Dated: December 20, 2000.

Richard Colbert,

Director, Agriculture and Ecosystems Division, Office of Compliance.

[FR Doc. 00–33173 Filed 12–27–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–990; FRL–6761–6

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 PF–990, must be received on or before January 29. 2001.

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 PF–990 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–3194; e-mail address: brothers.shaja@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	Crop production Animal production Food manufacturing
	32532	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/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–990. 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 control number PF–990 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 control number PF–990. 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 control 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 Comestic 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: December 22, 2000.

James Jones,

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 the petitioner and represents the view of the petitioners. 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.

Research Project Number 4 and Gowan Company

0E6198 and 0E6215

EPA has received pesticide petitions (0E6198 and 0E6215) from the Interregional Research Project Number 4 (IR–4), Technology Centre of New Jersey, 681 U.S. Highway #1 South, North Brunswick, New Jersey 08902–3390 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of the miticide, hexythiazox, *trans*-5- (4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3- carboxamide and its metabolites containing the (4-chlorophenyl-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parts per million (ppm) of the parent compound in or on the following raw agricultural commodities (RAC) at the tolerance levels listed:

- PP 0E6198 proposes the establishment of a tolerance for mint at 2.0 ppm.
- PP 0E6215 proposes the establishment of a tolerance for the caneberry subgroup at 1.0 ppm.

EPA has determined that the petitions contain 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 petitions. Additional data may be needed before EPA rules on these petitions. This notice includes a summary of the petitions prepared by Gowan Company, POB 5569, Yuma AZ 85366–5569.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of hexythiazox as well as the nature of the residues in plants is adequately understood for purposes of these tolerances. Metabolism studies were conducted in four crops, viz.; pears, grapes, citrus, and apples. The major residue component is unmetabolized parent. The metabolites are hydroxylcyclohexyl, and ketocyclohexyl analogs of hexythiazox, and the amide formed by loss of the cyclohexyl ring. Parent hexythiazox and its metabolites are converted to a common moiety for residue analysis.

2. *Analytical method*. A practical analytical method, high pressure liquid chromatography with a ultraviolet ray (UV) detector which detects and measures residues of hexythiazox and its metabolites as a common moiety, is available for enforcement purposes with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances.

3. *Magnitude of residues*. Hexythiazox was applied to mint in eastern Washington to support the proposed use. Two trials were conducted on spearmint and 1 on peppermint. There was no concentration of hexythiazox in the processed commodity, mint oil. This data support the proposed tolerance of 2.0 ppm on mint. Hexythiazox was applied to caneberries in Pennsylvania, Michigan, Washington, and Oregon to support the proposed use. Four trials were conducted on red raspberries and one on blackberries. The data support the proposed tolerance of 1.0 ppm in or on caneberries.

B. Toxicological Profile

1. *Acute toxicity*. A battery of acute toxicity studies places technical grade hexythiazox in toxicity category IV for acute oral lethal dose LD_{50} (LD_{50} >5,000 milligrams/kilogram (mg/kg)), category III for dermal LD_{50} (LD_{50} >5,000 mg/kg), category III for inhalation lethal concentration $(LC)_{50}$ (LC_{50}>2.0 mg/L), category III for primary eye irritation (showed mild irritation (reddened conjunctiva)), and category IV for dermal irritation (non irritant). Hexythiazox is a non-sensitizer. Acute toxicological studies place technical grade hexythiazox in toxicology category III.

2. *Genotoxicity*. The following genotoxicity studies were all negative: Ames gene mutation, chinese hamster ovary (CHO) gene mutation, chromosome aberration, mouse micronucleus, and rat hepatocyte unscheduled DNA synthesis.

3. *Reproductive and developmental toxicity*. In a developmental toxicity study in rats, the maternal no observed adverse effect level (NOAEL) was 240 mg/kg/day and the maternal lowest observed adverse effect level (LOAEL) was 720 mg/kg/day based on increased ovarian weights and decreased bone ossification.

In a developmental toxicity study in rabbits, the maternal NOAEL was 1,080 mg/kg/day highest dose tested (HDT); the maternal LOAEL was not determined. In a 2–generation reproduction study in rats, the parental

NOAEL was 35 mg/kg/day and the parental LOAEL was 200 mg/kg/day based on decreased body weight (bwt) gain, decreased food consumption and efficiency, and increased liver, kidney and ovarian weights. The reproductive NOAEL was 35 mg/kg/day and the reproductive LOAEL was 200 mg/kg/day based on decreased pup bwt during lactation, delayed hair growth and eye opening.

