

Coast Guard; telephone 415-399-7443, e-mail: [D11-PF-MarineEvents@uscg.mil](mailto:D11-PF-MarineEvents@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the safety zone for the annual Fourth of July Fireworks, City of Vallejo, safety zone in 33 CFR 165.1191 on July 4, 2010, from 9 a.m. through 10 p.m. During the fireworks display. The fireworks will be located on Mare Island adjacent to the dry docks in position

38°05'54.83" N. 122°16'01.69" W.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM. Additionally, each person who receives notice of a lawful order or direction issued by an official patrol vessel shall obey the order of direction. The PATCOM is empowered to forbid and control the regulated area. The PATCOM shall be designated by the Commander, Coast Guard Sector San Francisco. The PATCOM may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

This notice is issued under authority of 33 CFR 165.1191 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of this enforcement period via the Local Notice to Mariners.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: June 11, 2010.

P.M. Gugg,

*Captain, U.S. Coast Guard, Captain of the Port, Sector San Francisco.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2009-0737; FRL-8830-4]

### Thiamethoxam; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of thiamethoxam in or on onion, dry bulb. Syngenta Crop

Protection, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective June 23, 2010. Objections and requests for hearings must be received on or before August 23, 2010, 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-2009-0737. 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](mailto: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 Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>.

##### C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0737 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 23, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2009-0737, 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. Summary of Petitioned-For Tolerance

In the **Federal Register** of January 6, 2010, (75 FR 864) (FRL-8801-5), 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 9F7582) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.565 be amended by establishing tolerances for 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'*-nitroguanidine], in or on onion, dry bulb at 0.03 parts per million (ppm). That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available in the docket EPA-HQ-OPP-2009-0737, at <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

## 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 thiamethoxam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with thiamethoxam 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. Refer to the **Federal Register** of June 22, 2007 (72 FR 34401) (FRL-8133-6) for more information regarding the cancer classification of thiamethoxam.

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 assessments, which provide details regarding the toxicology of clothianidin,

are available in the docket EPA-HQ-OPP-2008-0945, at <http://www.regulations.gov>. Refer to the documents "Clothianidin: Human Health Risk Assessment for Proposed Uses on Berries (Group 13-07H), Brassica Vegetables (Group 5), Cotton, Cucurbit Vegetables (Group 9), Fig, Fruiting Vegetables (Group 8), Leafy Green Vegetables (Group 4A), Peach, Pomegranate, Soybean, Tree Nuts (Group 14), and Tuberous and Corm Vegetables (Group 1C);" and "Clothianidin: Human Health Risk Assessment for Proposed Seed Treatment Uses on Root and Tuber Vegetables (Group 1), Bulb Vegetables (Group 3), Leafy Green Vegetables (Group 4A), Brassica Leafy Vegetables (Group 5), Fruiting Vegetables (Group 8), Cucurbit Vegetables (Group 9), and Cereal Grains (Group 15, except rice)."

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 Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD), and a safe margin of exposure (MOE). 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 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.

Such effects were identified for thiamethoxam. 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 tolerance-level residues of

thiamethoxam and clothianidin. 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 tolerance level and/or anticipated residues from 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 (Food and Drinking Water) Exposure and Risk Assessments for the Section 3 Registration as a Seed Treatment on Onion, Dry Bulb, Removing the Geographical Limitations on the Foliar Treatment of Barley,” available in the docket EPA–HQ–OPP–2009–0737, at <http://www.regulations.gov>; and “Clothianidin Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments,” available in the docket EPA–HQ–OPP–2008–0945, at <http://www.regulations.gov>.

iii. *Cancer.* 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 and percent crop treated (PCT) information.* 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 FFDCA section 408(f)(1) 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 FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

EPA did not use PCT information in the dietary assessments for thiamethoxam or clothianidin.

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>.

For surface water, the estimated drinking water concentrations (EDWCs) are based on thiamethoxam concentrations in tail water from rice paddies and cranberry bogs that drain into adjacent surface water bodies. Because the uses on rice and cranberries involve flooding, for which Pesticide Root Zone Model/Exposure/Analysis Modeling System (PRZM/EXAMS) is not currently parameterized, these uses were assessed using the modified Tier I Rice Model and the Provisional Cranberry Model. Exposure estimates were refined with a default percent cropped area factor of 87%. The Tier I Rice Model is expected to generate conservative EDWCs that exceed peak measured concentrations of pesticides in water bodies well downstream of rice paddies by less than one order of magnitude to multiple orders of magnitude.

