agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA, if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement (5 U.S.C. 806(2)). As stated previously, EPA has made such a good cause finding, including the reasons therefore, and established an effective date of March 5, 2010. The 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 the rule in the Federal Register.

The EPA’s compliance with these statutes and Executive Orders for the underlying rule is discussed in the December 3, 2009, Federal Register notice containing the Area Source Paints and Allied Products Manufacturing final rule (74 FR 63504).

List of Subjects for 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.


Gina McCarthy,
Assistant Administrator, Office of Air and Radiation.

For the reasons set out in the preamble, title 40, chapter I, part 63, of the Code of Federal Regulations is amended as follows:

PART 63—[AMENDED]

§ 63.11601 What are the standards for new and existing paints and allied products manufacturing facilities?

(a) For each new and existing affected source, you must comply with the requirements in paragraphs (a)(1) through (5) of this section. These requirements apply at all times.

(4) You must:

(i) Capture particulate emissions and route them to a particulate control device meeting the requirements of paragraph (a)(5) of this section during the grinding and milling of materials containing compounds of cadmium, chromium, lead, or nickel; or

(ii) * * * * *

3. Section 63.11602 is amended by:

(a) In paragraph (a)(2)(iii) introductory text by revising the last sentence:

(b) In paragraph (a)(2)(iii)(A) by revising the last sentence;

(c) By revising paragraph (a)(2)(iii)(B).

§ 63.11602 What are the performance test and compliance requirements for new and existing sources?

(a) * * *

(2) * * *

(iii) * * * If the Method 203C test runs indicates an opacity greater than the limitation in § 63.11601(a)(5), you must comply with the requirements in paragraphs (a)(2)(iii)(A) through (C) of this section.

(A) * * * You must continue to take corrective action and retest each 15 days until a Method 203C test indicates an opacity equal to or less than the limitation in § 63.11601(a)(5).

(B) You must prepare a deviation report in accordance with § 63.11603(b)(3) for each instance in which the Method 203C opacity results were greater than the limitation in § 63.11601(a)(5).

* * * * *

4. Section 63.11603 is amended by:

(a) Revising paragraph (c) introductory text;

(b) Redesignating paragraph (e) as paragraph d).

§ 63.11603 What are the notification, reporting, and recordkeeping requirements?

(c) Records. You must maintain the records specified I paragraphs (c)(1) through (4) of this section in accordance with paragraphs (c)(5) through (6) of this section, for five years after the date of each recorded action.

* * * * *

[FR Doc. 2010–4754 Filed 3–4–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


Beauveria bassiana HF23; Amendment of Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends an exemption from the requirement of a tolerance for residues of the microbial insecticide, Beauveria bassiana HF23 (40 CFR 180.1273) on all food commodities when used to treat chicken and livestock facilities, from which manure will eventually be composted and used as fertilizer on agricultural crops. JABB of the Carolinas submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting this amendment of the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of Beauveria bassiana HF23.

DATES: This regulation is effective March 5, 2010. Objections and requests for hearings must be received on or before May 4, 2010, 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–2005–0316. All documents in the docket are listed in the docket index available at http://www.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:
Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8097; e-mail address: bacchus.shanaz@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:
- 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 provides 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 Get Electronic Access to Other Related Information?

C. Can I File an Objection or Hearing Request?
Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2005–0316 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 on or before May 4, 2010.

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 your copies, identified by docket ID number EPA–HQ–OPP–2005–0316 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 Facility’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. Background and Statutory Findings
In the Federal Register of March 16, 2009 (74 FR 11100) (FRL–8405–1), 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 tolerance petition (PP 877467) by JABB of the Carolinas, P.O. Box 310, Pine Level, NC 27568. The company’s supporting documents for the notice of filing of the petition incorrectly assigned PP 5F6960 to this petition. The petition requested that 40 CFR 180.1273 be amended by expanding the uses covered by the existing exemption from the requirement of a tolerance for residues of Beauveria bassiana HF23. This notice indicated that a summary of the petition prepared by the petitioner was included in the docket for this action.

One anonymous public comment was posted to the docket asserting that foods should have zero pesticide residues and requested labeling for all foods with any residue above the zero level. The commenter also referred to the toxicity of chemicals and their possible link to cancer.