4. *Subchronic toxicity*. In a 1–month feeding study in dogs, the NOAEL was 1.75 mg/kg/day and the LOAEL was 12.5 mg/kg/day, based on increased liver, and adrenal weights.

5. *Chronic toxicity*. In a 1–year feeding study in dogs, the NOAEL was 2.5 mg/kg/day and the LOAEL was 12.5 mg/kg/day, based on increased alkaline phosphatase, increased adrenal, and liver weights, liver, and adrenal lesions. In a carcinogenicity study in mice, the NOAEL was 36 mg/kg/day and the LOAEL was 215 mg/kg/day. Effects were decreased bwt in males and increased hepatocellular carcinomas and combined adenoma/carcinomas.

In a chronic feeding/carcinogenicity study in rats, the NOAEL (systemic) was 26 mg/kg/day and the LOAEL (systemic) was 180 mg/kg/day based on decreased bwt gain, and increased liver weights in both sexes.

The chronic reference dose (RfD) for hexythiazox is based on the 1–year dog feeding study with a NOAEL of 2.5 mg/kg/day and an uncertainty factor of 100. The Agency has classified hexythiazox as a category C (possible human) carcinogen based on an increased incidence of hepatocellular carcinomas ($p = 0.028$) and combined adenomas/carcinomas ($p = 0.024$) in female mice at the HDT (1,500 ppm) when compared to the controls as well as a significantly increased ($p < 0.001$) incidence of pre-neoplastic hepatic nodules in both males and females at the HDT. The decision supporting a category C classification was based primarily on the fact that only one species was affected and mutagenicity studies were negative. In classifying hexythiazox as a category C carcinogen, the Agency concluded that a quantitative estimate of the carcinogenic potential for humans should be calculated because of the increased incidence of liver tumors in the female mouse. A Q^{1*} of 0.022 $(mg/kg/day)^{-1}$ in human equivalents was published in the **Federal Register**, October 16, 1998, 63FR 55540 (FRL-6035-2).

6. *Animal metabolism*. The metabolism of hexythiazox has been studied in goats, hens, and rats. Metabolic pathways in the animal are similar to those in plants.

7. *Metabolite toxicology*. There are no metabolites of toxicological concern based on a differential metabolism between plants and animals.

8. *Endocrine disruption*. No specific tests have been conducted with hexythiazox to determine whether the chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects. However, there were no significant findings in other relevant toxicity tests, i.e., developmental and multi-generation reproduction studies, which would suggest that hexythiazox produces effects characteristic of the disruption of the estrogenic hormone.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Tolerances have been established (40 CFR 180.479) for residues of hexythiazox *trans*-5- (4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide] and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety in or on apples at 0.02 ppm, pears at 0.3 ppm, and hops (imported) at 2 ppm. Additional tolerances are pending for a variety of plant and animal RACs and process fractions including apple pomace at 0.7 ppm, apples at 0.4 ppm, almond hulls at 10 ppm, cattle fat at 0.05, cattle meat at 0.05 ppm, cattle MBTP at 0.01 ppm, cotton gin by-products at 3 ppm (California), cottonseed at 0.2 ppm (California), milk at 0.05 ppm, prunes at 5 ppm, raisins at 10 ppm, stone fruit at 1 ppm, strawberries at 3 ppm, and tree nuts (crop group 14) at 0.2 ppm. Additional tolerances are being requested in this petition by IR–4 for mint at 2.0 ppm, and caneberries at 1.0 ppm.

Chronic exposure. A chronic dietary exposure analysis for existing and pending proposed uses was conducted for the general U.S. population and 26 population subgroups. Mint and caneberry did not contribute to dietary exposure. In this analysis it was assumed that 100% of crops were treated for both crops. Chronic exposures of 0.000172 mg/kg/day and 0.000203 mg/kg/day were calculated for mint and caneberry respectively for the average U.S. population. Non-nursing infants, the most heavily exposed subgroup, had a calculated exposure of 0.000972 mg/kg/day and 0.001080 mg/kg/day respectively for mint and caneberry. Actual exposures would be much lower, however, because far less than 100% of crops would be treated.

