II. What Does this Correction Do?

FR Doc. E7–12161 published in the Federal Register of June 27, 2007 (72 FR 35182) (FRL–8133–1) is corrected as follows:

On page 35187, 180.511(a), the table in the amendment to § 180.511(a) establishing tolerances appeared as a two column table. The table should have appeared as a three column table. The omitted third column should include the heading “Expiration/Revocation Date”, and the entry “None” to correspond to the tolerance listed in each row. This document is being published to correct that omission.

III. Why is this Correction Issued as a Final Rule?

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the Agency may issue a final rule without providing notice and an opportunity for public comment. EPA rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making this technical amendment final without prior proposal and opportunity for comment, because the use of notice and comment procedures is unnecessary to effectuate this correction. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

IV. Do Any of the Statutory and Executive Order Reviews Apply to this Action?

No. This action only corrects typographical omissions for a previously published final rule and does not impose any new requirements.

V. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the Federal Register. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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


Lois Rossi,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:


2. Section 180.511 is amended in paragraph (a) in the table as follows:

i. By alphabetically adding “Apricot” and “Fruit, stone, group 12, except apricot and peach”; and

ii. By revising the entries for “Canistel,” “Grape,” “Mango,” “Papaya,” “Sapodilla,” “Sapote, black,” “Sapote, mamey,” and “Star apple.”

The amendments read as follows:

§ 180.511 Buprofezin; tolerances for residues.

(a) * * *

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
<th>Expiration/Revocation Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apricot ...........................................</td>
<td>9.0</td>
<td>None</td>
</tr>
<tr>
<td>Canistel ..........................................</td>
<td>0.90</td>
<td>None</td>
</tr>
<tr>
<td>Fruit, stone, group 12, except apricot and peach</td>
<td>1.9</td>
<td>None</td>
</tr>
<tr>
<td>Grape ...............................................</td>
<td>2.5</td>
<td>None</td>
</tr>
<tr>
<td>Mango ...............................................</td>
<td>0.90</td>
<td>None</td>
</tr>
<tr>
<td>Papaya ...............................................</td>
<td>0.90</td>
<td>None</td>
</tr>
<tr>
<td>Sapodilla .........................................</td>
<td>0.90</td>
<td>None</td>
</tr>
<tr>
<td>Sapote, black .....................................</td>
<td>0.90</td>
<td>None</td>
</tr>
<tr>
<td>Sapote, mamey .....................................</td>
<td>0.90</td>
<td>None</td>
</tr>
<tr>
<td>Star apple ........................................</td>
<td>0.90</td>
<td>None</td>
</tr>
</tbody>
</table>

* * * * *

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


AGENCY: Environmental Protection Agency (EPA).

ACTIONS: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of fipronil and its two metabolites and one photodegrade in or on potato and potato, wet peel, and indirect or inadvertent residues of fipronil and its two metabolites and one photodegrade in or on wheat, forage; wheat, grain;
wheat, hay, and wheat straw. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, this establishes time-limited tolerances for combined residues of fipronil in or on turnip and rutabaga. This action is in response to EPA’s granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on turnip and rutabaga. This regulation establishes maximum permissible levels for combined residues of fipronil in these food commodities. The tolerances for rutabaga and turnip expire and are revoked on December 31, 2010.

DATES: This regulation is effective August 22, 2007. Objections and requests for hearings must be received on or before October 22, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0206. To access the electronic docket, go to http://www.regulations.gov, select “Advanced Search,” then “Docket Search.” Insert the docket ID number where indicated and select the “Submit” button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at http://www.regulations.gov, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Ann Sibold, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6502; e-mail address: sibold.ann@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

• Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
• Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
• Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
• Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

B. How Can I Access Electronic Copies of this Document?


C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2005–0206 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before October 22, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, you must submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in ADDRESSES. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2005–0206, by one of the following methods:

• Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket’s normal hours of operation (6:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerances

In the Federal Register of August 24, 2005 (70 FR 49599) (FRL–7726–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 56948) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.517 be amended by establishing tolerances for combined residues of the insecticide fipronil, 5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-(1,1′-biphenyl-2-yl)pyrazole-3-carbonitrile and its 2 metabolites, MB45950 (5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-(1,1′-biphenyl-2-yl)pyrazole-3-carbonitrile) and MB46136 (5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-
established in response to EPA expire and are revoked on December 31, tolerances for combined residues of the potato. The reason for these changes is the tolerance for vegetable tuberous supporting the petition, EPA has revised in Unit IV.C.