The Agency’s response to this comment follows. This active ingredient, Beauveria bassiana HF23, occurs naturally in the environment and the human population is potentially exposed to it regardless of whether it is registered as a pesticide or not. Thus, it is not even possible to eliminate exposure to this substance since it is a naturally occurring ubiquitous soil microbe.

EPA regulates pesticides according to peer-reviewed and publicly available guidelines that describe endpoints for human health risk assessment. Tests are conducted with the active ingredient or end-use product in surrogate animals through various routes of administration (i.e., oral, dermal, pulmonary, etc.). Any effects seen are reported to the Agency, peer-reviewed, and evaluated to determine whether the effects of the test material demonstrate infectivity, acute toxicity, or pathogenicity. Beauveria bassiana HF23 has demonstrated a low toxicity profile in such testing and did not trigger the need for further testing for carcinogenicity. Summaries of data reviewed in support of this active ingredient are available in the Biopesticide Registration Action Document (BRAD) on Beauveria bassiana HF23 (www.epa.gov/pesticide/biopesticides) and in the final rule published for use of the active ingredient for chicken feed treatment in the Federal Register on January 10, 2007 (72 FR 1177) (FRL–8108–4).

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(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. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require 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.”

Additionally, section 408(b)(2)(D) of FFDCA requires that 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.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information 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.

*Beauveria bassiana* HF23 is a fungus with insecticidal properties. It is a naturally occurring, ubiquitous soil microbe. This strain, and other strains of *Beauveria bassiana* that are registered as pesticides, demonstrate low toxicity potential and are not likely to harm human adults, infants, and children. An exemption from tolerance has already been established in 40 CFR 180.1273 for residues of *Beauveria bassiana* HF23 on all food/feed commodities, when the pesticide is used to treat chicken manure (72FR 1177, January 10, 2007). The toxicological profile of this active ingredient was published in that final rule and summaries of the studies cited in support of this tolerance exemption amendment are available in the BRAD on [www.epa.gov/pesticides/biopesticides](http://www.epa.gov/pesticides/biopesticides). The registrant now cites those data and provides additional information to support expanding the tolerance exemption to include residues on food/feed commodities from agricultural crops fertilized with manure from livestock facilities, where the manure was treated with *Beauveria bassiana* HF23. Reference to those studies are included in the following discussion.

Based on the previously reviewed data, the Agency classified the active ingredient as Toxicity Category IV for acute oral and acute pulmonary effects and Toxicity Category III for acute dermal effects. These studies indicated that the pesticide was not toxic, infective or pathogenic via these routes of exposure. Also, the test organism was not toxic or pathogenic to rats via the intraperitoneal route. Immunotoxicity testing is not required for this active ingredient because it does not contain viruses that are known to interact in an adverse manner with the mammalian immune system.

No incidents of hypersensitivity associated with the TGAi or proposed components of the EP have been reported or are found in the scientific literature to date. However, as with all pesticides, any incidents of hypersensitivity or other adverse effects associated with the use of *Beauveria bassiana* HF23 must be reported to the Agency, in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 6(a)(2).

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. Food. The pesticide is intended for the control of houseflies in livestock and chicken facilities. In livestock facilities, the pesticide is to be applied as bait in stations that are not within reach of livestock or as a spray to the facilities. In chicken facilities, the pesticide is applied directly onto the chicken manure to control houseflies as well as to the walls of the chicken houses. The pesticide is not applied directly either to chicken or livestock, nor is it applied directly to food or feed. In light of these uses in chicken and livestock facilities, the Agency has evaluated whether there is any potential for residues of the pesticide to result in or on meat, milk, poultry, eggs, or other products derived from chickens or livestock present in such facilities. In addition, the Agency has considered whether there is any potential for residues to result in food or feed crops as a result of the use of treated manure as fertilizer for agricultural crops.