The Agency has not conducted a detailed analysis of potential exposure to hexythiazox via drinking water or outdoor ornamental plants from existing or pending proposed new uses. However, it is believed that chronic exposure from these sources is very small.

Acute exposure. No developmental, reproductive or mutagenic effects have been observed with hexythiazox. Therefore, an analysis of acute exposure has not been conducted.

ii. *Drinking water*. The environmental fate of hexythiazox has been evaluated, and Gowan Company believes that the compound is not expected to contaminate groundwater or surface water to any measurable extent.

2. *Non-dietary exposure*. Hexythiazox is also registered for use on outdoor ornamental plants by commercial applicators only. It is believed that non-occupational exposure from this use is very low. Hexythiazox is not registered for greenhouse, lawn, garden, or residential use.

D. Cumulative Effects

Gowan Company does not have, at this time, available data to determine whether hexythiazox has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, hexythiazox does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, Gowan Company has not assumed that hexythiazox has a common mechanism of toxicity with other substances. For purposes of these petitions only, the potential risks of hexythiazox in its aggregate exposure will be considered.

E. Safety Determination

1. *U.S. population*—i. *Chronic risk*. Chronic risk was calculated using anticipated residue concentrations from all current and proposed uses of hexythiazox and assuming that 100% of each crop is treated. Dietary exposure of the general U.S. population was equivalent to 0.7% of the RfD. Exposure of the most heavily exposed subgroup, non-nursing infants, was equivalent to 3.9% of the RfD.

ii. *Carcinogenic risk*. Carcinogenic risk was evaluated using anticipated residue concentrations and taking into account the percent of crop known or expected to be treated. Lifetime carcinogenic risk for the U.S. population was calculated, to be 4.5×10^{-7}.

iii. *Acute risk*. An estimate of acute risk with this compound has not been conducted since no acute reproductive

or developmental effects have been observed.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of hexythiazox, EPA considered data from developmental toxicity studies in the rat and rabbit, and a 2–generation study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to 1 or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

No developmental or reproductive effects have been observed in any study with hexythiazox. The lowest acute NOAEL was 2,400 ppm in the diet (200 mg/kg/day), HDT, in the 2–generation rat reproduction study. In the rat developmental study, the maternal and fetotoxic NOAEL was 240 mg/kg/day and the developmental NOAEL was 2,160 mg/kg/day, HDT. In the rabbit developmental study, the maternal and developmental NOAEL was 1,080 mg/kg/day, HDT.

Taking into account current toxicological data requirements, the data base for hexythiazox relative to prenatal and postnatal effects is complete. In the rat developmental study, the NOAELs for maternal toxicity and fetotoxicity were the same, which suggests that there is no special prenatal sensitivity in the absence of maternal toxicity. Furthermore, the lowest developmental or reproductive NOAEL is 2 orders of magnitude higher than the chronic NOAEL on which the RfD is based. It is concluded that there is a reasonable certainty of no harm to infants and children from aggregate exposure to hexythiazox residues.

F. International Tolerances

Codex MRLs for 12 commodities, not including mint, have been established. A MRL for blackberries at 0.2 ppm has been established in the Netherlands. There are no Canadian or Mexican MRLs for hexythiazox.

[FR Doc. 00–33174 Filed 12–27–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–50875; FRL–6757–3]

Experimental Use Permit; Receipt of Application of a Transgenic Plant-Pesticide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of an application to amend/extend 524–EUP–93 from Monsanto Company requesting an experimental use permit (EUP) for the plant-pesticide *Bacillus thuringiensis* Cry3Bb protein and the genetic material necessary for its production (Vector ZMIR13L) in corn plants. The Agency has determined that the application may be of regional and national significance. Therefore, in accordance with 40 CFR 172.11(a), the Agency is soliciting comments on this application.

DATES: Comments, identified by docket control number OPP–50875, must be received on or before January 29, 2001.

ADDRESSES: Comments and data 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 control number OPP–50875 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8715; e-mail address: mendelsohn.mike@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those persons who are interested in agricultural biotechnology or may be required to conduct testing of chemical substances under the Federal Food, Drug and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. 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 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/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–50875. The official record consists of the documents specifically referenced in this action, 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 Hwy., 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 control number OPP–50875 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),