III. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to James A. Hollins, at the address given above, postmarked before August 25, 1997. This written withdrawal of the request for cancellation will apply only to the applicable 6(f)(1) request listed in this notice. If the product(s) have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

IV. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks for 1 year after the date the cancellation request was received. This policy is in accordance with the Agency's statement of policy as prescribed in Federal Register (56 FR 29362) June 26, 1991; [FRL 3846–4]. Exceptions to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a data call-in. In all cases, product-specific disposition dates will be given in the cancellation orders.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product(s). Exceptions to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in Special Review actions, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: February 11, 1997.

Linda A. Travers,

Director, Program Management and Support Division, Office of Pesticide Programs.

[FR Doc. 97–4775 Filed 2–25–97; 8:45 am]

BILLING CODE 6560–50–F

[PF–713; FRL–5589–2]

Bayer Corporation; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the filing of a pesticide petition proposing the establishment of a regulation for residues of imidacloprid in or on cereal grain, sweet corn, safflower and soybeans. The notice contains a summary of the petition prepared by the petitioner, Bayer Corporation.

DATES: Comments, identified by the docket number [PF–713], must be received on or before March 28, 1997.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide 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 22202. Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: 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. Comments 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–713]. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit II of this document.

Information submitted as comments concerning this notice 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: Dennis H. Edwards, Jr., Product Manager (PM) 19, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: Rm. 207, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)–305–6386; e-mail: edwards.dennis@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP) 6F4765 pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. 346a(d), by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170, 110 Stat. 1489) from Bayer Corporation (''Bayer''), 8400 Hawthorn Rd., P.O. Box 4913, Kansas City, MO 64120–0013 proposing to amend 40 CFR 180.472 by establishing tolerances for inadvertent or indirect residues of the insecticide, imidacloprid: 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine and its metabolites containing the 6-chloro-pyridinyl moiety in or on cereal grain [grain 0.05 parts per million (ppm), forage (2.0 ppm), stover (0.3 ppm), hay (6.0 ppm), and straw (3.0 ppm)], sweet corn (0.05 ppm), legume vegetables (0.3 ppm) [and foliage thereof (2.5 ppm)], and safflower seed (0.05 ppm). The nature of the imidacloprid residue in plants and livestock is adequately understood. The analytical method 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. These tolerances would allow for a 1–month plant back interval for these crops following normal application of imidacloprid-containing products.

EPA has determined that the 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

As required by section 408(d) of the FFDCA, as recently amended by the FQPA, Bayer Corporation included in

the petition a summary of the petition and authorization for the summary to be published in the Federal Register in a notice of receipt of the petition. The summary represents the views of Bayer Corporation; EPA is in the process of evaluating the petition. As required by section 408(d)(3) EPA is including the summary as a part of this notice of filing. EPA may have made minor edits to the summary for the purpose of clarity.

I. Petition Summary

Imidacloprid is a broad-spectrum insecticide with excellent systemic and contact toxicity characteristics which is used primarily for sucking insects.

A. Plant Metabolism and Analytical Method

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. The analytical method is a common moiety method for imidacloprid and its metabolites containing the 6-chloropyridinyl 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.

B. Magnitude of the Residue

Field rotational crop studies were conducted in three states where soil was treated with imidacloprid at a rate of 0.3 lbs active ingredient per acre (ai/A) (1x). After 30 days, rotational crops were planted, grown to maturity, and harvested at appropriate times. Residue levels in cereal grain, sweet corn (K+CWHR), and safflower seed were <0.05 ppm. Maximum residues were 1.81 ppm in cereal grain forage, 0.26 ppm in cereal grain stover, 2.7 ppm in cereal grain straw, 0.22 ppm in legume vegetables, and 2.33 ppm in legume vegetable foliage. These residue data support tolerances of 0.05 ppm for cereal grain, sweet corn (K+CWHR), and safflower seed; 2.0 ppm for cereal grain forage; 0.3 ppm for cereal grain stover; 6.0 ppm for cereal grain hay; 3.0 ppm in cereal grain straw; 0.3 ppm in legume vegetables; and 2.5 ppm for the foliage of legume vegetables. No processing studies were submitted with this petition, however, available data would indicate that tolerances on corn meal (0.05 ppm), soybean meal (0.5 ppm) and a time-limited tolerance on safflower meal (0.5 ppm) could be considered. The registrant has committed to provide data to support these processed commodities. CBTS has concluded that existing poultry meat and egg tolerances are adequate to support the proposed new uses of imidacloprid.

C. Toxicological Profile of Imidacloprid

1. *Acute toxicity.* The acute oral LD_{50} values for imidacloprid technical ranged from 424 to 475 milligrams per kilogram of body weight (mg/kg bwt) in the rat. The acute dermal LD_{50} was greater than 5,000 milligrams per kilogram (mg/kg) in rats. The 4–hour rat inhalation LC_{50} was >69 milligrams per cubic meter (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 two-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 (90–day) feeding studies were conducted in rats and dogs. The NOEL's 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/oncogenicity.* 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 male and 7.6 mg/kg/bwt female) 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. *Endocrine effects.* The toxicology database 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- or long-term exposure. These studies revealed no primary endocrine effects due to imidacloprid.

7. *Mode of action.* Imidacloprid exhibits a mode of action different from traditional organophosphate, carbamate, or pyrethroid insecticides. Imidacloprid acts by binding to the nicotinergic receptor sites at the postsynaptic membrane of the insect nerve. Due to this novel mode of action, imidacloprid has not shown any cross resistance to registered alternative insecticides and is a valuable tool for use in IPM or resistance management programs.