With respect to meat, milk, poultry, eggs, or other products derived from chickens or livestock, the Agency has considered the following. First, as already explained in the aforementioned BRAD and in the prior final rule granting a tolerance exemption for *Beauveria bassiana* HF23 (Unit III.A. and B., 72 FR 1177, January 10, 2007), the acute oral and dermal toxicity tests in mammals resulted in the Agency classifying the fungus as a low Toxicity Category IV for acute oral effects and Toxicity Category III for acute dermal effects. Second, acute toxicology tests involving dermally administered *Beauveria bassiana* HF23 led to a toxicity Category III acute dermal classification for the fungus. Third, there were no signs of infectivity in tissues examined during the acute intraperitoneal test in mammalian rodents. Fourth, an acute oral toxicity test conducted in chicken also demonstrated that the active ingredient is not toxic, infective or pathogenic to chicken.

Fifth, clearance was observed in all tissues analyzed during these avian and mammalian tests and they were conducted with guideline levels of the active ingredient, with no toxic, infective or pathogenic effects to the avian and mammalian test organisms.

Summaries of these tests can be found in the prior final rule published on January 10, 2007 (72 FR 1177, Unit III, A, B, and E) and in the BRAD for *Beauveria bassiana* HF23. Based on all of this, the Agency concludes that residues of the pesticide are not likely to be transferred to meat, milk, eggs, poultry or other products derived from chicken and livestock as a result of treating chicken and livestock facilities with the pesticide.

Moreover, to the extent that there could be negligible residues resulting in meat, milk, eggs, poultry, or other products derived from the chicken and livestock from such facilities, it is expected that they will not be greater than naturally occurring background levels to which humans already are possibly exposed due to the fact that this is a ubiquitous soil microbe. In addition, to the extent that there were any potential negligible residues of the fungus *Beauveria bassiana* HF23 resulting in meat, milk, eggs, poultry, or other products derived from the chicken or livestock from treated facilities, which, again, is unlikely and not expected, it is expected that they would be removed in connection with the steps taken to prepare such products for market and consumption. For example, the shells of eggs are washed, and eggs are cooked prior to human consumption. The shells also can be expected to prevent any residues of the pesticide from getting into the edible...
portions of eggs. Feathers are removed from chickens and hides from livestock during dressing operations and meat and poultry preparation. These measures are expected to remove any potential negligible residues prior to human consumption. Similarly, washing, cleaning and other processes when preparing meat, as well as the pasteurization of milk, would remove any potential negligible residues from meat and milk.

In connection with the use of treated manure as fertilizer for agricultural crops, the Agency has concluded that while it is possible for extremely low or negligible residues to result in or on food and feed derived from those crops, this, nonetheless, is unlikely for the following reasons. First, prior to being used on agricultural crops, chicken and livestock manure is composted. This is significant because *Beauveria bassiana* HF23 does not survive temperatures greater than 37 degrees Centigrade (the average mammalian body temperature), and thus, would not be expected to survive the higher temperatures of composting (40-50 degrees Centigrade on average) (Master Records Identification (MRID) 46526011. In addition, *Beauveria bassiana* HF23 does not survive in Ultraviolet (UV) light, so it is likely that any residues that survived composting would be destroyed by UV light once the treated manure is applied to agricultural crops in the field if the pesticide is used as labeled.

On the basis of the foregoing considerations, and mindful of the previously mentioned studies that indicate that *Beauveria bassiana* HF23 is not toxic, infective or pathogenic via the tested routes of exposure, is not toxic or pathogenic to rats via the intraperitoneal route, and does not contain viruses that are known to interact in an adverse manner with the mammalian immune system, the Agency concludes that no harm is expected to human adults, children, or infants via consumption of any food products derived from chicken or livestock potentially exposed to the pesticide as a result of its use (in accordance with label directions) in chicken and livestock facilities, or via consumption of any food products derived from agricultural crops to which treated manure has been applied as a fertilizer.

2. Drinking water exposure. No drinking water exposure is anticipated because of the use patterns, use sites, and the nature of the active ingredient at issue. The pesticide is to be used for indoor treatment of chicken and livestock facilities. It will be applied in either a suspension or a granular bait formulation. Most notably, there are no aquatic use sites permitted for this pesticide. Thus, there is likely to be no access to sources of drinking water as a result of applications within such facilities. Moreover, even if the pesticide did somehow reach drinking water as a result of the permitted indoor uses, *Beauveria bassiana* HF23 is not known to proliferate in aquatic environments (BRAD Chapter III.C).