For ground water, the EDWCs are based on thiamethoxam concentrations resulting from use on grapes. Exposure in ground water due to leaching was assessed with the Screening

Concentration in Ground water (SCI-GROW) models.

Based on the Tier I Rice Model and SCI-GROW models, the EDWCs of thiamethoxam for acute exposures are 131.77 parts per billion (ppb) for tail water and 4.14 ppb for ground water. The EDWCs for chronic exposures for non-cancer assessments are 11.31 ppb for tail water and 4.14 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The most conservative EDWCs in both the acute and chronic exposure scenarios were for tail water, and represent worst case scenarios. Therefore, for the acute dietary risk assessments for thiamethoxam, the upper-bound EDWC value of 131.77 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessments for thiamethoxam, the upper-bound EDWC value of 11.31 ppb was used to assess the contribution to drinking 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 show 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.

Clothianidin is not a significant degradate of thiamethoxam in surface water or ground water sources of drinking water and, therefore, was not included in the EDWCs used in the thiamethoxam dietary assessments. For the clothianidin assessments, the acute EDWC value of 7.29 ppb for clothianidin was incorporated into the acute dietary assessment and the chronic EDWC value of 5.88 ppb for clothianidin was incorporated into the chronic dietary assessment.

A complete listing of the inputs used in these assessments can be found in the following documents "Thiamethoxam. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Section 3 Registration as a Seed Treatment on Onion, Dry Bulb, Removing the Geographical Limitations on the Foliar Treatment of Barley," available in the

docket EPA-HQ-OPP-2009-0737, at <http://www.regulations.gov>; and "Clothianidin Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments," available in the docket EPA-HQ-OPP-2008-0945, at <http://www.regulations.gov>.

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; indoor crack and crevice or spot treatments to control insects in residential settings. 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) and for indoor use to control insects in residential settings. Thiamethoxam is applied by commercial applicators only. Therefore, exposures resulting to homeowners from applying thiamethoxam 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 post-application scenarios.

Short-term exposures (1 to 30 days of continuous exposure) may occur as a result of activities on treated turf. Short-term and intermediate-term exposures (30 to 90 days of continuous exposure) may occur as a result of entering indoor areas previously treated with a thiamethoxam indoor crack and crevice product. The difference between short-term and intermediate-term aggregate risk is the frequency of hand-to-mouth events for children. For short-term exposure there are 20 events per hour and for intermediate-term exposure there are 9.5 events per hour. The doses and end-points for short-term and intermediate-term aggregate risk are the same.

EPA combined all non-dietary sources of post-application exposure to obtain an estimate of potential combined exposure. These scenarios consisted of adult and toddler dermal post-application exposure and oral (hand-to-mouth) exposures for toddlers. Since post-application scenarios for turf occur

outdoors, the potential for inhalation exposure is negligible and therefore does not require an inhalation exposure assessment. Since thiamethoxam has a very low vapor pressure ( $6.6 \times 10^{-9}$  Pa @ 25°C), inhalation exposure is also expected to be negligible as a result of indoor crack and crevice use. Therefore, a quantitative post-application inhalation exposure assessment was not performed.

A complete listing of the inputs used in these assessments can be found in the following documents "Thiamethoxam: Occupational and Residential Exposure/Risk Assessment for Proposed Section 3 Registration for Seed Treatment Use on Bulb Onions," available in the docket EPA-HQ-OPP-2009-0737, at <http://www.regulations.gov>.

