

Summary: EPA reviewed the FSEIS and found that the document adequately addresses the issues raised in our comment letter. Therefore, EPA has no objection to the action as proposed.

Dated: January 2, 2001.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 01-379 Filed 1-4-01; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-6930-3]

Availability of FY 99 Grant Performance Reports for States of Georgia and Mississippi, and the Commonwealth of Kentucky

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability of grantee performance evaluation reports.

SUMMARY: EPA's grant regulations (40 CFR 35.150) require the Agency to evaluate the performance of agencies which receive grants. EPA's regulations for regional consistency (40 CFR 56.7) require that the Agency notify the public of the availability of the reports of such evaluations. EPA recently performed end-of-year evaluations of three state air pollution control programs (States of Georgia and Mississippi, and the Commonwealth of Kentucky). The three evaluations were conducted to assess the agencies' performance under the grants awarded by EPA under authority of section 105 of the Clean Air Act. EPA Region 4 has prepared reports for each agency identified above and these reports are now available for public inspection.

ADDRESSES: The reports may be examined at the EPA's Region 4 office, 61 Forsyth Street, SW, Atlanta, Georgia 30303, in the Air, Pesticides, and Toxics Management Division.

FOR FURTHER INFORMATION CONTACT: Gloria Knight, (404) 562-9064, at the above Region 4 address, for information concerning the State of Mississippi, and Marie Persinger (404) 562-9048 for the State of Georgia and the Commonwealth of Kentucky.

Dated: December 22, 2000.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 01-364 Filed 1-4-01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[PF-991; FRL-6761-9]

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-991, must be received on or before February 5, 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-991 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Kerry Leifer, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8811; e-mail address: leifer.kerry@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/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-991. 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, 121 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-991 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-991. 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 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: 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 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 chemical residues or an explanation of why no such method is needed.

Gustafson LLC,

PP 6F4682

EPA has received a pesticide petition PP6F4682 from Gustafson LLC, 1400

Preston Road, Suite 400, Plano, TX 75093 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 imidacloprid: 1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine in or on the raw agricultural commodities: corn, field fodder at 0.20 parts per million (ppm); corn, field forage at 0.10 ppm; and corn, field grain at 0.05 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 metabolism of imidacloprid in plants is adequately understood for the purposes of these tolerances. The residues of concern are combined residues of imidacloprid and its metabolites containing the 6-chloro-pyridinyl moiety, all calculated as imidacloprid.

2. *Analytical method.* The analytical method is a common moiety method for imidacloprid and its metabolites containing the 6-chloro-pyridinyl moiety using a permanganate oxidation, silyl derivatization, and capillary GC-MS selective ion monitoring. This method has successfully passed a petition method validation in EPA labs. There is a confirmatory method specifically for imidacloprid and several metabolites utilizing GC/MS and HPLC-UV which has been validated by the EPA as well. Imidacloprid and its metabolites are stable for at least 24 months in the commodities when frozen.

3. *Magnitude of residues.* Corn seed was treated with imidacloprid, formulated as Gaucho 480 FS at a rate of 8.0 oz.ai/cwt seed. Field trials were conducted at twenty locations, one in Region 1, one in Region 2, seventeen in Region 5, and one in Region 6. The corn seed was planted and the RACs were harvested at the appropriate growth stages. The highest average residue level found in field corn forage was 0.064 ppm. The highest average residue level found in the field corn grain was less than the Limit of Quantitation, which was 0.05 ppm. The highest average residue level found in the field corn fodder was 0.150 ppm. The proposed tolerance for field corn forage is 0.10 ppm. The proposed tolerance for the field corn fodder is 0.20 ppm. The

proposed tolerance for the field corn grain is 0.05 ppm.

Since there were no quantifiable residues in the field corn grain RAC samples analyzed in the processing study or in the RAC study, neither a Section 409 food/feed additive tolerance or a Section 701 maximum residue level is required for the processed commodities.

