has been isolated as a rare contaminant from human infections. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety does not apply. Further, the considerations of consumption patterns, special susceptibility, and cumulative effects do not apply to pesticides without a demonstrated significant adverse effect.

VII. Other Considerations

A. Endocrine Disruptors

The Agency has no information to suggest that *Bacillus subtilis* GB03 has an effect on the endocrine system. No specific tests have been conducted with *Bacillus subtilis* GB03 to determine such effects. However, the submitted toxicity/pathogenicity studies in rodents indicated that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. *Bacillus subtilis* GB03 is a ubiquitous organism in the environment and there have been no reports of the organism affecting endocrine systems. Therefore, it is unlikely that this organism would have estrogenic or endocrine effects and it is practically non-toxic to mammals.

B. Analytical Method

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation; therefore, the Agency has concluded that an analytical method is not required for enforcement purposes for *Bacillus subtilis* GB03.

C. Codex Maximum Residue Level

No Codex maximum residue level exists for *Bacillus subtilis* GB03.

VIII. Conclusions

There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of the *Bacillus subtilis* GB03 in or on all food and feed commodities. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, no toxicity or pathogenicity to mammals has been observed in test animals.

IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 final rule has been exempted from review under Executive Order 12866, this final 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, such as the tolerance 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 9, 2000) do not apply to this final rule. In addition, this final 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).

X. 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.

Dated: August 14, 2008

W. Michael McDavit,

Acting Director, Biopesticides and Pollution Prevention 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:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1111 is revised to read as follows:

§ 180.1111 Bacillus subtilis GB03; exemption from the requirement of a tolerance.

The biofungicide *Bacillus subtilis* GB03 is exempted from the requirement of a tolerance in or on all raw agricultural commodities when used in accordance with good agricultural practices.

[FR Doc. E8–19860 Filed 8–26–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0987; FRL–8376–4]

Fenbuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of the fungicide fenbuconazole, alpha–[2–(4–

chlorophenyl)– ethyl]–alpha–phenyl–3–(1H–1,2,4–triazole)– 1–propanenitrile, and its metabolites RH–9129, cis–5–(4–chlorophenyl)– dihydro–3–phenyl–3–(1H–1,2,4– triazole–1–ylmethyl)–2–3 H–furanone, and RH–9130, trans–5–(4–chlorophenyl)dihydro–3–phenyl–3–(1H–1,2,4–triazole–1–ylmethyl)–2–3 H–furanone, expressed as fenbuconazole in or on pepper (7E7256). The Interregional Research Project Number 4 (IR–4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA) on behalf of the registrant, Dow AgroSciences LLC.

DATES: This regulation is effective August 27, 2008. Objections and requests for hearings must be received on or before October 27, 2008, 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–2007–0987. 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: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@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).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

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–2007–0987 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 27, 2008.

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–2007–0987 by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *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 (8:30 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 Tolerance

In the **Federal Register** of January 23, 2008 (73 FR 3964) (FRL–8345–7), 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 7E7256) by IR–4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.480 be amended by establishing tolerances for combined residues of the fungicide fenbuconazole, alpha–[2–(4–chlorophenyl)– ethyl]–alpha–phenyl–3–(1H–1,2,4–triazole)– 1–propanenitrile, and its metabolites RH–9129, cis–5–(4–chlorophenyl)– dihydro–3–phenyl–3–(1H–1,2,4– triazole–1–ylmethyl)–2–3 H–furanone, and RH–9130, trans–5–(4–chlorophenyl)dihydro–3–phenyl–3–(1H–1,2,4–triazole–1–ylmethyl)–2–3 H–furanone, expressed as fenbuconazole in or on pepper at 0.40 parts per million (ppm). That notice referenced a summary of the petition prepared by Dow AgroSciences LLC, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

In addition, §180.480(a)(1), is revised to remove reference to ''time-limited tolerance'' as this section is dedicated to, and only contains, permanent

tolerances. Also, §180.480(a)(2) is deleted in its entirety as it relates solely to time-limited tolerances in paragraph (a)(1) and there are no such tolerances in paragraph (a)(1). In addition, the time-limited tolerance under §180.480(b) Section 18 emergency exemptions, for blueberry at 1.0 ppm that expired on 12/31/07 is deleted.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for combined residues of fenbuconazole on pepper at 0.40 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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.

