protected by shoes and socks. Further, based on the limited frequency of use on turfgrass, this non-food use is not likely to result in potential chronic exposure and thus should not be factored into a chronic exposure assessment. Exposures resulting from application to ornamentals is also anticipated to be negligible because consumers will not be in contact with treated plants until after the foliage is dry.

E. Endocrine Disruptors

Auxein has no information to suggest that GABA will adversely affect the immune or endocrine systems.

F. Safety Considerations

GABA is naturally-occurring in food and is a pharmaceutical agent. Incremental exposure to GABA resulting from the application of AuxiGro is minimal to negligible. Considering the negligible contributions of GABA to the environment resulting from the application of AuxiGro, the biochemical's prevalence in nature, and its role and abundance in foods, GABA does not pose a human health risk.

G. Analytical Method

An analytical method using High Performance Liquid Chromatography (HPLC) for determining the GABA content in AuxiGro, the end-use product, is available. However, because GABA is found naturally in plants, residue analysis would not yield meaningful results, i.e., the analysis would not discern whether the source of GABA was the plant or the product treatment.

H. Codex Maximum Residue Level

There are no CODEX tolerances or international tolerance exemptions for GABA.

[FR Doc. 97–28664 Filed 10–28–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–775; FRL–5752–2]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by the docket control number PF–775, must be received on or before November 28, 1997.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7502C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Elizabeth Haeberer, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 250, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–2891; e-mail: haeberer.elizabeth@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals 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 these petitions contain 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–775] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF–775] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

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

Dated: October 16, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them 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.

Gustafson, Inc.

PP 4F4415

EPA has received a pesticide petition (PP 4F4415) from Gustafson, Inc., 1400 Preston Road, Suite 400, Plano, Texas 75093, proposing pursuant to section 408(d) of the Federal Food, Drug and

Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR Part 180 to make the time limited tolerances permanent by establishing a tolerance for residues of imidacloprid in or on the raw agricultural commodity sorghum grain 0.05 parts per million (ppm), forage 0.10 ppm, and stover 0.10 ppm. The proposed analytical method involves homogenization, filtration, partition and cleanup with analysis by high performance liquid chromatography using UV detection'' for determining residues is a common moiety method for imidacloprid and its metabolites containing the 6-chloro-pyridinyl moiety using oxidation, derivatization, and analysis by capillary gas chromatography with a mass-selective detector. 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*. Sorghum 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 fifteen locations: Arkansas, California, Colorado (two locations), Kansas (two locations), Louisiana, Missouri, Nebraska (two locations), North Carolina, Oklahoma, South Dakota, and Texas (two locations). The sorghum seed was planted and the RACs were harvested at the appropriate growth stages. Residue levels in the sorghum grain were less than 0.05 ppm. Maximum residues were 0.058 ppm in the forage and 0.065 ppm in the stover. These residue data support tolerances of 0.05 ppm for sorghum grain, 0.10 ppm for sorghum forage, and 0.10 ppm for sorghum stover. A processing study was submitted with this petition. No tolerances were required for processed fractions of sorghum grain since residues in the sorghum grain when treated at the 2X rate (which is higher than the maximum theoretical concentration factor of 1.6X) were less than the limit of quantitation (LOQ) of 0.05 ppm.

B. Toxicological Profile

1. *Acute toxicity*. The acute oral LD_{50} values for imidacloprid technical ranged from 424 to 475 mg/kg bwt in the rat. The acute dermal LD_{50} was greater than 5,000 mg/kg in rats. The 4-hour inhalation LC_{50} was less than 69 mg/m^3 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-effect level (NOEL) 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 NOELs 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 NOEL of 100 ppm (5.7 mg/kg/bwt in males and 7.6 mg/kg/bwt in females for noncarcinogenic 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 NOEL of 1,250 ppm (41 mg/kg/bwt). A 2-year mouse carcinogenicity study that was negative for carcinogenic effects under conditions of the study and that had a NOEL 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 reference dose (RfD) based on the 2-year rat feeding/carcinogenic study with a NOEL 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 nature of the imidacloprid residue in animals is adequately understood. The residues of concern are combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all calculated as imidacloprid.

7. *Metabolite toxicology*. Metabolites, at the levels reported, are not toxicologically significant. No separate regulation of metabolites is warranted, and there is no scientific objection to the tolerance expression being for the combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety.

C. Aggregate Exposure

1. *Dietary exposure*. The EPA has determined that the reference dose (RfD) based on the 2-year rat feeding/carcinogenicity study with a NOEL 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) (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 December 1, 1994 **Federal Register** (59 FR 61552) indicates that the tolerances for sorghum contribute 0.000001188 mg/kg/bwt/day which represents 0.002% of the RfD which is included in the total values published in the June 12, 1996 **Federal Register**. Therefore, dietary exposure from the existing uses including the current temporary tolerances will not exceed the reference dose for any subpopulation (including infants and children).

2. *Food*. Dietary exposure from the existing uses including the current temporary tolerances will not exceed the reference dose for any subpopulation (including infants and children).

3. *Drinking water*. Although the various imidacloprid labels contain a

statement that this chemical demonstrates the properties associated with chemicals detected in groundwater, the Registrant is not aware of imidacloprid being detected in any wells, ponds, lakes, streams, etc. from its use in the United States. In studies conducted in 1995, imidacloprid was not detected in seventeen wells on potato farms in Quebec, Canada. In addition, groundwater monitoring studies are currently underway in California and Michigan. Therefore, contributions to the dietary burden from residues of imidacloprid in water would be inconsequential.

4. *Non-dietary exposure*— a. *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 no-observable effect level 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/cm^2 and for 5 year old children from 5.1 - 33.3 g/cm^2. This compares with the average imidacloprid transferable residue level of 0.080 g/cm^2 present immediately after the sprays have dried. These data indicate that children can safely contact. Bayer Corporation has conducted an exposure imidacloprid-treated turf as soon after application as the spray has dried.

b. *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 x 10^7 and 2.4 x 10^8, respectively, and exposure can thus be considered negligible.

c. *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 NOEL of 5.5 mg/m^3, it is apparent that exposure to imidacloprid from smoking (direct and/or indirect exposure) would not be significant.

d. *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. 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 two 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 pre- and post-natal effects and the completeness of the toxicity database. Based on current toxicological data requirements, the toxicology database for imidacloprid relative to pre- and post-natal effects is complete. Further for imidacloprid, the NOEL 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 NOELs 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. Therefore, dietary exposure from the existing uses including the currently proposed tolerances will not exceed the reference dose for any subpopulation (including 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. 97–28663 Filed 10–28–97; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–771; FRL–5749–7]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by the docket control number PF–771, must be received on or before November 28, 1997.