Based upon review of the data

EPA also establishing time-limited tolerances for combined residues of the insecticide fipronil, in or on turnip and rutabaga at 1.0 ppm. These

Because the rutabaga and turnip tolerances are being approved under emergency conditions, EPA has not made any decisions about whether fipronil meets EPA’s registration requirements for use on rutabaga and turnip after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed levels that were authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because the rutabaga and turnip tolerances are being approved under emergency conditions, EPA has not made any decisions about whether fipronil meets EPA’s registration requirements for use on rutabaga and turnip after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed levels that were authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

The apparent increasing resistance of the maggot to the organophosphate registered alternative.

Phytotoxicity of the organophosphate alternative to the emerging seedlings.

The Applicant stated that significant economic losses would occur without the requested use of fipronil under an emergency exemption. After having reviewed the submission, EPA concurs that emergency conditions exist for this State. As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of fipronil in or on rutabaga and turnip. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerances under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although the tolerances expire and are revoked on December 31, 2010, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on rutabaga and turnip after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed levels that were authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by fipronil as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicology studies can be found at http://www.regulations.gov. The referenced document, “Fipronil:
Third Reevaluation—Report of the Hazard Identification Assessment Review Committee, December 6, 2000,” is available in the docket established by this action, which is described under ADDRESSES, and is identified as EPA–HQ–OPP–2005–0206 in that docket.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UF) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable uncertainty/safety factors is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see http://www.epa.gov/fedrsst/EPA-PEST/1997/November/Day-26/p30948.htm.

A summary of the toxicological endpoints for fipronil used for human risk assessment is shown in Table 1 of this unit.

<table>
<thead>
<tr>
<th>Exposure Scenario</th>
<th>Dose Used in Risk Assessment, UF</th>
<th>FQPA SF and Endpoint for Risk Assessment</th>
<th>Study and Toxicological Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dietary</td>
<td>NOAEL = 2.5 milligrams/kg (mg/kg)</td>
<td>FQPA SF = 1 aPAD = acute RID = LOC = 0.025 mg/kg</td>
<td>Acute neurotoxicity—rat LOAEL = 7.0 mg/kg based on: Decreased hind leg splay in males at 7 hours</td>
</tr>
<tr>
<td>Chronic dietary</td>
<td>NOAEL = 0.019 mg/kg/day UF = 100 chronic RID = 0.0002 mg/kg/day</td>
<td>FQPA SF = 1 cPAD = chronic RID = LOC = 0.0002 mg/kg/day</td>
<td>Chronic/carcinogenicity study—rat LOAEL = 0.059 mg/kg/day based on: Increased incidence of seizures and death, alterations in clinical chemistry (protein), increased thyroid stimulating hormone (TSH), and decreased T4</td>
</tr>
<tr>
<td>Short-term oral (1–7 days) (Residential)</td>
<td>Oral study maternal LOAEL = 0.1 mg/kg/day UF of 3 for no NOAEL, 100 for interspecies extrapolation and intraspecies variation</td>
<td>LOC for MOE = 300 (Residential, includes the FQPA SF)</td>
<td>Developmental toxicity study—rabbit maternal LOAEL = 0.1 mg/kg/day based on: Maternal toxicity of decreased body weight gain, decreased food consumption, and decreased food efficiency</td>
</tr>
<tr>
<td>Intermediate-term oral (1 week—several months) (Residential)</td>
<td>Oral study LOAEL = 0.01 mg/kg/day UF of 3 for no NOAEL, 100 for interspecies extrapolation and intraintra variation</td>
<td>LOC for MOE = 300 (Residential, includes the FQPA SF)</td>
<td>Developmental toxicity study—rabbit LOAEL = 0.1 mg/kg/day based on: Maternal toxicity of decreased body weight gain, decreased food consumption, and decreased food efficiency</td>
</tr>
<tr>
<td>Short-term dermal (1–7 days) (Residential)</td>
<td>Dermal study NOAEL = 5 mg/kg/day</td>
<td>LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes FQPA SF)</td>
<td>Chronic/carcinogenicity study—rat LOAEL = 0.059 mg/kg/day based on: Increased incidence of seizures and death, alterations in clinical chemistry (protein), increased TSH, and decreased T4</td>
</tr>
<tr>
<td>Intermediate-term dermal (1 week—several months) (Residential)</td>
<td>Dermal study NOAEL = 5 mg/kg/day</td>
<td>LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes FQPA SF)</td>
<td>Developmental neurotoxicity—rat LOAEL = 0.90 mg/kg/day based on: Decrease in group mean pup weights during lactation, and significant increase in time of preputial separation in males (dietary)</td>
</tr>
<tr>
<td>Long-term dermal (several months—lifetime) (Residential)</td>
<td>Oral study NOAEL = 0.019 mg/kg/day (dermal absorption rate = 1%)</td>
<td>LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes FQPA SF)</td>
<td>Developmental neurotoxicity—rat LOAEL = 0.90 mg/kg/day based on: Decrease in group mean pup weights during lactation, and significant increase in time of preputial separation in males (dietary)</td>
</tr>
</tbody>
</table>

