certainty that no harm will result to the U.S. population from aggregate exposure to aminopyralid residues.

2. *Infants and children*. FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base. Based on the current toxicological data requirements, the data base for aminopyralid relative to prenatal and postnatal effects for children is complete. Overall, aminopyralid had no effect on reproduction or embryo-fetal development at any dosage tested. No quantitative or qualitative susceptibility was seen following prenatal and postnatal exposures. In a 2-generation reproductive toxicity study in rats, no effects on reproductive performance or neonatal development were observed. Dow AgroSciences concluded that there is no indication of increased sensitivity of infants and children relative to adults and that no additional Food Quality Protection Act (FQPA) safety factor is required. Using the above conservative assumptions, aggregate exposure to aminopyralid will utilize only 0.1% of the cPAD for all infants <1 year old, 0.2% of the cPAD for children 1–2 years old and 0.1% of the cPAD for children 6–12 years old. Even when considering the potential exposure to drinking water, the aggregate exposure is not expected to exceed 100% of the cPAD. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Dow AgroSciences concludes, with reasonable certainty that no harm will result to infants and children from the aggregate exposure to aminopyralid residues.

F. International Tolerances

No Codex maximum residue levels are established for residues of aminopyralid on any food or feed crop. Therefore, no compatibility problems exist for the proposed tolerances.

[FR Doc. 04–12020 Filed 6–1–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0185; FRL–7361–1]

Thiamethoxam; 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 ID number OPP–2004–0185, must be received on or before July 2, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Dani Daniel, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; 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 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:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food Manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2004–0185. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether

submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2004–0185. The system is an''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP–2004–0185. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2004–0185.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2004–0185. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed 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 theelements set forth in FFDCA 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: May 24, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemicalresidues or an explanation of why no such method is needed.

Syngenta Crop Protection Inc. and Interregional Research Project #4

PP 2E6363, 3E6781, 3E6800, 3E6806, 3E6805, 3E6807, 4E6819, 9F5051 and 0F6142

EPA has received pesticide petitions (PP 2E6363, 3E6781, 3E6800, 3E6806, 3E6805, 3E6807, 4E6819, 9F5051 and 0F6142) from Syngenta Crop Protection Inc., P.O. Box 18300, Greensboro, NC 27419-8300 and Interregional Research Project #4 (IR-4), 681 US Highway #1 South, North Brunswick, NJ 08902-3390, 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 tolerances for residues of thiamethoxam [3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-*N*-nitro-4*H*-1,3,5-oxadiazin-4-imine] (CAS Reg. No. 153719–23–4) and its metabolite [*N*-(2-chloro-thiazol-5-ylmethyl)-*N*′-methyl-*N*″-nitro-guanidine) in or on the raw agricultural commodities peppermint and spearmint, tops at 4.0 parts per million (ppm); legume vegetables (succulent or dried) at 0.02 ppm; root vegetables (except sugar beet) crop subgroup (1b) at 0.10 ppm and for radish tops at 0.80 ppm; strawberry at 0.30 ppm; cranberry at 0.01 ppm; bushberry crop subgroup (13B) and juneberry, lingonberry and salal at 0.25 ppm; rapeseed, seed; Indian rapeseed; Indian mustard, seed; field mustard, seed; black mustard, seed; flax, seed; safflower, seed; crambe, seed; and borage, seed at 0.02 ppm; grapes at 0.15 ppm; grape juice at 0.20 ppm and raisins at 0.30 ppm; a tolerance increase for tuberous and corm crop subgroup (1C) from 0.02 ppm to 0.25 ppm; leafy vegetables (except brassica vegetables) at 2.0 ppm; leafy brassica greens crop subgroup 5B at 2.0 ppm; and head and stem brassica crop subgroup 5A at 1.0 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 supports 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 spectrometry (MS) detection. The limit of detection (LOD) for each analyte of this method is 1.25 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*. IR-4 has submitted complete residue data for thiamethoxam on peppermint and spearmint tops; legume vegetables; root and tuber vegetables (except sugar beet); strawberry; cranberry; bushberry subgroup plus juneberry, lingonberry and salal; and oil seed crops.

Syngenta has submitted complete residue data for the proposed tolerances on leafy vegetables, head and stem brassica vegetables, leafy brassica vegetables, grape commodities and the proposed increase in tolerance for the tuberous and corm vegetable subgroup.

