injection. Injections should be given twice daily at approximately 12-hour intervals. For cats fed twice daily, the injections should be concurrent with or right after a meal. For cats fed ad libitum, no change in feeding is needed. Adjust the dose at appropriate intervals based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained.

(ii) *Indications for use.* For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in cats with diabetes mellitus.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: April 4, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–8347 Filed 4–17–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[USCG–2008–0267]

Drawbridge Operation Regulation; Illinois Waterway, Joliet, IL 8K Run

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District has issued a temporary deviation from the regulation governing the operations of the Cass Street Drawbridge, across the Illinois Waterway, Mile 288.1, at Joliet, Illinois. The deviation is necessary for the bridge to remain closed to navigation during the effective period for the Joliet City Center Partnership 8K Run.

DATES: This temporary deviation is effective from 8:30 a.m. to 11:30 a.m., May 10, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2008–0267 and are available online at *http://www.regulations.gov.* They are also available for inspection or copying at two locations: The Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays, and the Robert A. Young Federal Building, Room 2.107F, 1222 Spruce Street, St. Louis, MO 63103–2832, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FUTHER INFORMATION CONTACT: Roger K. Wiebusch, Bridge Administrator, (314) 269–2378.

SUPPLEMENTARY INFORMATION: The Illinois Department of Transportation requested a temporary deviation for the Cass Street Drawbridge, mile 288.1, at Joliet, Illinois across the Illinois Waterway as the drawbridge is along the route of the Joliet City Center Partnership 8K Run. The Cass Street Drawbridge currently operates in accordance with 33 CFR 117.393(c), which states the general requirement that drawbridges shall open promptly and fully for the passage of vessels when a request to open is given in accordance with the subpart, except that they need not open from 7:30 a.m. to 8:30 a.m. and from 4:15 p.m. to 5:15 p.m., Monday through Saturday. In order to facilitate the annual event, the drawbridge must be kept in the closed-to-navigation position. This deviation allows the drawbridge to remain closed to navigation from 8:30 a.m. to 11:30 a.m., May 10, 2008.

There are no alternate routes for vessels transiting this section of the Illinois Waterway.

The Cass Street Drawbridge, in the closed-to-navigation position, provides a vertical clearance of 16.5 feet above normal pool. Navigation on the waterway consists primarily of commercial tows and recreational watercraft. This temporary deviation has been coordinated with waterway users. No objections were received.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: April 8, 2008.

Roger K. Wiebusch,

Bridge Administrator.

[FR Doc. E8–8472 Filed 4–17–08; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0139; FRL–8359–9]

Thiamethoxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of the insecticide thiamethoxam and its metabolite, CGA-322704, in or on soybean, hulls and soybean, aspirated grain fractions. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 18, 2008. Objections and requests for hearings must be received on or before June 17, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0139. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. 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 an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2008–0139 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 17, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0139, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of March 12, 2008 (73 FR 13225) (FRL–8354–6), 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 7F7301) 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 a tolerance 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 soybean, hulls at 2.0 ppm and soybean, aspirated grain fractions at 0.08 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.

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 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 soybean, hulls at 2.0 ppm and soybean, aspirated grain fractions at 0.08 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. 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, (72 FR 34401) (FRL–8133–6).

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 Unit III.B. of the final rule published in the **Federal Register** of June 22, 2007 (72 FR 34401) (FRL–8133–6).

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 EPA combined residues of clothianidin coming from thiamethoxam with residues of thiamethoxam per se. As discussed above, thiamethoxam's major metabolite is CGA-322704, which is also the registered active ingredient clothianidin. There is available information indicating 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 to estimate dietary exposure. This aggregation of thiamethoxam and clothianidin began with the initial assessment of thiamethoxam, prior to the requested registration of clothianidin as an active ingredient, and is being maintained in this action for historical purposes. In future assessments, as time and resources allow, the EPA will provide a rationale for the separate analysis of risks coming from thiamethoxam and clothianidin, and will conduct separate evaluations of exposure and risk for each chemical. The combining of these residues, as was done in these assessments, results in highly conservative estimates of dietary exposure and risk.

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 U.S. 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 are treated. This assumption is highly conservative with respect to thiamethoxam use and removes the need to include residues of clothianidin coming from the use of that active ingredient.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 Nationwide 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 are treated. This assumption is highly conservative with respect to thiamethoxam use and removes the need to include residues of clothianidin coming from the use of that active ingredient.

A complete listing of the inputs used in these assessments can be found in the document titled ''Thiamethoxam Acute and Chronic Aggregate Dietary and Drinking Water Exposure and Risk Assessments for FIFRA Section 3 Registration,'' available in the docket EPA–HQ–OPP–2006–0523, *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. Therefore, the Agency concluded that thiamethoxam is not expected to pose a carcinogenic risk and an exposure assessment pertaining to cancer risk is not necessary.

iv. *Anticipated residue 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. For the present action, EPA has used maximum residue values from field trials. These trials are designed to produce worst-case residue levels in foods, and likely overestimate residues of thiamethoxam and clothianidin that may actually occur in or on foods.

