

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0115; FRL-7183-2]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food
AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number OPP-2002-0115, must be received on or before July 29, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-2002-0115 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Dani Daniel, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5409; e-mail address: daniel.dani@epa.gov.

SUPPLEMENTARY INFORMATION:
I. General Information
A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System

(NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the **Federal Register**—Environmental Documents. You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00>Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-2002-0115. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket ID

number OPP-2002-0115 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP-2002-0115. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 17, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by Syngenta Crop Protection Inc. and represents the view of Syngenta. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of

a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

PP OF6142

EPA has received a pesticide petition (OF6142) from Syngenta Crop Protection Inc., P.O. Box 18300, Greensboro, NC 27419-8300 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180, by establishing a tolerance for residues of thiamethoxam and its metabolite in or on the raw agricultural commodity corn forage at 0.10 parts per million (ppm); corn stover at 0.05 ppm; and popcorn, corn grain and sweet corn (kernal and cob with husk removed) at 0.02 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. Plant metabolism. The primary metabolic pathways of thiamethoxam in plants (corn, rice, pears, and cucumbers) were similar to those described for animals, with certain extensions of the pathway in plants. Parent compound and CGA-322704 were the major residues in all crops. The metabolism of thiamethoxam in plants and animals is understood for the purposes of the proposed tolerances. Parent thiamethoxam and the metabolite, CGA-322704, are the residues of concern for tolerance setting purposes.

2. Analytical method. Syngenta Crop Protection Inc. has submitted practical analytical methodology for detecting and measuring levels of thiamethoxam in or on raw agricultural commodities. The method is based on crop specific cleanup procedures and determination by liquid chromatography with either ultraviolet (UV) or mass spectroscopy (MS) detection. The limit of detection (LOD) for each analyte of this method is 1.25 nanogram (ng) injected for samples analyzed by UV and 0.25 ng injected for samples analyzed by MS, and the limit of quantitation (LOQ) is 0.005 ppm for milk and juices and 0.01 ppm for all other substrates.

3. Magnitude of residues. A residue program was performed for thiamethoxam used as a seed treatment for corn. Seed was treated at label rates of 100 to 450 (maximum) grams of

thiamethoxam per 100 kilograms of seed. A 3X exaggerated rate trial was also conducted to determine the magnitude of the residue in processed field corn commodities.

Thirty-six field trials were conducted in 19 states representing typical corn growing areas of the United States, including 21 field corn, 12 sweet corn, and 3 popcorn field trials. There were no detectable residues (<0.01 ppm) of either thiamethoxam or the major metabolite in any grain, ear or field corn processed fraction. The maximum residues in animal feed commodities were 0.09 ppm in forage and 0.03 ppm in stover (total thiamethoxam equivalents).

B. Toxicological Profile

1. Acute toxicity. The acute oral LD₅₀ for thiamethoxam in the rat is 1,563 milligrams/kilogram body weight (mg/kg bwt). The acute dermal LD₅₀ of thiamethoxam is >2,000 mg/kg bwt. Thiamethoxam is non-toxic at atmospheric concentrations of 3.72 mg/L. Thiamethoxam is minimally irritating to the eye, non-irritating to skin and is not a dermal sensitizer.

In an acute neurotoxicity screening study in rats (OPPTS 870.6200), the no observed adverse effect level (NOAEL) was 100 mg/kg/day with a NOAEL of 500 mg/kg/day based on drooped palpebral closure, decrease in rectal temperature and locomotor activity and increase in forelimb grip strength (males only). At higher dose levels, mortality, abnormal body tone, ptosis, impaired respiration, tremors, longer latency to first step in the open field, crouched over posture, gait impairment, hypoarousal, decreased number of rears, uncoordinated landing during the righting reflex test, slight lacrimation (females only) and higher mean average input stimulus value in the auditory startle response test (males only).

2. Genotoxicity. In gene mutation studies with *S. typhimurium* and *E. coli* (OPPTS 870.5100 and 870.5265, there was no evidence of gene mutation when tested up to 5,000 µg/plate and there was no evidence of cytotoxicity.

In a gene mutation study with Chinese hamster V79 cells at hypoxanthine guanine phosphoribosyl transferase (HGPRT) focus (OPPTS 870.5300), there was no evidence of gene mutation when tested up to the solubility limit.