B. Toxicological Profile

1. *Acute toxicity*. The acute oral LD_{50} for thiamethoxam in the rat is 1,563 milligrams per kilogram of bodyweight(mg/kg bw). The acute dermal LD_{50} of thiamethoxam is >2,000 mg/kg bw. Thiamethoxam is non-toxic at atmospheric concentrations of 3.72 milligrams per liter (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 milligrams per kilograms per day (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, hypo-arousal, 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. *Genotoxicty*. 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 HGPRT focus (OPPTS 870.5300) there was no evidence of gene mutation when tested up to the solubility limit.

In a 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. A 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 anomolies/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 F_0 and F_1 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 F_1 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 a 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 hepatocelluar adenocarcinoma (both sexes) and the number of animals with multiple tumors, evidence of carcinogenicity.

In a combined chronic caricinogenicity 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, heptocellular glycogenesis/fatty change, heptocellular 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 syntesizing 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 glutathionw S-transfersase 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 most risk assessment purposes, residues of the metabolite corrected for molecular weight are considered to be toxicologically equivalent to parent

thiamethoxam. However, EPA has determined that the metabolite should not be included in cancer risk assessment.

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-4*H*-1,3,5-oxadiazin-4-imine and it's 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, coffee (imported), corn, cotton, cucurbit vegetables, fruiting vegetables, pecans, pome fruits, sorghum, stone fruits, succulent beans, sunflowers, wheat, tuberous and corm vegetables and livestock commodities).

Pending tolerances include: brassica (head and stem), brassica (leafy), bushberry subgroup (plus lingonberry, juneberry and salal), cranberry, grapes (fruit, raisins and juice), leafy vegetables, legume vegetable group, mint (peppermint and spearmint tops), oil seed crops (mustards, rapes, crambe, flax, safflower and borage), root vegetable (except sugar beets) subgroup and strawberry and a proposed tolerance increase for tuberous and corm vegetables.

Tier I acute, tier II chronic and tier III cancer dietary exposure evaluations were made using the Dietary Exposure Evaluation Model (DEEM®), version 7.76 from Exponent. All processing factors were taken from the EPA assessment of August 28, 2000 (DP Barcode D268606, PC Code 060109). Tolerance values have been established (40 CFR 180.565(a)) for the combined residues of both thiamethoxam (CGA-293343) and its metabolite (CGA-322704) in or on a variety of raw agricultural commodities including meat, milk and eggs. These assessment results include all registered uses and proposed uses on mint, leafy vegetables, leafy Brassica vegetables, Brassica head and stem vegetables, grapes, cranberries, strawberries, oilseed crops, legume vegetables (crop subgroup 6), bushberries (crop subgroup 13B), root vegetables (except sugarbeets, crop subgroup 1B) and soybeans.

For the tier I acute assessment, the proposed tolerance residues for these commodities (mint, 4.0 ppm; oilseed crops, 0.02 ppm; leafy vegetables, 2.0 ppm; leafy brassica vegetables, 2.0 ppm; brassica head and stem vegetables, 1.0 ppm; strawberries, 0.30 ppm; grapes, 0.15 ppm; grape juice, 0.20 ppm; grape raisins, 0.30 ppm; cranberries, 0.01 ppm; bushberries, 0.25 ppm; root vegetables subgroup 1A and 1B (except sugar beets), 0.10 ppm, root vegetables subgroup 1C, 0.25 ppm; legume vegetables, 0.02 ppm and soybeans, 0.02 ppm) were used along with the published tolerances for all other commodities. One-hundred percent of crop treated was assumed for all commodities in the acute assessment.

In the tier II chronic assessment, the residue of concern was the sum of CGA-293343 and CGA-322704. Addition of the proposed crops mentioned above to the animal diets did not increase the previously calculated dietary burdens for any livestock commodities. Therefore, the residue values for secondary animal commodities were taken from the EPA assessment of August 28, 2000 which uses average field trial residue data with one-half limit of quantitation (LOQ) substitutions for all non-detectable residues. For the remaining registered and the proposed commodities listed above, the following residue data was used in the DEEM®: cucurbit, leafy and Brassica vegetables and tomatoes - average field trial residues from soil-only (Platinum) application residue studies; stone fruits, mint, succulent beans, sunflower seed, and coffee - average field trial residue data with one-half LOQ substitutions for non-detectable residues; all other commodities - the proposed tolerances listed in the acute section above.