B. Toxicological Profile

1. *Acute toxicity.* The acute oral LD₅₀ values for imidacloprid technical ranged from 424 - 475 milligrams/kilograms (mg/kg) body weight (bwt) in the rat. The acute dermal LD₅₀ was greater than 5,000 mg/kg in rats. The 4-hour inhalation LC₅₀ was less than 69 mg/m³ air (aerosol). Imidacloprid was not irritating to rabbit skin or eyes. Imidacloprid did not cause skin sensitization in guinea pigs.

2. *Genotoxicity.* Extensive mutagenicity studies conducted to investigate point and gene mutations, DNA damage and chromosomal aberration, both using *in vitro* and *in vivo* test systems show imidacloprid to be non-genotoxic.

3. *Reproductive and developmental toxicity.* A 2-generation rat reproduction study gave a no observed adverse effect level (NOAEL) of 100 ppm (8 mg/kg/bwt). Rat and rabbit developmental toxicity studies were negative at doses up to 30 mg/kg/bwt and 24 mg/kg/bwt, respectively.

4. *Subchronic toxicity.* Ninety-day feeding studies were conducted in rats and dogs. The NOAELs for these tests were 14 mg/kg/bwt/day (150 ppm) and 5 mg/kg/bwt/day (200 ppm), for the rat and dog studies, respectively.

5. *Chronic toxicity.* A 2-year rat feeding/carcinogenicity study was negative for carcinogenic effects under the conditions of the study and had a NOAEL of 100 ppm (5.7 mg/kg/bwt in males and 7.6 mg/kg/bwt in females for non-carcinogenic effects that included decreased body weight gain in females at 300 ppm and increased thyroid lesions in males at 300 ppm and females at 900 ppm. A 1-year dog feeding study indicated a NOAEL of 1,250 ppm (41 mg/kg/bwt). A 2-year mouse carcinogenicity study was negative for carcinogenic effects under conditions of the study and had a NOAEL of 1,000 ppm (208 mg/kg/day).

Imidacloprid has been classified under "Group E" (no evidence of carcinogenicity) by EPA's OPP/HED's Reference Dose (RfD) Committee. There is no cancer risk associated with exposure to this chemical. The RfD based on the 2-year rat feeding/carcinogenic study with a NOAEL of 5.7

mg/kg/bwt and 100-fold uncertainty factor, is calculated to be 0.057 mg/kg/bwt. The theoretical maximum residue contribution (TMRC) from published uses is 0.008358 mg/kg/bwt/day utilizing 14.7% of the RfD.

6. *Animal metabolism.* The metabolism of imidacloprid in rats was reported in seven studies. Data in these studies show that imidacloprid was rapidly absorbed and eliminated in the excreta (90% of the dose within 24 hours), demonstrating no biologically significant differences between sexes, dose levels, or route of administration. Elimination was mainly renal (70-80% of the dose) and fecal (17-25%). The major part of the fecal activity originated in the bile. Total body accumulation after 48 hours consisted of 0.5% of the radioactivity with the liver, kidney, lung, skin and plasma being the major sites of accumulation. Therefore, bioaccumulation of imidacloprid is low in rats. Maximum plasma concentration was reached between 1.1 and 2.5 hours. Two major routes of biotransformation were proposed for imidacloprid. The first route included an oxidative cleavage of the parent compound rendering 6-chloronicotinic acid and its glycine conjugate. Dechlorination of this metabolite formed the 6-hydroxynicotinic acid and its mercapturic acid derivative. The second route included the hydroxylation followed by elimination of water from the parent compound.

7. *Metabolite toxicology.* Several metabolites of imidacloprid have been investigated for acute toxicity and genotoxicity. No evidence for genotoxicity was found, and acute toxicity values for all metabolites studied ranged from slightly more toxic to significantly less toxic than parent imidacloprid.

8. *Endocrine disruption.* The toxicology data base for imidacloprid is current and complete. Studies in this database include evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following short-term or long-term exposure. These studies revealed no primary endocrine effects due to imidacloprid.

