for immunotoxicity related to these effects for the following reasons:

- In general, the Agency does not consider alterations in hematology parameters alone to be a significant indication of potential immunotoxicity. In the case of thiamethoxam, high-dose females in the subchronic dog study had slight microcytic anemia as well as leukopenia characterized by reductions in neutrophils, lymphocytes and monocytes; the leukopenia was considered to be related to the anemic response to exposure. Further, endpoints and doses selected for risk assessment are protective of the observed effects on hematology.
- Spleen weight decreases, while considered treatment-related, were associated with decreases in body

weight gain, and were not statistically significant. In addition, spleen weight changes occurred only at very high doses, more than 70 times higher than the doses selected for risk assessment.

Therefore, an additional 10x safety factor is not warranted at this time.

ii. For the reasons discussed in Unit III.D.2., there is low concern for an increased susceptibility in the young.

iii. Although there is evidence of neurotoxicity after acute exposure to thiamethoxam at doses of 500 mg/kg/day including drooped palpebral closure, decrease in rectal temperature and locomotor activity and increase in forelimb grip strength, no evidence of neuropathology was observed. These effects occurred at doses at least fourteen-fold and 416-fold higher than the doses used for the acute, and chronic risk assessments, respectively; thus, there is low concern for these effects since it is expected that the doses used for regulatory purposes would be protective of the effects noted at much higher doses.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on assumption that the maximum residues of thiamethoxam and clothianidin observed in the thiamethoxam field trials were remaining on crops. Although there is available information indicating that thiamethoxam and clothianidin have different toxicological effects in mammals and should be assessed separately, the residues of each have been combined in these assessments to ensure that the estimated exposures of thiamethoxam do not underestimate actual potential thiamethoxam exposures. An assumption of 100 PCT was made for all foods evaluated in the assessments. For both the acute and chronic assessments the acute EDWC of 12.26 ppb (0.0123 ppm) was used as a worst-case estimate of exposure via drinking water. Compared to the results from small-scale prospective ground water studies where the maximum observed residue levels from any monitoring well were 1.0 ppb for thiamethoxam and 0.73 ppb for CGA-322704, the modeled estimates are protective of what actual exposures are likely to be. Similarly conservative Residential SOPs as well as a chemical-specific turf transfer residue (TTR) study were used to assess post-application exposure to children and incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by thiamethoxam.

v. The FQPA safety factor for clothianidin has been retained as a 10x UFDB for the lack of a developmental immunotoxicity study. Refer to the final rule published in the **Federal Register** of February 6, 2008 (*http://www.epa.gov/fedrgstr/EPA-PEST/2008/February/Day-06/p1784.htm*).

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to thiamethoxam will occupy 3% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Acute dietary exposure from food and water to clothianidin is estimated to occupy 45% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to thiamethoxam from food and water will utilize 42% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Similarly, chronic exposure to clothianidin from food and water will occupy 16% of the cPAD for children 1 to 2 years old. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of thiamethoxam and clothianidin is not expected.

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

Thiamethoxam is currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term residential exposures for thiamethoxam. The level of concern for the margin of exposure (MOE) is 100 for aggregate short-term exposures (i.e., MOEs less than 100 indicate potential risks of concern). The level of concern for clothianidin MOEs is 1,000.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the aggregated short-term food, water, and residential exposures to thiamethoxam result in MOEs of 730 through 2,800 for all exposure scenarios for infants, children and adults. Aggregate MOEs associated with clothianidin range from 1,100 to 23,000.

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

Thiamethoxam is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to thiamethoxam or clothianidin through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population*. The Agency has classified thiamethoxam as not likely to be a human carcinogen based on convincing evidence that a non-genotoxic mode of action for liver tumors was established in the mouse and that the carcinogenic effects are a result of a mode of action dependent on sufficient amounts of a hepatotoxic metabolite produced persistently. Thiamethoxam is not expected to pose a cancer risk. Clothianidin has been classified as a ''not likely to be a human carcinogen.'' It is not expected to pose a cancer risk.

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, or to infants and children from aggregate exposure to thiamethoxam or clothianidin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography/ultraviolet (HPLC/UV) or mass spectrometry (MS)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental 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 or Mexican maximum residue limits (MRLs) for thiamethoxam. A number of Canadian MRLs exist for this chemical and are in accord with U.S. tolerances. The new/revised tolerances established by this rule have been derived using the NAFTA Tolerance Harmonization Spreadsheet.