Fenbuconazole has low acute toxicity and is neither skin or eye irritants nor a dermal sensitizer. In subchronic and chronic feeding studies the liver was the main target of toxicity. At the LOAEL in the subchronic studies, there were changes in liver histopathology, predominantly hepatocellular hypertrophy. At doses higher than the LOAEL in the rat, the thyroid was a secondary target organ with increased follicular cell size. In the chronic studies, liver effects were seen (including hepatocellular hypertrophy and vacuolization, changes in liver enzymes, and increased liver weights), as well as decreased body weight gains. Again, in the chronic rat study, the thyroid was a secondary target with increased thyroid and parathyroid weights and thyroid follicular cell hypertrophy. In addition, increased mean T4 and decreased TSH were found in the high-dose rats near the end of the study. In the chronic dog study, kidney and adrenal weights were also increased. Males and females throughout the studies appeared to be equally sensitive to fenbuconazole toxicity, except in the chronic mouse study, where male mice appeared to be more sensitive than the females.

In the rat and rabbit developmental toxicity studies and the two generation study in rats, all effects in the pups occurred in the presence of maternal toxicity, including changes in body weight and body weight gains in rats and decreased food consumption and clinical signs in rabbits. Developmental effects included increased post-implantation loss and decreased fetuses per dam in the rat developmental study; increased early resorptions in the rabbit developmental study; and decreased mean pup body weight, increased number of stillborn pups, decreased number of total offspring delivered, and decreased viability index of pups in the two generation study in rats. No increased qualitative or quantitative susceptibility was observed in any of the studies. There was no evidence of neurotoxicity in any of the studies available in the toxicology database.

Fenbuconazole is not mutagenic. Fenbuconazole is classified as a Group C, possible human carcinogen, and febuconazole's human cancer risk is assessed quantitatively by a low dose extrapolation model applied to the experimental animal tumor data.

Specific information on the studies received and the nature of the adverse effects caused by fenbuconazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document Fenbuconazole (7E7256) – Human Health Risk Assessment for the Proposed Use on Peppers at page 14 in docket ID number EPA–HQ–OPP–2007–0987–0003.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as 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) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD 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 dietary risks by comparing aggregate food and water 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 POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. 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/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for fenbuconazole used for human risk assessment can be found at *http://www.regulations.gov* in document Fenbuconazole (7E7256) – Human Health Risk Assessment for the Proposed Use on Peppers at page 25 in docket ID number EPA–HQ–OPP–2007–0987–0003.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fenbuconazole, EPA considered exposure under the petitioned-for tolerances as well as all

existing fenbuconazole tolerances in (40 CFR 180.480). EPA assessed dietary exposures from fenbuconazole 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 1–day or single exposure.

In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model (DEEM–FCID, Version 2.03), which uses food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, the acute dietary exposure analysis is based on tolerance-level residues and 100% crop treated assumptions. The only population subgroup that is relevant for this acute assessment is females of child-bearing age (i.e., females 13–49 years old).

ii. *Chronic(non-cancer) exposure*. In conducting the chronic dietary (food + water) exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, the chronic (non-cancer) dietary exposure analyses uses average residues from field trials. For many of the crops, separate studies were submitted and reviewed. For those crops, multiple averages were calculated and the highest average value was used in the analysis. The non-cancer dietary analysis assumes 100% crop treated.

iii. *Cancer*. The cancer exposure analysis uses average residues from field trials. In addition, estimates of average percent crop treated were used for certain commodities.

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 require pursuant to FFDCA section 408(f)(1) 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.

Anticipated residue data were used in the chronic (non-cancer) and cancer dietary risk analyses but not in the acute dietary risk analysis. For many crops, the anticipated residues used were the highest per-study-volume average residue value from the field trial studies for each crop that were submitted by the registrant.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

In the cancer dietary exposure analysis, the Agency used the following estimated PCT information:

Apples 1%, apricots 10%, blueberries 40%, cherries 20%, grapefruit 40%, nectarines 10%, oranges 1%, peaches 15%, pecans 15%, prunes 1%, and tangerines 1%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in the preceding paragraphs have been met. With respect to Condition a, PCT estimates are derived from sources as discussed in the preceding paragraphs including Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which fenbuconazole may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models to determine the drinking water concentrations that were used in the dietary exposure analysis and risk assessment for fenbuconazole. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fenbuconazole. 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*.

The assessments included conservative estimated drinking water concentrations (EDWC) based on either the pepper or the cherry use. Modeled surface water EDWCs are based on the maximum label application rate to peppers (acute value) or cherries (chronic and cancer values) while the groundwater EDWC is based on the maximum label application rate to cherries. The acute assessment is highly conservative with respect to evaluating potential impacts of dietary exposure to fenbuconazole on human health. The chronic (non-cancer) and cancer assessments are moderately conservative with respect to evaluating potential impacts of dietary exposure to fenbuconazole on human health.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking

water concentrations (EDWCs) of fenbuconazole for acute exposures are estimated to be 24.1 parts per billion (ppb) for surface water and 0.031 ppb for ground water. The EDWCs for chronic exposures for non-cancer assessments are estimated to be 16.5 ppb for surface water and 0.031 ppb for ground water. The EDWCs for chronic exposures for cancer assessments are estimated to be 11.7 ppb for surface water and 0.031 ppb for ground 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, termiticides, and flea and tick control on pets). Fenbuconazole is not registered for any specific use patterns that would result in residential exposure.