C. Aggregate Exposure

1. *Dietary exposure.* Imidacloprid is a broad-spectrum insecticide with excellent systemic and contact toxicity characteristics with both food and non-food uses. Imidacloprid is currently registered for use on various food crops including seed treatments, tobacco, turf, ornamentals, buildings for termite control, and cats and dogs for flea

control. Those potential exposures are addressed below:

i. *Food.* The EPA has determined that the reference dose (RfD) based on the 2 year rat feeding/carcinogenicity study with a NOAEL of 5.7 mg/kg/bwt and 100-fold uncertainty factor, is calculated to be 0.057 mg/kg/bwt. As published in the **Federal Register** June 12, 1996 (61 FR 29674) (FRL-5367-8) (petition to establish tolerances on leafy green vegetables (PP 5F4522/R2237)), the theoretical maximum residue contribution (TMRC) from published uses is 0.008358 mg/kg/bwt utilizing 14.7% of the RfD for the general population. For the most highly exposed subgroup in the population, non-nursing infants (less than 1 year old), the TMRC for the published tolerances is 0.01547 mg/kg/day. This is equal to 27.1% of the RfD.

The TMRC for corn is calculated to be 0.000055 mg/kg/bwt/day for the general population, which represents 0.1% of the RfD. The TMRC for the most highly exposed subgroup in the population, non-nursing infants is 0.000131 mg/kg/bwt/day, which represents 0.2% of the RfD. The TMRC for children ages 1 to 6 years is 0.000130 mg/kg/bwt/day, which represents 0.2% of the RfD, and for nursing infants is 0.000032 mg/kg/bwt/day, which represents 0.1% of the RfD. For children 7 to 12 years of age, the TMRC is 0.000098 mg/kg/bwt/day, which represents 0.2% of the RfD. Therefore, dietary exposure from field corn will not exceed the reference dose for any subpopulation (including infants and children).

ii. *Drinking water.* Although the various imidacloprid labels contain a statement that this chemical demonstrates the properties associated with chemicals detected in ground water, the Registrant is not aware of imidacloprid being detected in any wells, ponds, lakes, streams, etc. from its use in the United States. Imidacloprid is hydrolytically stable at pH 5 and 7 with photolytic degradation in water having a half-life of 4.2 hours. Under aerobic soil conditions in laboratory studies, imidacloprid has a half-life of 188 to >366 days. Under laboratory anaerobic aquatic conditions, the half-life was 27 days. Adsorption/desorption studies indicate that aged imidacloprid residues do not leach into the soil. Imidacloprid dissipates under actual field conditions with a half-life of 7 to 196 days. Imidacloprid remained in the top six inches of the soil in U.S. tests for the duration of nine of ten field dissipation studies. The presence of growing vegetation significantly increased the rate of degradation of imidacloprid. In studies conducted in

1995, imidacloprid was not detected in seventeen wells on potato farms in Quebec, Canada. In addition, ground water monitoring studies are currently underway in California and Michigan. Therefore, contributions to the dietary burden from residues of imidacloprid in water would be inconsequential.

2. *Non-dietary exposure*— i. *Residential turf.* Bayer Corporation has conducted an exposure study to address the potential exposures of adults and children from contact with imidacloprid treated turf. The population considered to have the greatest potential exposure from contact with pesticide treated turf soon after pesticides are applied are young children. Margins of safety (MOS) of 7,587 - 41,546 for 10 year old children and 6,859 - 45,249 for 5 year old children were estimated by comparing dermal exposure doses to the imidacloprid NOAEL of 1,000 mg/kg/day established in a 15 day dermal toxicity study in rabbits. The estimated safe residue levels of imidacloprid on treated turf for 10 year old children ranged from 5.6 - 38.2 g/cm² and for 5 year old children from 5.1 - 33.3 g/cm². This compares with the average imidacloprid transferable residue level of 0.080 g/cm² present immediately after the sprays have dried. These data indicate that children can safely contact imidacloprid-treated turf as soon after application as the spray has dried.

ii. *Termiticide.* Imidacloprid is registered as a termiticide. Due to the nature of the treatment for termites, exposure would be limited to that from inhalation and was evaluated by EPA's Occupational and Residential Exposure Branch (OREB) and Bayer Corporation. Data indicate that the Margins of Safety for the worst case exposures for adults and infants occupying a treated building who are exposed continuously (24 hours/day) are 8.0×10^7 and 2.4×10^8 , respectively, and exposure can thus be considered negligible.