In a Chinese hamster ovary (CHO) cell cytogenetics study (OPPTS 870.5375), there was no evidence of

chromosomal aberrations when tested up to cytotoxic or solubility limit concentrations.

An *in vivo* mouse bone marrow micronucleus study (OPPTS 870.5395) was negative when tested up to levels of toxicity in whole animals; however, no evidence of target cell cytotoxicity.

An unscheduled DNA synthesis (UDS) assay (OPPTS 870.5550) was negative when tested up to precipitating concentrations.

3. Reproductive and developmental toxicity. A prenatal developmental study in the rat (OPPTS 870.3700) resulted in maternal and developmental NOAELs of 30 mg/kg/day and 200 mg/kg/day, respectively. The maternal lowest observed adverse effect level (LOAEL) is 200 mg/kg/day based on decreased body weight, body weight gain and food consumption. The developmental LOAEL was 750 mg/kg/day based on decreased fetal body weight and an increased incidence of skeletal anomalies.

A prenatal developmental study in the rabbit (OPPTS 870.3700) resulted in maternal and developmental NOAELs of 50 mg/kg/day. The maternal and developmental LOAEL is 150 mg/kg/day. The maternal LOAEL is based on maternal deaths, hemorrhagic discharge, decreased body weight and food intake during the dosing period. The developmental LOAEL is based on decreased fetal body weights, increased incidence of post-implantation loss and a slight increase in the incidence of a few skeletal anomalies/variations.

In a reproduction and fertility effects study in rats (OPPTS 870.3800) the parental/systemic NOAEL is 1.84 (males), 202.06 (females) mg/kg/day; the reproductive NOAEL is 0.61 (males), 202.06 (females) mg/kg/day; and the offspring NOAEL is 61.25 (males), 79.20 (females) mg/kg/day. The parental/systemic LOAEL is 61.25 (males), not determined (females) mg/kg/day based on increased incidence of hyaline change in renal tubules in F0 and F1 males. The reproductive LOAEL is 1.84 (males), not determined (females) mg/kg/day based on increased incidence and severity of tubular atrophy observed in testes of the F1 generation males. The offspring LOAEL is 158.32 (males), 202.06 (females) mg/kg/day based on reduced body weight gain during the lactation period in all litters.

4. Subchronic toxicity. A 90-day oral toxicity study in rats (OPPTS 870.3100) resulted in a NOAEL of 1.74 (males), 92.5 (females) mg/kg/day. The LOAEL is 17.64 (male), 182.1 (female) mg/kg/day based on increased incidence of hyaline change of renal tubules epithelium (males), fatty change in adrenal-gland of

females, liver changes in females, all at the LOAEL. A 90-day oral toxicity study in mice (OPPTS 870.3100) resulted in an NOAEL of 1.41 (males), 19.2 (females) mg/kg/day. The LOAEL was 14.3 (male) 231 (female) mg/kg/day based on increased incidence of hepatocellular hypertrophy. At higher dose levels: Decrease in body weight and body weight gain, necrosis of individual hepatocytes, pigmentation of Kupffer cells, and lymphocytic infiltration of the liver in both sexes; slight hematologic effects and decreased absolute and relative kidney weights in males; and ovarian atrophy, decreased ovary and spleen weights and increased liver weights in females.

In a 90-day oral toxicity study in dogs (OPPTS 870.3150), the NOAEL is 8.23 (males), 9.27 (females) mg/kg/day. The LOAEL is 32.0 (male), 33.9 (female) mg/kg/day based on slightly prolonged prothrombin times and decreased plasma albumin and A/G ration (both sexes); decreased calcium levels and ovary weights and delayed maturation in the ovaries (female); decreased cholesterol and phospholipid levels, testis weights, spermatogenesis, and spermatic giant cells in testes (male).

In a 28-day dermal study in rats (OPPTS 870.3200), the NOAEL was 250 (male), 60 (female) mg/kg/day. The LOAEL was 1,000 (male), 250 (female) mg/kg/day based on increased plasma glucose, triglyceride levels, and alkaline phosphatase activity and inflammatory cell infiltration in the liver and necrosis if single hepatocytes in females and hyaline change in renal tubules and a very slight reduction in body weight in males. At higher dose levels in females, chronic tubular lesions in the kidneys and inflammatory cell infiltration in the adrenal cortex were observed.