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FIPRONIL FOR USE IN HUMAN RISK ASSESSMENT
### Table 1.—Summary of Toxicological Dose and Endpoints for Fipronil for Use in Human Risk Assessment—Continued

<table>
<thead>
<tr>
<th>Exposure Scenario</th>
<th>Dose Used in Risk Assessment, UF</th>
<th>FQPA SF and Endpoint for Risk Assessment</th>
<th>Study and Toxicological Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-term inhalation (several months—lifetime) (Residential)</td>
<td>Oral study NOAEL = 0.019 mg/kg/day (inhalation absorption rate = 100%)</td>
<td>acceptable MOE = 100 (Occupational), acceptable MOE = 100 (Residential, includes FQPA SF)</td>
<td>Chronic/carcinogenicity rat study LOAEL = 0.059 mg/kg/day based on: Increased incidence of seizures and death, alterations in clinical chemistry (protein), increased TSH, and decreased T4 Increases in thyroid follicular cell tumors with fipronil (male/female)</td>
</tr>
<tr>
<td>Cancer (Oral, dermal, inhalation)</td>
<td>Group C—possible human carcinogen</td>
<td>Use chronic RfD to estimate human risk</td>
<td></td>
</tr>
</tbody>
</table>

UF = uncertainty factor, FQPA SF = FQPA Safety Factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic), RfD = reference dose, LOC = level of concern, MOE = margin of exposure.

**C. Exposure Assessment**

1. **Dietary exposure from food and feed uses.** In evaluating dietary exposure to fipronil, EPA considered exposure under the petitioned-for tolerances, as well as the turnip and rutabaga tolerances to support the authorized section 18s, and all existing fipronil tolerances in (40 CFR 180.517). EPA assessed dietary exposures from fipronil in food as follows:
   i. **Acute exposure.** Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one-day or single exposure. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed all foods for which there are tolerances were treated.
   
   ii. **Chronic exposure.** In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 1994–1996 and 1998 Nationwide CSFII. As to residue levels in food, EPA relied upon anticipated residues and percent crop treated information for some commodities. A partially refined analysis was performed using anticipated residues from field trial data for existing uses for which data were available. Anticipated residues were also used for potato commodities. Processing factors were used for existing uses. Percent crop treated was not used.

   iii. **Cancer.** Fipronil has been classified as a Group C—possible Human Carcinogen, based on increases in thyroid follicular cell tumors in both sexes of the rat, which were statistically significant by both pair-wise and trend analyses. There is no apparent concern for mutagenicity (no mutagenic activity). The RfD methodology should be used to estimate human risk for the following reasons: The thyroid tumors appear to be related to a disruption in the thyroid-pituitary status, and fipronil is not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis. In addition, the cRfD is based on the NOAEL from the combined chronic/carcinogenicity study in rats. The NOAEL is based on increased incidence of seizures and death, alterations in clinical chemistry (protein) and thyroid toxicity (increase in TSH, decrease in thyroxine (T4)). Therefore, the cRfD is considered to be protective of both cancer and non-cancer effects of fipronil.

   iv. **Anticipated residue and percent crop treated (PCT) information.** Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must pursuant to FFDCA section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such Data Call-Ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. **Dietary exposure from drinking water:** The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for fipronil in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of fipronil. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at http://www.epa.gov/oppefed1/models/water/index.htm.

   Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of fipronil for acute exposures are estimated to be 2.654 parts per billion (ppb) for surface water and 0.021 ppb for ground water. The EECs for chronic exposures are estimated to be 0.3179 ppb for surface water and 0.021 ppb for ground water.

   Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 2.654 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.3179 ppb was used to access the contribution to drinking water.