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, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate 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 the Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of thiamethoxam for acute exposures are estimated to be 12.26 parts per billion (ppb) for surface water and 7.94 ppb for ground water. The EDWCs for chronic exposures are

estimated to be 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 quantitation (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 above, 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 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.

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 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.

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, there is currently no evidence to indicate that neonicotinoids share common mechanisms of toxicity, and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the neonicotinoids. 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 both two-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 F_1 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 the more recent two-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 F_1 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 F_1 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 pre- 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.

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

3. *Conclusion*. The final rule published in the **Federal Register** of January 5, 2006 (*http://www.epa.gov/fedrgstr/EPA-PEST/2005/January/Day-05/p089.htm*) reported that the EPA had determined that the 10X special safety factor to protect infants and children should be retained for thiamethoxam based on the following factors: Effects on endocrine organs observed across species; the significant decrease in alanine amino transferase levels in the companion animal studies and in the dog studies; the mode of action of this chemical in insects (interferes with the nicotinic acetyl choline 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 a Developmental Neurotoxicity (DNT) study in rats and an additional Reproduction study in rats. Taking the results of this study into account, 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 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.

ii. For the reasons discussed above, 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 fourteenfold 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% crop treated was made for all foods evaluated in the assessments. For both the acute and chronic assessments the acute EEC 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 as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by thiamethoxam.

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.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to thiamethoxam from food and water will utilize 42% of the cPAD for children 1 to 2 years old, the population group with greatest exposure. Based on the use patterns proposed, chronic residential exposure to residues of thiamethoxam is not expected.

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

Thiamethoxam is currently registered for use 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 exposures for thiamethoxam. The level of concern for the margin of exposure (MOE) is 100 for all residential uses (i.e., MOEs less than 100 indicate potential risks of concern). Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and

residential exposures aggregated result in aggregate MOEs of 730 through 2,800 for all exposure scenarios (dermal exposures, and oral non-dietary ingestion) for infants, children and adults.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). There are no use patterns for thiamethoxam that indicate intermediate-term (1 to 6 months of continuous exposure) exposures are likely to occur.

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.

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 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.

V. Conclusion

Based upon review of the supporting data, EPA has determined that tolerance levels for the following crops should be set as follows: soybean, hulls at 2.0 ppm; and soybean, aspirated grain fractions at 0.08 ppm. Therefore, tolerances are established for the 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 soybean, hulls at 2.0 ppm and soybean, aspirated grain fractions at 0.08 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, *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: April 9, 2008.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.565 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.565 Thiamethoxam; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Soybean, aspirated grain fractions	0.08
Soybean, hulls	2.0
* * *	* *

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[FR Doc. E8–8398 Filed 4–17–08; 8:45 am]
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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 65

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: Modified Base (1% annual-chance) Flood Elevations (BFEs) are finalized for the communities listed below. These modified BFEs will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: The effective dates for these modified BFEs are indicated on the following table and revise the Flood Insurance Rate Maps (FIRMs) in effect for the listed communities prior to this date.

ADDRESSES: The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: William R. Blanton, Jr., Engineering Management Branch, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3151.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below of the modified BFEs for each community listed. These modified BFEs have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Mitigation Division Director of FEMA resolved any appeals resulting from this notification.

The modified BFEs are not listed for each community in this notice. However, this final rule includes the address of the Chief Executive Officer of the community where the modified BFEs determinations are available for inspection.

The modified BFEs are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities.

These modified BFEs are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings. The changes in BFEs are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This final rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This final rule involves no policies that have federalism implications under Executive Order 13132, Federalism.

Executive Order 12988, Civil Justice Reform. This final rule meets the applicable standards of Executive Order 12988.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

■ Accordingly, 44 CFR part 65 is amended to read as follows:

PART 65—[AMENDED]

■ 1. The authority citation for part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p.376.

§ 65.4 [Amended]

■ 2. The tables published under the authority of § 65.4 are amended as follows:

State and county	Location and case No.	Date and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Arizona:					
Pima (FEMA Docket No. B–7750).	Town of Marana (07–09–1759P).	September 6, 2007; September 13, 2007; *The Daily Territorial*.	The Honorable Ed Honea, Mayor, Town of Marana, Marana Municipal Complex, 11555 West Civic Center Drive, Marana, AZ 85653.	December 13, 2007	040118
Pima (FEMA Docket No. B–7750).	Unincorporated areas of Pima County (07–09–1759P).	September 6, 2007; September 13, 2007; *The Daily Territorial*.	The Honorable Richard Elias, Chairman, Pima County Board of Supervisors, 130 West Congress Street, 11th Floor, Tucson, AZ 85701.	December 13, 2007	040073
California:					
Riverside (FEMA Docket No: B–7761).	City of Perris (07–09–0955P).	November 8, 2007; November 15, 2007; *The Press-Enterprise*.	The Honorable Daryl R. Busch, Mayor, City of Perris, 101 North D Street, Perris, CA 92570.	February 14, 2008	060258