iii. *Tobacco smoke.* Studies have been conducted to determine residues in tobacco and the resulting smoke following treatment. Residues of imidacloprid in cured tobacco following treatment were a maximum of 31 ppm (7 ppm in fresh leaves). When this tobacco was burned in a pyrolysis study only two percent of the initial residue was recovered in the resulting smoke (main stream plus side stream). This would result in an inhalation exposure to imidacloprid from smoking of approximately 0.0005 mg per cigarette. Using the measured subacute rat inhalation NOAEL of 5.5 mg/m³, it is apparent that exposure to imidacloprid from smoking (direct and/or indirect exposure) would not be significant.

iv. *Pet treatment.* Human exposure from the use of imidacloprid to treat dogs and cats for fleas has been addressed by EPA's Occupational and Residential Exposure Branch (OREB) who have concluded that due to the fact that imidacloprid is not an inhalation or dermal toxicant and that while dermal absorption data are not available, imidacloprid is not considered to present a hazard via the dermal route.

D. Cumulative Effects

No other chemicals having the same mechanism of toxicity are currently registered, therefore, there is no risk from cumulative effects from other substances with a common mechanism of toxicity.

E. Safety Determination

1. *U.S. population.* Using the conservative exposure assumptions described above and based on the completeness and reliability of the toxicity data, it can be concluded that total aggregate exposure to imidacloprid from all current uses including those currently proposed will utilize little more than 15% of the RfD for the U.S. population. EPA generally has no concerns for exposures below 100% of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. The TMRC from exposure to field corn for the general population, is 0.000055 mg/kg/bwt/day, which represents 0.1% of the RfD. Thus, it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to imidacloprid residues.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of imidacloprid, the data from developmental studies in both rat and rabbit and a 2-generation reproduction study in the rat have been considered. The developmental toxicity studies evaluate potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates effects from exposure to the pesticide on the reproductive capability of mating animals through 2 generations, as well as any observed systemic toxicity.

FFDCA Section 408 provides that the EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for prenatal and postnatal effects and the completeness of the toxicity database. Based on current toxicological data requirements, the toxicology database for imidacloprid relative to prenatal and

postnatal effects is complete. Further for imidacloprid, the NOAEL of 5.7 mg/kg/bwt from the 2-year rat feeding/carcinogenic study, which was used to calculate the RfD (discussed above), is already lower than the NOAELs from the developmental studies in rats and rabbits by a factor of 4.2 to 17.5 times. Since a 100-fold uncertainty factor is already used to calculate the RfD, it is surmised that an additional uncertainty factor is not warranted and that the RfD at 0.057 mg/kg/bwt/day is appropriate for assessing aggregate risk to infants and children. Using the conservative exposure assumptions described above, EPA has concluded that the TMRC from use of imidacloprid from published uses is 0.008358 mg/kg/bwt/day utilizing 14.7% of the RfD for the general population. For the most highly exposed subgroup in the population, non-nursing infants (less than 1 year old), the TMRC for the published tolerances is 0.01547 mg/kg/day. This is equal to 27.1% of the RfD. The TMRC from exposure to field corn to non-nursing infants is 0.000131 mg/kg/bwt/day, which represents 0.2% of the RfD. The TMRC for children ages 1 to 6 years is 0.000130 mg/kg/bwt/day, which represents 0.2% of the RfD. For nursing infants, the TMRC is 0.000032 mg/kg/bwt/day, which is 0.1% of the RfD. For children ages 7 to 12 years, the TMRC is 0.000098 mg/kg/bwt/day, which is 0.2% of the RfD. Thus, it can be concluded that there is a reasonable certainty that no harm will result from additional exposure of infants and children.

F. International Tolerances

No CODEX Maximum Residue Levels (MRLs) have been established for residues of imidacloprid on any crops at this time.

[FR Doc. 01-370 Filed 1-4-01; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[PF-989; FRL-6761-4]

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.