Thiamethoxam use on turf or as an indoor crack and crevice or spot treatment does not result in significant residues of clothianidin. In addition, clothianidin residential and aggregate risks are not of concern. For further details, refer to the documents "Clothianidin: Human Health Risk Assessment for Proposed Uses on Berries (Group 13-07H), Brassica Vegetables (Group 5), Cotton, Cucurbit Vegetables (Group 9), Fig, Fruiting Vegetables (Group 8), Leafy Green Vegetables (Group 4A), Peach, Pomegranate, Soybean, Tree Nuts (Group 14), and Tuberosous and Corm Vegetables (Group 1C);" and "Clothianidin: Human Health Risk Assessment for Proposed Seed Treatment Uses on Root and Tuber Vegetables (Group 1), Bulb Vegetables (Group 3), Leafy Green Vegetables (Group 4A), Brassica Leafy Vegetables (Group 5), Fruiting Vegetables (Group 8), Cucurbit Vegetables (Group 9), and Cereal Grains (Group 15, except rice)," available in the docket EPA-HQ-OPP-2008-0945, at <http://www.regulations.gov>.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

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 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 parent (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.

3. *Conclusion.* a. In the final rule published in the **Federal Register** of January 5, 2005 (70 FR 708) (FRL-7689-7), EPA had previously determined that the FQPA SF should be retained at 10X for thiamethoxam, based on the following factors: Effects on endocrine organs observed across species; significant decrease in alanine amino transferase levels in companion animal studies and in dog studies; the mode of action of this chemical in insects (interferes with the nicotinic acetylcholine receptors of the insect's nervous system); the transient clinical signs of neurotoxicity in several studies across species; and the suggestive evidence of increased quantitative susceptibility in the rat reproduction study.

Since that determination, EPA has received and reviewed an developmental neurotoxicity (DNT) study in rats, and an additional reproduction study in rats. Taking the results of these studies into account, as well as the rest of the data on thiamethoxam, 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 DNT 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 now 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. 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). 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 for thiamethoxam 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 using tolerance-level and/or anticipated residues that are based on reliable field trial data observed in the thiamethoxam field trials. 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 the acute and chronic assessments, the EDWCs of 131.77 ppb and 11.3 ppb, respectively, were used to estimate 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 SOP, 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.

b. In the final rule published in the **Federal Register** of February 6, 2008 (73 FR 6851) (FRL-8346-9), EPA had previously determined that the FQPA SF for clothianidin should be retained at 10X because EPA had required the submission of a developmental immunotoxicity study to address the combination of evidence of decreased absolute and adjusted organ weights of the thymus and spleen in multiple studies in the clothianidin database, and evidence showing that juvenile rats in the 2-generation reproduction study appear to be more susceptible to these potential immunotoxic effects. In the absence of a developmental immunotoxicity study, EPA concluded that there was sufficient uncertainty regarding immunotoxic effects in the young that the 10X FQPA factor should be retained as a database uncertainty factor.

Since that determination, EPA has received and reviewed an acceptable/guideline developmental immunotoxicity study, which demonstrated no treatment-related effects. Taking the results of this study into account, as well as the rest of the data on clothianidin, EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF for clothianidin were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for clothianidin is complete. As noted, the

prior data gap concerning developmental immunotoxicity has been addressed by the submission of an acceptable developmental immunotoxicity study.

ii. A rat developmental neurotoxicity study is available and shows evidence of increased quantitative susceptibility of offspring. However, EPA considers the degree of concern for the developmental neurotoxicity study to be low for prenatal and postnatal toxicity because the NOAEL and LOAEL were well characterized, and the doses and endpoints selected for risk assessment are protective of the observed susceptibility; therefore, there are no residual concerns regarding effects in the young.

iii. While the rat multi-generation reproduction study showed evidence of increased quantitative susceptibility of offspring compared to adults, the degree of concern is low because the study NOAEL and LOAEL have been selected for risk assessment purposes for relevant exposure routes and durations. In addition, the potential immunotoxic effects observed in the study have been further characterized with the submission of a developmental immunotoxicity study that showed no evidence of susceptibility. As a result, there are no concerns or residual uncertainties for prenatal and postnatal toxicity after establishing toxicity endpoints and traditional UFs to be used in the risk assessment for clothianidin.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on assumptions that were judged to be highly conservative and health-protective for all durations and population subgroups, including tolerance-level residues, adjustment factors from metabolite data, empirical processing factors, and 100 PCT for all commodities. Additionally, EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to clothianidin in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children and adults as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by clothianidin.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer

risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

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 9.5% 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 23% 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. Chronic exposure to clothianidin from food and water will utilize 19% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. 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 exposure through food and water with short-term residential exposures to thiamethoxam.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures for thiamethoxam result in aggregate MOEs of: 380 for the general U.S. population; 500 for all infants (<1 year); 440 for children 1 to 2 years; 460 for children 3-5 years; 370 for children 6-12 years; 380 for youth 13-19 years, adults 20-49 years, adults 50+ years, and females 13-49 years. Because EPA's level of concern for thiamethoxam is a MOE of 100 or below, these MOEs are not of concern.