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's residues and ''other substances that have a common mechanism of toxicity.''

Fenbuconazole is a member of the triazole-containing class of pesticides. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events. In conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity, and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, refer to EPA's website at *http://www.epa.gov/pesticides/cumulative*.

Fenbuconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazole alanine and triazole acetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including fenbuconazole, U.S. EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazole alanine, and triazole acetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at *http://www.regulations.gov*, docket ID number EPA–HQ–OPP–2005–0497. Additional information regarding the use proposed for fenbuconazole in this action can also be found at *http://www.regulations.gov* in document: ''Dietary Exposure Assessments for the Common Triazole Metabolites 1,2,4-Triazole, Triazolylalanine, Triazolylacetic Acid, and Triazolylypyruvic Acid; Updated to Include New Uses of Fenbuconazole, Ipconazole, Metconazole, Tebuconazole, and Uniconazole; and a Change in Plant-back Restriction for Tetraconazole'' in docket ID number EPA–HQ–OPP–2007–0987–0006.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. Available data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to fenbuconazole. In the prenatal developmental study in rats and rabbits and the 2-generation study in rats, effects in the offspring were observed only at or above those treatment levels which resulted in maternal toxicity.

The degree of concern for infants and children exposed to fenbuconazole *in utero* and/or postnatally is low; there are no residual uncertainties. The toxicology database for fenbuconazole is complete and adequate for risk assessment purposes. Acceptable developmental studies in rats and rabbits and the 2-generation reproduction study in rats did not show evidence of increased susceptibility in offspring exposed to fenbuconazole *in utero* and/or postnatally. A NOAEL for acute effects has been selected for the subpopulation females (13–49 years old) based on developmental effects (increased resorptions and decreased live fetuses per dam) seen at the LOAEL in the developmental rat study. By regulating on the effects of concern for this subpopulation, the risk assessment is protective of potential effects to infants and children.

3. *Conclusion*. There is a complete toxicity data base for fenbuconazole and exposure data are complete or are estimated based on data that reasonably account for potential exposures. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for fenbuconazole is complete.

ii. There is no indication that fenbuconazole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that fenbuconazole results in increased susceptibility *in utero* to rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study

iv. There are no residual uncertainties identified in the exposure databases. Although somewhat refined, the dietary food exposure assessments were based on reliable data that will not underestimate exposure to fenbuconazole residues in food. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure

to fenbuconazole in drinking water. These assessments will not underestimate the exposure and risks posed by fenbuconazole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs 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 fenbuconazole will occupy 3.1 % of the aPAD for females 13–49 years old, the only subgroup of concern because of the toxicological properties of fenbuconazole.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fenbuconazole from food and water will utilize 6.8% of the cPAD for all infants less than 1 year old, the population group receiving the greatest exposure, and 2.3% of the cPAD for the general U.S. population. There are no residential uses for fenbuconazole that result in chronic exposure. EPA does not expect aggregate exposure to exceed 100% of the cPAD for any population subgroup.

3. *Short- and intermediate-term risks*. Short- and intermediate-term aggregate exposures take into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fenbuconazole is not registered for any use patterns that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from exposure to fenbuconazole through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population*. Dietary exposure (food + water) is the only source of exposure to fenbuconazole that is expected to be chronic (cancer exposure is considered to be life-time exposure). The chronic (cancer) aggregate exposure and risk estimates are based on those for the general U.S. population group. In this case the risk is based on a cancer potency (Q_1*) value of 3.59×10^{-3} and a dietary exposure to fenbuconazole of 0.000473 mg/kg/day. The estimated cancer risk that resulted from this assessment is 1.7×10^{-6}. Typically, EPA is concerned when the cancer risk estimate associated with food and drinking water exceeds the range of 1 in 1 million (1×10^{-6}) . This risk range includes computed risks as high as 3×10^{-6}. As a result, cancer risk to the general U.S. population is below the Agency's level of concern.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to fenbuconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with nitrogen-phosphorus detection) 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

Maximum Residue Levels (MRLs) for residues of fenbuconazole have been established by Codex, Canada, and Mexico. The residue definition for both Codex and Mexico is fenbuconazole, *per se*. The Canadian residue definition, however, is the combined residues of fenbuconazole and its metabolites, RH–9129 and RH–9130, each expressed as parent (i.e., the same as the U.S. tolerance definition). There are no established or proposed Canadian, Mexican, or Codex MRLs for fenbuconazole on pepper.