For the cancer assessment, the residue values used for all animal commodities were the same as those used in the chronic assessment. For all of the remaining commodities, the residue of concern was only CGA-293343 since CGA-322704 was found to be ''not carcinogenic to humans'' (EPA Memorandum, 12/24/03, DP Barcode 278328). Residue values were taken from field trial data where thiamethoxam was applied at the maximum labeled use rate and resulting crops were harvested at the minimum labeled PHI. For a number of crops, average residue values from field trials with soil-only (Platinum) applications of thiamethoxam were calculated to reflect currently proposed use directions. These crops included: leafy vegetables (crop group 4), Brassica vegetables (crop group 5), cucurbit vegetables (crop group 9) and fruiting vegetables (except peppers). Non-detectable residue values for these crops were substituted with a value of one-half LOQ. For the remaining crops, the average field trial residue values with one-half LOQ substitutions for non-detectable residues were used in the assessment if available and proposed tolerance residues were used if the field trial data was not available.

All consumption data for these assessments was taken from the USDA's Continuing Survey of Food Intake by individuals (CSFII) with the 1994-96 consumption database and the Supplemental CSFII children's survey (1998) consumption database. For the chronic and cancer assessments, the percent of crop treated values for all proposed crops were estimated by Syngenta Crop Protection according to current pest pressures and competitor's products. All other percent of crop treated values were estimated from the 2000-2003 Doane's Agricultural Marketing Service Database.

i. *Food*. For the purposes of assessing the potential dietary exposure under the proposed tolerances, Syngenta Crop Protection has estimated aggregate exposure from all crops for which tolerances are established or proposed. The Tier I acute assessment utilized tolerance values and 100% of crop treated values. The Tier II chronic and Tier III cancer assessments utilized the residue and percent of crop treated values described above.

a. *Acute exposure.* An acute reference dose of 0.10 mg/kg-bw/day for all population subgroups was based on a NOAEL of 100 mg/kg-bw/day from an acute neurotoxicity study in rats and an uncertainty factor of 100X (100X for combined interspecies and intraspecies variability). An additional FQPA safety factor of 10X was applied to all population subgroups due to the absence of a developmental neurotoxicity study. For the purpose of aggregate risk assessment, the exposure value was expressed in terms of margin of exposure (MOE). The MOE was calculated by dividing the NOAEL by the exposure for each population subgroup. In addition, exposure was expressed as a percent of the acute reference dose (%aRfD). Acute exposure to the most exposed sub-population (children 1 - 2 years old) resulted in a MOE of 6,873 (14.6 % of the acute RfD (aRfD) of 0.10 mg/kg-bw/day) at the 95th percentile of exposure. Since the benchmark MOE for this assessment was 1,000 and since EPA generally has no concern for exposures below 100% of the aRfD, Syngenta believes that there is a reasonable certainty that no harm will result from acute dietary (food) exposure to residues arising from the current and proposed uses for thiamethoxam.

b. *Chronic exposure.* The chronic reference dose (RfD) for thiamethoxam is 0.0006 mg/kg-bw/day for all population subgroups and is based on a NOAEL of 0.6 mg/kg-bw/day from a two

generation rat reproduction study. An uncertainty factor of 100X (for combined interspecies and intraspecies variability) and an additional FQPA safety factor of 10X was applied due to evidence of increased susceptibility to young rats following pre-/postnatal exposure. Exposure was expressed as MOE and percent of the reference dose (%RfD). Chronic exposure to the most exposed sub-population (children 1-2 years old) resulted in a MOE of 5,607 (17.8% of the chronic RfD of 0.0006 mg/kg-bw/day). Since the benchmark MOE for this assessment was 1,000 and since EPA generally has no concern for exposures below 100% of the RfD, Syngenta believes that there is a reasonable certainty that no harm will result from chronic dietary (food) exposure to residues arising from the current and proposed uses for thiamethoxam.

c. *Lifetime exposure.* The Q* value for thiamethoxam is 0.0377 $(mg/kg/day)^{-1}$ and is based on benign and malignant heptocellular tumors in mice in an 18–month carcinogenicity study. Lifetime exposure to the U.S. population of 0.000023 mg/kg-bw/day resulted in a Lifetime Risk of 8.63×10^{-7} which represents 86.3% of the EPA's Lifetime Risk limit of 1.0×10^{-6}.

ii. *Drinking water.* The 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, the EPA calculated that estimated environmental concentrations of thiamethoxam at the highest use rate (0.125 lb active ingredients/Acre) are 1.9 parts per billion (ppb) for acute and chronic exposure to ground water and 7.1 ppb and 0.43 ppb for acute and chronic exposure, respectively, to surface water. The EPA model-estimated estimated environenmental concentrations (EECs) are used below for comparison to Drinking Water Levels of Comparison (DWLOC) for hte acute, chronic and cancer assessments.