C. Revisions to Petitioned-For Tolerances

Available field trial data support a tolerance for combined residues of thiamethoxam and CGA-322704 in/on citrus (group 10) at 0.40 ppm. Therefore, the proposed tolerance of 0.30 ppm should be raised to 0.40 ppm.

The data submitted with the petition support the proposed tolerance of 0.02 ppm for tree nuts (group 14). However, because the petitioner is seeking a tolerance to cover use on pistachios and pistachios are not, pending a proposed revision of the tree nut group definition, included in the tree nut group, a separate tolerance should be established for pistachio at 0.02 ppm.

The data supporting the petition indicate that combined residues of thiamethoxam and CGA-332704 may concentrate in dried citrus pulp. Therefore, a tolerance for citrus, dried pulp should be established and EPA has determined that the appropriate level is 0.60 ppm.

V. Conclusion

Therefore, tolerances are established for combined residues of thiamethoxam, [3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-*N*-nitro-4*H*-1,3,5-oxadiazin-4-imine], and its metabolite, CGA-322704 [*N*-(2-chloro-thiazol-5-ylmethyl)-*N*'-methyl-*N*'-nitro-guanidine], in or on nut, tree (crop group 14) at 0.02 ppm; almond, hulls at 1.2 ppm; fruit, citrus (crop group 10) at 0.40 ppm; citrus, dried pulp at 0.60 ppm; pistachio at 0.02 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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 9, 2000) do not apply to this final rule. In addition, this final 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: March 30, 2009.

Daniel J. Rosenblatt,

Acting 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 revising the introductory text in paragraph (a); removing the commodity ''pecan'' from the table in paragraph (a); alphabetically adding the following commodities to the table; and removing paragraph (b) and reserving the heading to read as follows:

§ 180.565 Thiamethoxam; tolerances for residues.

(a) *General.* A tolerance is established for the combined residues of the insecticide thiamethoxam [3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-*N* -nitro-4 *H* -1,3,5-oxadiazin-4-imine] (CAS Reg. No. 153719–23–4) and its metabolite [*N*-(2-chloro-thiazol-5-ylmethyl) -*N* ′-methyl- *N* ′-nitro-guanidine], calculated as parent equivalents, in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	1.2 ppm
* * * * *	
Citrus, dried pulp	0.60 ppm
* * * * *	
Fruit, citrus, group 10	0.40 ppm
* * * * *	
Nut, tree, group 14)	0.02 ppm
* * * * *	
Pistachio	0.02 ppm
* * * * *	

* * * * *

(b) *Section 18 emergency exemptions.* [Reserved]

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[FR Doc. E9–7966 Filed 4–7–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0361; FRL–8406–8]

Cyhalofop-butyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of cyhalofop-butyl, cyhalofop acid and the di-acid metabolite in or on rice, grain and rice, wild, grain. Interregional Research Project Number 4 (IR-4) and Dow AgroSciences, LLC, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also removes the expired, time-limited tolerances for residues of cyhalofop-butyl, cyhalofop acid and the di-acid metabolite in or on on rice, grain and rice, straw.

DATES: This regulation is effective April 8, 2009. Objections and requests for hearings must be received on or before June 8, 2009, 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–2008–0361. All documents in the docket are listed in the docket index available at *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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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 those engaged in the following activities:

- 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 to provide 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 electronically available documents 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0361 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 as required by 40 CFR part 178 on or before June 8, 2009.

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 this copy, identified by docket ID number EPA–HQ–OPP–2008–0361, 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 Facility'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. Petition for Tolerance

In the **Federal Registers** of June 4, 2008 (73 FR 31862) (FRL–8365–3) and August 29, 2008 (73 FR 50963) (FRL–8379–2), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7341) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W, Princeton, NJ, 08540; and a pesticide petition (PP 8F7403) by Dow AgroSciences, LLC, 9330 Zionsville Rd., Indianapolis, IN 46268, respectively. The petitions requested that 40 CFR 180.576 be amended by establishing tolerances for combined residues of the herbicide cyhalofop-butyl, R-(+)-n-butyl-2-(4(4-cyano-2-fluorophenoxy)-phenoxy)propionate, plus cyhalofop acid, R-(+)-2-(4(4-cyano-2-fluorophenoxy)-phenoxy)propionic acid) and the di-acid metabolite, (2R)-4-[4-(1-carboxyethoxy)phenoxy]-3-fluorobenzoic acid, in or on rice, grain (PP 8F7403) and rice, wild, grain (PP 8E7341) at 0.03 parts per million (ppm);