   3. **From non-dietary exposure.** The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiteicides, and flea and tick control on pets). Fipronil is currently registered for the following residential non-dietary sites: For use on cats and dogs for flea control and on turf to control fire ants. These products may be applied by homeowners. EPA assessed residential exposure using the following assumptions: The probability of applying fipronil to dogs and cats to control fleas and ticks and applying fipronil to control turf pests on the same day is considered to be negligible for the following reasons: Use on turf application is limited to application one per year. For the pet care products, fipronil is applied as a Ready-to-Use (RTU) pump spray to the fur of the animal or as a RTU, pour-on, spot...
treatment made on the back of the animal between the shoulder blades. Repeated applications if necessary may be made once every one to three months during flea or tick season. Therefore, since these applications are infrequent, for aggregate risk assessment, exposure from pet and turf treatments were not combined. Based on the existing and proposed uses, the pet uses result in the highest estimated handler exposure. Since more exposure is expected from the pet care spray product, exposure to the spray product represents the worst case for all residential scenarios. For post-application risk, the use on pets is used to estimate exposure to toddlers. Adult post-application exposure is considered negligible.

4. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide and “other substances that have a common mechanism of toxicity.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fipronil and any other substances and fipronil does not appear to produce a toxic metabolite produced by other substances. For the purposes of these tolerance actions, therefore, EPA has not assumed that fipronil has a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at http://www.epa.gov/pesticides/cumulative.

D. Safety Factor for Infants and Children

1. In general. Section 408 of FFDCA provides that EPA shall apply an additional (“10X”) tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X or uses reliable data that do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional uncertainty/safety factors and/or special FQPA safety factors, as appropriate.

2. Prenatal and postnatal sensitivity. EPA concluded that there is no indication of increased susceptibility of rats or rabbits to in utero and/or postnatal exposure to fipronil. In the prenatal developmental toxicity studies in rats and rabbits and in the 2-generation reproduction study in rats, developmental toxicity occurred at the same or greater doses than those that caused maternal toxicity. In particular, the toxicity endpoint used for the short term oral exposure scenario was based on maternal effects seen in the developmental toxicity study. However, because no maternal NOAEL was established, an additional 3X safety factor was added to the maternal LOAEL. The developmental or offspring NOAEL was 10X greater than the maternal LOAEL. In addition, the combined chronic/carcinogenicity study in rats is based on increased incidence of seizures and deaths, alterations in clinical chemistry (protein) and an increase in TSH and a decrease in T4 at the LOAEL of 0.059 mg/kg/day. No effects on body weights and body weight gains were observed at the LOAEL in the chronic toxicity study. For this reason EPA believes that the additional 3X safety factor is protective of infants and children.

However, the developmental neurotoxicity study identified a developmental NOAEL (0.05 mg/kg/day) which is less than the maternal NOAEL of 0.9 mg/kg/day, indicating an apparent susceptibility issue. EPA determined that the evidence regarding appearance of susceptibility was not convincing for several reasons. First, the findings at 0.9 mg/kg/day in the developmental neurotoxicity study (decrease in offspring body weight and delayed time to preputial separation) were equivocal. EPA, using a conservative approach, established the LOAEL for offspring developmental toxicity at 0.9 mg/kg/day with the understanding that these effects, although statistically significant, were marginal and appeared to define a threshold response level. This conservative approach resulted in the NOAEL for offspring developmental toxicity (0.05 mg/kg/day) being lower than the NOAEL for maternal toxicity (0.9 mg/kg/day) giving an appearance of increased susceptibility. Second, the findings from the developmental neurotoxicity study were not supported by the overall weight-of-the-evidence from the fipronil database. Evaluation of the database indicated that:

• The offspring body weight findings in the developmental neurotoxicity study are not supported by the results of the 2-generation reproduction study in rats at similar treatment levels.
• Increased susceptibility to the offspring was not demonstrated following prenatal and/or postnatal dosing in the prenatal developmental toxicity study nor the 2-generation reproduction study in rats.
• No increased susceptibility was seen in the prenatal developmental toxicity study in rats following in utero exposure to the photodegradate, MB46513.

More specific information may be found in the referenced document, “Fipronil: Third Reevaluation—Report of the Hazard Identification Assessment Review Committee, December 6, 2000,” available in the docket established by this action, as noted in this unit.