Using the exposure assumptions described in this unit for short-term

exposures, EPA has concluded the combined short-term food, water, and residential exposures for clothianidin result in aggregate MOEs of 1,700 for the general U.S. population; 480 for all infants (<1 year); 380 for children 1 to 2 years; 500 for children 3-5 years; 1,400 for children 6-12 years; 2,200 for youth 13-19 years, adults 20-49 years, and females 13-49 years; 2,100 for adults 50+ years. Because EPA's level of concern for clothianidin is a MOE of 100 or below, these MOEs are not of concern.

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 currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to thiamethoxam.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 380 for the general U.S. population; 540 for all infants (<1 year); 480 for children 1 to 2 years; 500 for children 3-5 years; 370 for children 6-12 years; 380 for youth 13-19 years, adults 20-49 years, adults 50+ years, and females 13-49 years. Because EPA's level of concern for thiamethoxam is a MOE of 100 or below, these MOEs are not of concern.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures for clothianidin result in aggregate MOEs of 1,700 for the general U.S. population; 480 for all infants (<1 year); 380 for children 1 to 2 years; 500 for children 3-5 years; 1,400 for children 6-12 years; 2,200 for youth 13-19 years, adults 20-49 years, and females 13-49 years; 2,100 for adults 50+ years. Because EPA's level of concern for clothianidin is a MOE of 100 or below, these MOEs are not of concern.

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. Therefore, thiamethoxam 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](mailto:residuemethods@epa.gov).

For further details, refer to the document "Thiamethoxam. Petition to Establish a Permanent Tolerance for Residues of the Insecticide Resulting from Food/Feed Use as a Seed Treatment on Bulb Onions. Response to Data Gaps from Conditional Registration of Various Food/Feed Crops (as Specified in HED Memo D281702; M. Doherty; 17 April 2007). Summary of Analytical Chemistry and Residue Data," available in the docket EPA-HQ-OPP-2009-0737, at <http://www.regulations.gov>.

##### B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for thiamethoxam.

#### V. Conclusion

Therefore, tolerances are established for residues of thiamethoxam (3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-



methyl-*N*-nitro-4H-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 onion, dry bulb at 0.03 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: June 14, 2010.

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 following commodity to the table in paragraph (a) to read as follows:

§ 180.565 Thiamethoxam; tolerances for residues.

(a) \* \* \*

Commodity	Parts per million
Onion, dry bulb	0.03

\* \* \*

[FR Doc. 2010–15035 Filed 6–22–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[EPA–R01–RCRA–2010–0468; FRL–9165–8]

Massachusetts: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

**ACTION:** Immediate final rule.

**SUMMARY:** The Commonwealth of Massachusetts has applied to EPA for final authorization of certain changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA has determined that these changes satisfy all requirements needed to qualify for final authorization and is authorizing the State’s changes through this immediate final action.

**DATES:** This final authorization will become effective on August 23, 2010 unless EPA receives adverse written comment by July 23, 2010. If EPA receives such comment, it will publish

a timely withdrawal of this immediate final rule in the **Federal Register** and inform the public that this authorization will not take immediate effect.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R01–RCRA–2010–0468, by one of the following methods:

- *http://www.regulations.gov*: Follow the on-line instructions for submitting comments.
- *E-mail*: [biscaia.robin@epa.gov](mailto:biscaia.robin@epa.gov).
- *Fax*: (617) 918–0642, to the attention of Robin Biscaia.
- *Mail*: Robin Biscaia, RCRA Waste Management Section, Office of Site Remediation and Restoration (OSRR 07–