D. Aggregate 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, tobacco, turf, ornamentals, buildings for termite control, and cats and dogs for flea control. Those potential exposures are addressed below:

1. *Dietary.* The EPA has determined that 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. As published in the Federal Register of December 13, 1995 (60 FR 64006)(FRL–4990–5) and June 12, 1996 Federal Register (61 FR 2674)(FRL–5367–8) (petition to establish tolerances on leafy green vegetables (PP 5F4522/R2237)), the TMRC 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 (< 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, Bayer believes that dietary exposure from the existing uses including the currently proposed inadvertent or indirect residue tolerances will not exceed the RfD for

any subpopulation (including infants and children).

2. *Water.* Although the various imidacloprid labels contain a statement that this chemical demonstrates the properties associated with chemicals detected in groundwater, Bayer 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 17 wells on potato farms in Quebec, Canada. In addition, groundwater monitoring studies are currently underway in California and Michigan. Therefore, Bayer believes that contributions to the dietary burden from residues of imidacloprid in water would be inconsequential.

3. *Non-occupational*— a. *Residential turf.* Bayer 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 to 41,546 for 10–year–old children and 6,859 to 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 to 38.2 g/cm^2 and for 5–year–old children from 5.1 to 33.5 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 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's (OREB) and Bayer. 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.

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 2 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 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.

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

E. Safety Determinations

1. *U.S. population in general.* Using the conservative exposure assumptions described above and based on the completeness and reliability of the toxicity data, Bayer concludes 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, Bayer concludes 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 two-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 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, Bayer surmises 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 (< 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, Bayer concludes that dietary exposure from the existing uses including the currently proposed tolerances will not exceed the RfD for any subpopulation (including infants and children).

F. Other Considerations

The nature of the imidacloprid residue in plants and livestock is adequately understood. The residues of concern are combined residues of imidacloprid and it metabolites containing the 6-chloropyridinyl moiety, all calculated as imidacloprid. The analytical method is a common moiety method for imidacloprid and its metabolites containing the 6-chloropyridinyl moiety using a permanganate oxidation, silyl derivatization, and capillary GC-MS selective ion monitoring. There is an additional confirmatory method available. Imidacloprid and its metabolites have been shown to be stable for at least 24 months in frozen storage.

G. International Tolerances

No CODEX Maximum Residue Levels (MRL's) have been established for residues of Imidacloprid on any crops at this time.

II. Public Record

EPA invites interested persons to submit comments on this notice of

filing. Comments must bear a notification indicating the docket control number [PF–713].

A record has been established for this notice under docket numbers [PF–713] (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 public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

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.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and record keeping requirements.

Dated: February 10, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–4627 Filed 2–25–97; 8:45 am]

BILLING CODE 6560–50–F

[PF–706; FRL–5585–7]

Bioxy, Inc.; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the filing of a pesticide petition proposing the exemption from the requirement of a tolerance for sodium chlorite residues in or on meat and meat byproducts of cattle, sheep, hogs, goats, horses, and poultry when applied as a bactericide for the generation of chlorine dioxide in livestock drinking water.

DATES: Comments, identified by the docket control number PF–706, must be received on or before, March 28, 1997.

ADDRESSES: By mail, submit written comments to Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide 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 22202.

Comments and data may also be submitted electronically be sending electronic mail (e-mail) to: 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. Comments 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 docket control number PF–706. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit II. of this document.

Information submitted as comments 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: Vivian A. Turner, Acting Product Manager (PM) 32, Registration Division (7505C), Rm., 237, Crystal Mall #2, Jefferson Davis Highway, Arlington, VA. 703–305–7460. e-mail: turner.vivian@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP 6F4783) from Bioxy, Inc. 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 an exemption from tolerance for residues of sodium chlorite and its hydrolysis by-product, chlorine dioxide, in or on meat and meat byproducts of cattle, sheep, goats, horses and poultry when such residues result from the use of sodium chlorite to generate the bactericide, chlorine dioxide, in poultry drinking water and livestock drinking water at a concentration of up to 18.34 parts per million (ppm). The proposed analytical method is ultraviolet spectrophotometric analysis. Pursuant to the section 408(d)(2)(A)(i) of the FFDCA, as amended, Bioxy, Inc. has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Bioxy, Inc. and EPA has not fully evaluated the merits of the petition. EPA edited the summary to clarify that the conclusions and arguments were the petitioner's and not necessarily EPA's and to remove certain extraneous material.

I. Petition Summary

This section has been arranged to provide a justification for this tolerance exemption and a summary of available data.

The request is to exempt from the requirement of a tolerance, residues of sodium chlorite and its hydrolysis product, chlorine dioxide, in or on meat and meat byproducts of cattle, sheep, hogs, goats, horses, and poultry, and milk and eggs when such residues result from the use sodium chlorite to generate the bactericide, chlorine dioxide in poultry drinking water and livestock drinking water.

EPA has exempted sodium chlorite from the requirement of a tolerance when used as a seed-soak treatment of the raw agricultural commodities (RACs) crop group Brassica (cole) leafy vegetables and radishes (40 CFR 180.170). Sodium chlorate is chemically similar to sodium chlorite, and sodium chlorate is exempt from the requirement of a tolerance when used as a defoliant, desiccant, or fungicide on various RACs (40 CFR 180.1020). Chlorine gas is exempted from the requirement of a tolerance when used pre- or post-harvest in solution on all RACs (40 CFR 180.1095). Calcium hypochlorite is exempted from the requirement of a tolerance when used harvest or postharvest on all RACs and in or on grapes when used as a fumigant