3. Conclusion. EPA has determined that reliable data showed that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for fipronil is complete for food use.
ii. The weight of the evidence does not indicate that there is increased sensitivity in young animals. In any event, there is a clear NOAEL identified in the one study where there was an appearance of sensitivity in the young. The degree of concern for prenatal and/or postnatal toxicity is low.
iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated (CT) and anticipated residues were used as described in this unit. They are based in reliable data and will not underestimate the exposure and risk. Conservative ground and surface water modeling estimates were used. Similarly conservative Residential Standard Operating Procedures (SOPs) were used to assess post-application exposure to children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fipronil.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the ("aPAD") and ("cPAD"). The aPAD and cPAD are determined by dividing the level of concern (LOC) by all applicable uncertainty/safety factors. For linear
cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable uncertainty/safety factors is not exceeded.

1. Acute risk. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fipronil will occupy 25% of the aPAD for the population group (children 1–2 years old) receiving the greatest exposure.

2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fipronil from food and water will utilize 96% of the cPAD for the population group (children 1–2 years old). Based on the use pattern, chronic residential exposure to residues of fipronil is not expected.

3. Short-term risk. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Fipronil is currently registered for use(s) that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for fipronil. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs as follows: The short-term aggregate risk assessment takes into account average exposure estimates from dietary consumption of fipronil (food and drinking water) and non-occupational exposures (pet uses). Postapplication exposure from the use on pets is considered short-term. Therefore, a short-term aggregate risk assessment was conducted, using children with combined dermal and oral exposures from pet uses as a worst case. Table 3 of this unit summarizes the results. Since the LOC is different for oral and dermal exposures, 300 and 100, respectively, the Aggregate Risk Index (ARI) method was used to determine short-term aggregate risk. The aggregate ARI from food, water, and non-occupational exposures is 1.5.

Therefore, short-term aggregate risk estimates do not exceed the Agency’s level of concern (i.e., ARIs greater than or equal to 1). Adult post-application risk is considered negligible and so an aggregate risk assessment for adults is not considered necessary.

### Table 3.—AGGREGATE SHORT-TERM

<table>
<thead>
<tr>
<th>Population</th>
<th>Food + Water</th>
<th>Oral</th>
<th>Dermal</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOC 1</td>
<td>MOE 2</td>
<td>LOC 1</td>
<td>MOE 2</td>
</tr>
<tr>
<td>Children (1–2 years old)</td>
<td>300</td>
<td>532</td>
<td>300</td>
</tr>
</tbody>
</table>

1 LOC = Level of Concern
2 MOE = NOAEL (or LOAEL) + exposure
3 ARI = MOE = Calculated = MOE LOC
4 ARI = Aggregate = 1/(1-ARI food)+(1-ARI oral)+(1-ARI dermal).

### IV. Other Considerations

#### A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method EC–95–303) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: residuemethods@epa.gov.

#### B. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) established for fipronil + metabolites MB46136 and MB45950 + photodegradate MB46513 on the commodities included in this request.

#### C. Response to Comments

One comment was received from a private citizen who opposes the approval of any pesticide that leaves a residue on food. The comment contained no specific information pertaining to fipronil but was limited to general claims such as EPA was providing inadequate protection for Americans. The Agency has received the same comment from this commenter on numerous previous occasions and rejects it for the reasons previously stated in the Federal Registers of January 7, 2005 (70 FR 1349) (FRL–7691–4), June 30, 2005 (70 FR 37686) (FRL–7718–3), and October 29, 2004 (69 FR 63996) (FRL–7681–9).

#### V. Conclusion

Therefore, the tolerances are established for combined residues of fipronil [5-aminol-(2,6-dichloro-4-[(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile) and its two metabolites MB45950 (5-aminol-2,6-dichloro-4-[(trifluoromethyl)phenyl]-4-[(trifluoromethyl)thio]-1H-pyrazole-3-carbonitrile) and MB46136 (5-aminol-2,6-dichloro-4-[(trifluoromethyl)sulfonyl]-1H-pyrazole-3-carbonitrile) and its photodegradate MB46513 (5-aminol-2,6-dichloro-4-[(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfonyl]-1H-pyrazole-3-carbonitrile) and its photodegradate MB46513 (5-aminol-2,6-dichloro-4-[(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfonyl]-1H-pyrazole-3-carbonitrile), in or on potato at 0.03 ppm, potato, wet peel at 0.1 ppm and indirect or inadvertent residues of fipronil and its metabolites and its degradation on wheat, forage at 0.02 ppm, wheat, grain at 0.005 ppm, wheat, hay at 0.03 ppm, and wheat, straw at 0.03 ppm. Time-limited tolerances are also
established for combined residues of fipronil and its metabolites and degradate on turnip at 1.0 ppm and rutabaga at 1.0 ppm.