In a subchronic neurotoxicity screening study in rats (OPPTS 870.6200), the NOAEL was 95.4 (male), 216.4 (female) mg/kg/day, both at highest dose tested. The LOAEL was not determined. No treatment related observations at any dose level. LOAEL was not achieved. May not have been tested at sufficiently high dose levels; however, a new study is not required because the weight of the evidence from other toxicity studies indicates no evidence of concern.

5. Chronic toxicity. In a chronic toxicity study in dogs (OPPTS 870.4100), the NOAEL was 4.05 (male), 4.49 (female) mg/kg/day. The LOAEL was 21.0 (male), 24.6 (female) mg/kg/day based on increase of creatinine in both sexes, transient decrease in food consumption in females, and occasional increase in urea levels, decrease in ALT,

and atrophy of seminiferous tubules in males.

In a mouse carcinogenicity study (OPPTS 870.4200), the NOAEL was 2.63 (male), 3.68 (female) mg/kg/day. The LOAEL was 63.8 (male), 87.6 (female) mg/kg/day based on hepatocyte hypertrophy, single cell necrosis, inflammatory cell infiltration, pigment deposition, foci of cellular alteration, hyperplasia of kupffer cells and increased mitotic activity, also an increase in the incidence of hepatocellular adenoma (both sexes). At higher doses, there was an increase in the incidence of hepatocellular adenocarcinoma (both sexes) and the number of animals with multiple tumors, evidence of carcinogenicity.

In a combined chronic carcinogenicity study in rats (OPPTS 870.4300), the NOAEL was 21.0 (male), 50.3 (female) mg/kg/day. The LOAEL was 63.0 (male), 255 (female) mg/kg/day based on increased incidence of lymphocytic infiltration of the renal pelvis and chronic nephropathy in males and decreased body weight gain, slight increase in the severity of hemosiderosis of the spleen, foci of cellular alteration in liver and chronic tubular lesions in kidney in females. No evidence of carcinogenicity.

In a hepatic cell proliferation study in mice, the NOAEL was 16 (male), 20 (female) mg/kg/day. The LOAEL was 72 (male), 87 (female) mg/kg/day based on proliferative activity of hepatocytes. At higher dose levels, increases in absolute and relative liver weights, speckled liver, hepatocellular glycogenesis/fatty change, hepatocellular necrosis, apoptosis and pigmentation were observed.

In a 28-day feeding study to assess replicative DNA synthesis in the male rat, the NOAEL was 711 mg/kg/day. The LOAEL was not established. Immunohistochemical staining of liver sections from control and high dose animals for proliferating cell nuclear antigen gave no indication for a treatment related increase in the fraction of DNA synthesizing hepatocytes in S-phase. CGA293343 did not stimulate hepatocyte cell proliferation in male rats.

In a special study to assess liver biochemistry in the mouse, the NOAEL was 17 (male), 92 (female) mg/kg/day. The LOAEL was 74 (male), 92 (female) mg/kg/day based on marginal to slight increases in absolute and relative liver weights, a slight increase in the microsomal protein content of the livers, moderate increases in the cytochrome P450 content, slight to moderate increases in the activity of several microsomal enzymes, slight to

moderate induction of cytosolic glutathione S-transferase activity. Treatment did not affect peroxisomal fatty acid B-oxidation.

6. *Animal metabolism.* The metabolism of thiamethoxam in rats and livestock animals is adequately understood. The residues of concern have been determined to be parent thiamethoxam and its metabolite (N-(2-chloro-thiazol-5-ylmethyl)-N' methyl-N'-nitro-guanidine).

7. *Metabolite toxicology.* For risk assessment purposes, residues of the metabolite corrected for molecular weight are considered to be toxicologically equivalent to parent thiamethoxam.

C. Aggregate Exposure

1. *Dietary exposure.* Permanent tolerances have been established (40 CFR 180.565) for the combined residues of the insecticide thiamethoxam, 3-[(2-chloro-5-thiazolyl) methyl] tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4-imine and its metabolite (N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-N'-nitro-guanidine), in or on a variety of RACs at levels ranging from 0.02 ppm to 1.5 ppm (including barley, canola, cotton, sorghum, wheat, cucurbit vegetables, fruiting vegetables, pome fruits and livestock commodities). Pending tolerances include coffee, grapes, raisins, grape juice, pecans, peanut nutmeats, peanut hay, corn grain, sweet corn (kernal with husk removed), pop corn, corn forage and stover, head and stem brassica, leafy brassica greens and leafy vegetables.