The Agency also does not expect any residues in drinking water or ground water as a result of application of treated manure that is used as fertilizer on agricultural crops. *Beauveria bassiana* HF23 is a soil microbe. As discussed in Unit IV.A.1, this microbe is not likely to survive composting temperatures or subsequent exposure to UV light. In addition, because soil microbes generally tend to seek their nutrients and grow in the upper levels of soil and do not, as a result, penetrate lower soil levels that are more akin to filtration beds, *Beauveria bassiana* HF23 is not expected to percolate into soil and reach ground water (see BRAD Chapter III.C.). Thus, transfer of this naturally occurring, low toxicity, soil borne microbe from soil to ground water is unlikely.

Accordingly, the Agency concludes that *Beauveria bassiana* HF23, when used as labeled and in accordance with good agricultural practices, is not likely to pose any incremental dietary risk to human adults, children, or infants via consumption of drinking water (see BRAD and 72 FR 11777, Jan. 10, 2007).

B. Other Non-Occupational Exposure

1. Dermal exposure. EPA has concluded that there is unlikely to be any non-occupational dermal exposure because the use sites are commercial and agricultural.

2. Inhalation exposure. Similarly, non-occupational inhalation exposure to *Beauveria bassiana* HF23 from its proposed commercial and agricultural use as a pesticide to treat chicken manure or livestock facilities is not anticipated.

In summary, the potential aggregate exposure as a result of the use of the pesticidal active ingredient *Beauveria bassiana* HF23 is not likely to pose a hazard via aggregate exposure. This includes potential hazards derived from (i.) dietary exposure from the treated food/feed commodities. (ii.) drinking water potentially exposed secondary to treatment of sites with this pesticide; and (iii.) dermal and inhalation non-occupational exposure of populations exposed to *Beauveria bassiana* HF23.

V. Cumulative Effects

Three other *Beauveria bassiana* strains are registered. While they show the same mechanism as entomopathogens, they are involved in treatments of specific target pests. In this instance, *Beauveria bassiana* HF23 is directed against the public health hazard, houseflies. Because *Beauveria bassiana* HF23 does not operate via a toxic mechanism, section 408(b)(2)(D)(v) does not apply. In any event, since none of the registered strains are toxic, infective or pathogenic to humans and other mammals or other non-target organisms, cumulative adverse health or environmental effects of *Beauveria bassiana* HF23 are not expected.

VI. Determination of Safety for U.S. Population, Infants and Children

The Agency has concluded that there is a reasonable certainty that no harm will result from aggregate exposures to *Beauveria bassiana* HF23 in or on all food commodities, when the pesticide is used to treat manure in chicken and livestock facilities, which manure will in turn be used as fertilizer on agricultural crops. The Agency bases this conclusion on the data that demonstrate this substance has little to no toxicity or infectivity. Based on all the available information, the Agency concludes that the fungus, *Beauveria bassiana* HF23, is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children, and adults when *Beauveria bassiana* HF23 is used as a pesticidal active ingredient, the Agency has determined that the additional margin of safety is not necessary to protect infants and children, and that not adding any additional margin of safety will be safe for infants and children. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of *Beauveria bassiana* HF23.

VII. Other Considerations

A. Endocrine Disruptors


B. Analytical Method(s)


C. Codex Maximum Residue Level

There is no Codex Maximum Residue Level (MRL) for residues of *Beauveria bassiana* HF23 on all food commodities.

VIII. Conclusions

In summary, the Agency has determined that, based on available data
and information, there is a reasonable certainty of no harm from aggregate exposure to Beauveria bassiana HF23 on all food commodities, resulting either from its use (in accordance with all label direction and good agricultural practices) in chicken and livestock facilities or as a result of the subsequent use of treated manure from livestock and chicken facilities as fertilizer on agricultural crops. Thus, an exemption from the requirement of a tolerance is being granted for residues of Beauveria bassiana HF23 on all food commodities in response to pesticide petition PP 8F7467.

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, entitled 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 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. Congress and to 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.


Keith A. Matthews,
Acting Director, Biocides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

§ 180.1273. Beauveria bassiana HF23; exemption from the requirement of a tolerance.

Residues of Beauveria bassiana HF23 are exempt from the requirement of a tolerance on all food/feed commodities, when the pesticide is used for the treatment of chicken and livestock facilities, including the treatment of chicken and livestock manure.