The registrant petitioned for tolerances on vegetable, tuberous corm, subgroup 1C. In evaluating this petition, the Agency determined that planting methods associated with the different members of crop subgroup vegetable, tuberous corm, subgroup 1C result in different amounts of fipronil and its metabolites and degradate being loaded into the environment. Further, because of the planting depth of potatoes, the environmental loading of fipronil and its metabolites and degradate is expected to be lower for potatoes than other members of vegetable tuberous corm crop group 1C and is expected to be below levels of concern. For this reason, the Agency is establishing tolerances only for potato and the rotational crop wheat at this time. The Agency is working to resolve these issues as they relate to other members of vegetable tuberous corm crop group 1C.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, or are established under section 408(f)(6) of FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. This final rule directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, this rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States prior to the effective date. EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will also send copies of the rule report to the Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:


2. Section 180.517 is amended by alphabetically adding commodities to the table in paragraph (a) and by adding text to paragraphs (b) and (d) to read as follows:

§180.517 Fipronil; tolerances for residues.

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potato</td>
<td>0.03</td>
</tr>
<tr>
<td>Potato, wet peel</td>
<td>0.10</td>
</tr>
</tbody>
</table>

(b) Section 18 emergency exemptions.

Time-limited tolerances are established for combined residues of the insecticide, fipronil, 5-amino-1-(2,6-dichloro-4-[(trifluoromethyl)phenyl]-4-((1R,S)-trifluoromethyl)sulfinyl)-1H-pyrazole-3-carbonitrile and its 2 metabolites MB45550 (5-amino-1-(2,6-dichloro-4-[(trifluoromethyl)phenyl]-4-((1R,S)-trifluoromethyl)sulfinyl)-1H-pyrazole-3-carbonitrile) and MB46136 (5-amino-1-(2,6-dichloro-4-[(trifluoromethyl)phenyl]-4-((1R,S)-trifluoromethyl)sulfinyl)-1H-pyrazole-3-carbonitrile), in connection with use of the pesticide under Section 18 emergency exemptions granted by EPA. The tolerances expire and are revoked on the dates specified in the table for this paragraph.

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
<th>Expiration/revocation date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rutabaga</td>
<td>1.0</td>
<td>12/31/10</td>
</tr>
<tr>
<td>Turnip</td>
<td>1.0</td>
<td>12/31/10</td>
</tr>
</tbody>
</table>

(d) Indirect or inadvertent residues.

Tolerances are established for combined indirect or inadvertent residues of the insecticide fipronil and its metabolites and photodegrade in or on food commodities when present therein as a result of the application of fipronil to growing crops listed in paragraphs (a) and (b) of this section and other nonfood crops to read as follows:

List of Subjects in 40 CFR Part 180:

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.
ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

Pyriproxyfen; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyriproxyfen in or on animal feed, nongrass, group 18, forage; animal feed, nongrass, group 18, hay; animal feed, nongrass, group 18, seed; banana; beet, sugar, dried pulp; cacao bean, dried; caneberry, subgroup 13-A; canola, seed; coffee, instant; coffee, green bean; cranberry; date; grain, cereal, group 15; grain, cereal, group 16; pawpaw; peanut; pineapple; pineapple, process residue; pomegranate; potato, chips; potato, granules/ flakes; potato, wet peel; rice, hulls; safflower, seed; sesame, seed; sugarcane; tea; vegetable, bulb, group 3, except onion, bulb; and vegetable, root and tuber, group 1. Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201 W, Princeton, NJ 08540 requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 22, 2007. Objections and requests for hearings must be received on or before October 22, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0889. To access the electronic docket, go to http://www.regulations.gov, select “Advanced Search,” then “Docket Search.” Insert the docket ID number where indicated and select the “Submit” button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at http://www.regulations.gov, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT:
Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; 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 potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

• Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.

• Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.

• Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.

• Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

B. How Can I Access Electronic Copies of this Document?


C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0889 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before October 22, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in ADDRESSES. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2006–0889, by one of the following methods:

• Federal eRulemaking Portal: http://www.epa.gov/fedreg. Follow the on-line instructions for submitting comments.


• Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket’s normal business hours (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wheat, forage</td>
<td>0.02</td>
</tr>
<tr>
<td>Wheat, grain</td>
<td>0.005</td>
</tr>
<tr>
<td>Wheat, hay</td>
<td>0.03</td>
</tr>
<tr>
<td>Wheat, straw</td>
<td>0.03</td>
</tr>
</tbody>
</table>