i. *Food—a. Acute risk.* The acute dietary exposure evaluation (food only) for thiamethoxam (CGA-293343) was based on a point residue (highest average field trial residue value) DEEM acute analysis. This assessment was based on a Monte Carlo analysis (1,000 iterations) and utilized an acute endpoint of 100 mg/kg-bw/day (acute neurotoxicity study). Residue values for thiamethoxam (CGA-293343) and its corresponding acid metabolite (CGA-322704) were compiled using data from field trial studies. For those field trial samples which had non-detectable residues, a value of $\frac{1}{2}$ the statistically derived limit of detection ($\frac{1}{2}$ sLOD) was used. Non-nursing infants (<1 year old) were the most sensitive subpopulation with a total exposure of 0.42% of the acute reference dose (aRfD). The next most sensitive subpopulation was all infants <1 year old) with an exposure of 0.37% of the aRfD. Acute exposure for the U.S. population was 0.12% of the aRfD at the 99.9th percentile of exposure. Therefore, it is expected that the proposed tolerances for corn

commodities will have minimal impact on acute dietary risk and that the aggregate exposure will not exceed 100% of the acute RfD.

b. *Chronic and lifetime risk.* For the chronic and lifetime exposure assessments, all of the DEEM™ inputs including residue and percent of crop treated (%CT) for currently registered uses were from EPA's August 28, 2000 dietary exposure assessment on thiamethoxam (DP Barcode D268606, PC Code 060109). For these assessments, the 1996–1998 CSFII was used and %CT value for apples was 2%. All residue data were from field trials where thiamethoxam was applied at the maximum intended use rate and the samples were harvested at the minimum pre-harvest interval (PHI) to obtain maximum expected residues. All values from the EPA "baseline" assessment assumed one-half limit of quantitation ($\frac{1}{2}$ LOQ) for all non-detects in the field trial samples.

c. *Chronic risk.* The chronic dietary exposure from food use indicated that chronic dietary exposure from food utilizes 3.5% of the chronic RfD for the U.S. population and 7.9% of the chronic RfD for children 1–6 years old. Addition of corn field trial residues to the assessment caused a negligible increase in chronic exposure (0.1% for the U.S. population and 0.3% for children 1–6 years old). Therefore, the proposed tolerances for corn commodities will have minimal impact on chronic dietary risk and that the aggregate exposure will not exceed 100% of the chronic RfD.

d. *Lifetime risk.* Results from the lifetime dietary exposure analysis (food only) show that there are acceptable safety margins with respect to chronic exposures incurred by the dietary consumption of thiamethoxam-treated commodities, including corn. Lifetime exposures to the U.S. population (48 states, all seasons) resulted in a value of 8.13×10^{-7} which represents 81.3% of the lifetime risk limit of 1×10^{-6} . This represents a slight increase (2.1%) in the lifetime risk of 7.92×10^{-7} (79.2%) associated with currently registered uses of thiamethoxam.

ii. *Drinking water.* EPA used the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to

provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern. Based on the SCI-GROW and PRZM/EXAMS models, EPA calculated that estimated environmental concentrations (EECs) of thiamethoxam at the highest use rate of 0.125 pound active ingredient per acre (lb a.i./acre) are 1.94 parts per billion (ppb) for acute and chronic exposure to ground water and 8 ppb and 0.6 ppb for acute and chronic exposure, respectively, to surface water. Based on both field and laboratory data, Syngenta predicts that the potential exposure to ground water is much lower than that predicted by the conservative SCI-GROW model. EPA determined EECs are used for comparison to drinking water levels of comparison (DWLOC).

a. *Acute risk.* Acute drinking water levels of comparison were calculated based on an acute populated adjusted dose (aPAD) of 0.1 mg/kg/day. For the acute assessment, the non-nursing infants (<1 year old) subpopulation generated the lowest acute DWLOC of approximately 996 ppb. EPA has determined that the surface water acute EEC is 8 ppb and the ground water EEC is 1.94 ppb. Since the surface water value is greater than the ground water value, the surface water value will be used for comparison purposes and will protect for any concerns for ground water concentrations. Since the acute DWLOC of 996 ppb is considerably higher than the acute EEC of 8 ppb, EPA should not have a concern for acute risk to either surface or ground water.