C. Revisions to Petitioned-For Tolerances

By this action, §180.480(a)(1), is revised to remove reference to ''time-limited tolerance'' as this section is dedicated to, and only contains, permanent tolerances. Also, §180.480(a)(2) is deleted in its entirety as it relates solely to time-limited tolerances in paragraph (a)(1) and there are no such tolerances in paragraph (a)(1). In addition, the time-limited tolerance under §180.480(b), section 18 emergency exemptions, for blueberry at 1.0 ppm that expired on 12/31/07 is deleted.

V. Conclusion

Therefore, tolerances are established for combined residues of the fungicide fenbuconazole, alpha–[2–(4–chlorophenyl)– ethyl]–alpha–phenyl–3–(1H–1,2,4–triazole)– 1–propanenitrile, and its metabolites RH–9129, cis–5–(4–chlorophenyl)– dihydro–3–phenyl–3–(1H–1,2,4– triazole–1–ylmethyl)–2–3 H–furanone, and RH–9130, trans–5–(4–chlorophenyl)dihydro–3–phenyl–3–(1H–1,2,4–triazole–1–ylmethyl)–2–3 H–furanone, expressed as fenbuconazole in or on pepper at 0.40 ppm.

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 final rule has been exempted from review under Executive Order 12866, this final 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, such as the tolerance 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 9, 2000) do not apply to this final rule. In addition, this final 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. 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.

Dated: August 15, 2008.

Lois Rossi,

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:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.480 is amended by removing paragraph (a)(2); redesignating paragraph (a)(1) as paragraph (a); revising the introductory text in paragraph (a); adding alphabetically a commodity to the table in paragraph (a); and revising paragraph (b) to read as follows:

§ 180.480 Fenbuconazole; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the fungicide fenbuconazole, alpha–[2–(4–chlorophenyl)– ethyl]–alpha–phenyl–3–(1H–1,2,4–triazole)– 1–propanenitrile, and its metabolites RH–9129, cis–5–(4–chlorophenyl)– dihydro–3–phenyl–3–(1H–1,2,4– triazole–1–ylmethyl)–2–3 H–furanone, and RH–9130, trans–5–(4–chlorophenyl)dihydro–3–phenyl–3–(1H–1,2,4–triazole–1–ylmethyl)–2–3 H–furanone, expressed as fenbuconazole in or on the following agricultural commodities.

Commodity	Parts per million
* * * * *	
Pepper	0.40
* * * * *	

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for fenbuconazole (alpha-[2-4-chlorophenyl)-ethyl]alpha-phenyl-3-(1 H -1,2,4-triazole)-1-propanenitrile] and its metabolites, cis-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1 H -1,2,4-triazole-1-ylmethyl)-2-3 H -furanone and trans-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1 H 1,2,4-triazole-1-ylmethyl-2-3 H -furanone, expressed as fenbuconazole in or on the following raw agricultural commodities in connection with use of the pesticide under a section 18 exemption granted by EPA. The time-limited tolerances will expire on the date specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Cattle, fat	0.01	12/31/08
Cattle, meat	0.01	12/31/08
Goat, fat	0.01	12/31/08
Goat, meat	0.01	12/31/08
Hog, fat	0.01	12/31/08
Hog, meat byproducts	0.01	12/31/08
Hog, meat	0.01	12/31/08
Horse, fat	0.01	12/31/08
Horse, meat	0.01	12/31/08
Sheep, fat	0.01	12/31/08
Sheep, meat	0.01	12/31/08

* * * * *

[FR Doc. E8–19858 Filed 8–26–08; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0604; FRL–8377–7]

Dichlobenil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of dichlobenil and its metabolite, 2,6-dichlorbenzamide, in or on bushberry subgroup 13–07B, caneberry subgroup 13–07A and rhubarb. It also removes existing tolerances on individual members of bushberry subgroup 13–07B (blueberry) and caneberry subgroup 13–07A (blackberry and raspberry) that are superseded by the new crop subgroup tolerances at the same tolerance levels. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 27, 2008. Objections and requests for hearings must be received on or before October 27, 2008, 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–2007–0604. 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

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–2007–0604 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 27, 2008.

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–2007–0604, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *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 (8:30 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 Tolerance

In the **Federal Register** of August 22, 2007 (72 FR 47010) (FRL–8142–5), 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 7E7230) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201W, Princeton, NJ 08540–6635. The petition requested that 40 CFR 180.231 be amended by establishing tolerances for combined residues of the herbicide dichlobenil, 2,6-dichlorobenzonitrile, and its metabolite, 2,6-