a. *Acute drinking water risk.* Acute DWLOC were calculated based on an acute Populated Adjusted Dose (aPAD) of 0.1 mg/kg/day. For the acute assessment, the children (1-2 years old) subpopulation generated the lowest acute DWLOC of 854 ppb. The EPA has determined that the surface water acute EEC is 7.1 ppb and the ground water EEC is 1.9 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 854 ppb is considerably higher than the acute EEC of 7.1 ppb, the EPA should not have a concern for acute risk to either surface or ground water.

b. *Chronic drinking water risk.* Chronic DWLOC were calculated based on a chronic Populated Adjusted Dose (cPAD) of 0.0006 mg/kg/day. For the chronic assessment, the children (1-2 years old) subpopulation generated the lowest chronic DWLOC of approximately 4.9 ppb. The EPA has determined that the surface water chronic EEC is 0.43 ppb and the ground water EEC is 1.9 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 4.9 ppb is higher than the chronic EEC of 1.9 ppb, the EPA should not have a concern for chronic risk to either surface or ground water.

c. *Lifetime cancer drinking water risk.* Based on currently registered and proposed uses for thiamethoxam, Syngenta has determined a DWLOC for Lifetime Exposure of 2.0 ppb. At the currently registered maximum use rate of 0.125 lbs. active ingredient per acre per growing season, the EPA has used the SCI-GROW model to predict a ground water EEC of 1.9 ppb and used PRZM/EXAMS to predict a long-term average surface water EEC of 0.13 ppb. Since neither the ground water EEC nor the long-term average surface water EEC exceeds the cancer DWLOC for the general population, the cancer drinking water risk is below the EPA's level of concern.

The EPA SCI-GROW model is a conservative screening level tool specifically designed to estimate pesticide concentrations in shallow ground water based on only three parameteres: use rate, laboratory determined aerobic soil degradation half life, and soil organic matter adsorption partition coefficient (K_{oc}). The model is not able to separately predict acute and long-term average concentrations. A number of factors lead the EPA to believe that the actual lifetime exposure through drinking water will be less than the Lifetime DWLOC. These reasons are as follows:

(a) Thiamethoxam is a systemic pesticide. The EPA's Tier I ground water model assumes that all of the product that is applied to the crop is available for runoff. Syngenta has submitted data to show that a percentage (15-25%) of the product is absorbed by the plant, resulting in that much less product available to leach into ground water. Although data submitted is on only two crops (beans and cucumbers), it is likely that the total amount of thiamethoxam available for ground water leaching is less than the amount the EPA uses as a model input.

(b) Although the Agency model is based on aerobic soil half lives, the EPA's Lifetime Risk assessment is for lifetime exposure. Data indicate the anaerobic aquatic half-life for thiamethoxam is shorter than the aerobic soil half-life and longer than the aerobic aquatic half-life. Although the EPA is unable to predict, with a high degree of certainty, what happens to thiamethoxam in ground water over time, this does provide some support for the expectation that concentrations in ground water will decline between annual applications.

(c) Shallow ground water modeling is not the perfect model for representing all drinking water from ground water sources. It is likely to be an overestimate of most drinking water concentrations, which tend to originate from deeper sources. The EPA's experience is that the model is reasonably accurate for shallow drinking water, but the Agency believes that it is less accurate for estimating concentrations in drinking water from deeper sources.

(d) The Agency has established conditions of registration for the previous uses that include two prospective ground water studies and a retrospective monitoring study, so that the reasonable certainty of no harm finding will be sustained.

(e) The dietary food risk is based on residue data derived from the average of field trials, which were performed at a higher application rate than what was accepted by the EPA. It is not unusual in the Agency's experience for field trial data to be an order of magnitude above actual monitoring. Since thiamethoxam has only recently been registered, actual monitoring data is not yet available. It is likely that the actual risk contribution from food will be much lower than current data indicate, which would result in a larger lifetime DWLOC. EPA should expect that this refined lifetime DWLOC would be larger than the EECs for the proposed uses.

Based on the previous points, the EPA should not expect that the general population would be exposed to levels exceeding the lifetime DWLOC

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 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 dietary exposure to thiamethoxam residues including the proposed commodities.

F. International Tolerances

There are no Codex MRLs established for residues of thiamethoxam.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0117; FRL–7357–8]

Cloquintocet Mexyl; 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 apesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2004–0117, must be received on or before July 2, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions asprovided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Bipin Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8380; e-mail address: *gandhi.bipin@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 agriculturalproducer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2004–0117. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is