b. *Chronic risk.* Chronic drinking water levels of comparison were calculated based on a chronic populated adjusted dose (cPAD) of 0.0006 mg/kg/day. For the chronic assessment, the non-nursing infants subpopulation generated the lowest chronic DWLOC of approximately 5.5 ppb. EPA has determined that the surface water chronic EEC is 0.6 ppb and the ground water EEC is 1.94 ppb. Since the ground water value is greater than the surface water value, the ground water value will be used for comparison purposes and will protect for any concerns for surface water concentrations. Since the chronic DWLOC of 5.5 ppb is higher than the chronic EEC of 1.94 ppb, EPA should not have a concern for chronic risk to either surface or ground water.

c. *Cancer risk.* Based on currently registered uses for thiamethoxam, EPA has determined a drinking water level of comparison for cancer (cancer DWLOC) of 2.14 ppb based upon a 2% market share for apples. Based on the addition of the proposed corn seed treatment use,

the cancer DWLOC would be 2.12 ppb, representing only a minimal change. At the currently registered maximum use rate of 0.125 lb. a.i./acre per growing season, EPA has used the SCI-GROW model to predict a ground water EEC of 1.94 ppb; therefore, the cancer DWLOC (2.12 ppb) is not exceeded. For the proposed corn seed treatment uses, the maximum use rate on a per acre basis is 0.123 lb active ingredient. This maximum rate (0.123 lb) would be applicable only to field corn and would represent only 0.18% of all corn acres grown. Ninety-seven percent of thiamethoxam treated corn (5.4% of all corn acres grown) will be planted with a maximum rate on a per acre basis of 0.070 lbs a.i. per acre. Using EPA determined input values, the SCI-GROW model predicts an EEC of 1.90 ppb for the 0.123 lb rate and an EEC of 1.08 ppb for the 0.070 lb rate. Neither of these EECs (1.90 or 1.08 ppb) exceeds the cancer DWLOC (2.12 ppb).

The SCI-GROW model uses extremely conservative assumptions. However, even when using the conservative SCI-GROW model, it can be concluded that the proposed corn seed treatment use of thiamethoxam presents a negligible risk concern for exposure through drinking water.

2. Non-dietary exposure.

Thiamethoxam is not currently registered for use on any sites that would result in residential exposure.

D. Cumulative Effects

The potential for cumulative effects of thiamethoxam and other substances that have a common mechanism of toxicity has also been considered.

Thiamethoxam belongs to a new pesticide chemical class known as the neonicotinoids. There is no reliable

information to indicate that toxic effects produced by thiamethoxam would be cumulative with those of any other chemical including another pesticide. Therefore, Syngenta believes it is appropriate to consider only the potential risks of thiamethoxam in an aggregate risk assessment.

E. Safety Determination

1. *U.S. population.* Syngenta concludes, as described above, that there is reasonable certainty that no harm to the U.S. population will result from aggregate acute or chronic dietary exposure to thiamethoxam residues including the proposed tolerances for corn commodities.

2. *Infants and children.* Syngenta concludes, as described above, that there is reasonable certainty that no harm to infants and children will result from aggregate acute or chronic exposure to thiamethoxam residues including the proposed tolerances for corn commodities.

F. International Tolerances

There are no codex MRLs established for residues of thiamethoxam on corn commodities.

[FR Doc. 02-16276 Filed 6-26-02; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0124; FRL-7185-3]

Carbofuran; Receipt of Application for Emergency Exemption, Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific exemption request from the Louisiana Department of Agriculture and Forestry to use the pesticide carbofuran (CAS No. 1563-66-2) to treat up to 100,000 acres of rice to control the rice weevil.

Because this application for an emergency exemption program involves the use of a chemical which has been the subject of a Special Review by EPA under 40 CFR part 154, EPA is soliciting public comment on the exemption.

DATES: Comments, identified by docket ID number OPP-2002-0124, must be received on or before July 2, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the

SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0124 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Dan Rosenblatt, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9366; fax number: (703) 308-5433; e-mail address: rosenblatt.dan@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you petition EPA for emergency exemption under section 18 of FIFRA. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
State government	9241	State agencies that petition EPA for section 18 pesticide exemption

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. Other types of entities not listed in the table in this unit could also be regulated. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action applies to certain entities. To determine whether you or your business is affected by this action, you should carefully examine the applicability provisions in Unit II. If you have any questions regarding the applicability of this action

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1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations

and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0124. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business