based on the completeness and reliability of the toxicity data and the conservative exposure assessment, there is a reasonable certainty that no harm will result from aggregate exposure to residues of carfentrazone-ethyl, including all anticipated dietary exposure and all other non-occupational exposures.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of carfentrazone-ethyl, EPA considers data from developmental toxicity studies in the rat and rabbit and the 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to effects on the reproductive capacity of males and females exposed to the pesticide. Developmental toxicity was not observed in developmental toxicity studies using rats and rabbits. In these studies, the rat and rabbit maternal NOELs were 100 mg/kg/day and 150 mg/kg/day, respectively. The developmental NOEL for the rabbit was greater than 300 mg/kg/day which was the HDT and for the rat was 600 mg/kg/day based on increased litter incidences of thickened and wavy ribs. These two findings are not considered adverse effects of treatment but related delays in rib development which are generally believed to be reversible.

In a 2-generation reproduction study in rats, no reproductive toxicity was observed under the conditions of the study at 4,000 ppm which was the HDT.

Section 408 of the FFDCA provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database relative to pre- and post-natal effects for children is complete and an additional uncertainty factor is not warranted. Therefore at this time, the provisional RfD of 0.06 mg/kg/day is appropriate for assessing aggregate risk to infants and children.

F. Reference Dose

Using the conservative exposure assumptions described above, the percent of the RfD that will be utilized by aggregate exposure to residues of carfentrazone-ethyl for non-nursing infants (<1-year old) would be 0.28% and for children 1-6 years of age would be 1.37% (the most highly exposed group). Based on the completeness and reliability of the toxicity data and the conservative exposure assessment, there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the residues of carfentrazone-ethyl including all anticipated dietary exposure.

G. International Tolerances

There are no Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs) for carfentrazone-ethyl on any crops at this time. However, MRLs for small grains in Europe have been proposed which consist of carfentrazone-ethyl and carfentrazone-ethyl-chloropropionic acid.

[FR Doc. 98–15177 Filed 6–9–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–812; FRL–5793–4]

Notice of Filing of a Pesticide Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the amendment of pesticide petition (PP 5F4483), proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–812, must be received on or before July 10, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7502C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

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

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. CS51B6, Westfield Building North Tower, 2800 Crystal Drive, Arlington, VA 22202, (703) 308–8097; e-mail: bacchus.shanaz@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–812] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF–812] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

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

Dated: May 29, 1998.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summary of the Petition

Petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Troy Biosciences, Inc.

PP 5F4483

EPA has received an amended pesticide petition (PP 5F4483) from Troy Biosciences, Inc., 2620 North 37th Dr., Phoenix, Arizona 85009, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the microbial pesticide *Beauvaria bassiana* ATCC 74040 in or on all raw agricultural commodities. The initial notice of filing was published in the **Federal Register** of June 15, 1995 (60 FR 31465) (FRL–4955–4). This amended petition was submitted to comply with the provisions of the 1996 Food Quality Protection Act (FQPA).

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Troy Biosciences, Inc. has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Troy Biosciences, Inc. and EPA has not fully evaluated the merits of the petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary was not clear that it reflected the conclusion of the petitioner and not necessarily EPA.

A. Product Name and Proposed Use Practices

Beauvaria bassiana ATCC 74040 is the active ingredient in the technical product Naturalis. End-use products are to be used to treat all food commodities using standard ground and aerial application equipment.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* The active ingredient, *Beauveria bassiana* ATCC # 74040 (TBI#1), is a naturally occurring, soil-borne fungal entomopathogen that is found in soil environments worldwide. This particular strain was isolated for TBI from an infected boll weevil collected from the Rio Grande Valley in Texas. *Beauveria bassiana* organisms, and particularly the spores, do not display good viability outside soil environments. They are extremely sensitive to high ambient temperatures, low humidity and intense light. Following foliar application to RACs, it is unlikely spores will survive beyond 3 to 5 days. Data generated under experimental use permits and data obtained from use of *Beauveria bassiana* ATCC # 74040 (TBI#1) on ornamentals and turf demonstrate that there are no detectable organisms.

2. *Magnitude of residue at the time of harvest and method used to determine the residue— Plant metabolism. Beauveria bassiana* is a well-known, soil-inhabiting fungal organism. It is not pathogenic to plants, and will not invade plant tissue. Results of research conducted under the Experimental Use Permit (EUP) also document that the conidia of *Beauveria bassiana* are not viable 96 hours following foliar applications.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An acceptable analytical method exists to determine the viability of spores on the foliar surface. Troy Biosciences also has developed a method to enumerate viable spores per unit volume. Additionally, Troy Biosciences has developed methods and provided data required by EPA on screens for bacterial contaminants, including human pathogens, and on beauvericin and aflatoxins, potential metabolites of concern for the active ingredient. Further, the inert ingredients used in the formulated product are food grade or meet all other applicable FDA standards. Finally, all lots of the active ingredient and the formulated product are monitored as part of Troy Biosciences' rigorous quality control program.

C. Mammalian Toxicological Profile

Acute toxicity. The acute oral toxicity/pathogenicity of the technical grade active ingredient (TGAI) in the rat was determined following a single exposure to 10^8 colony forming units (CFU). The organism was not infectious to the rat and total clearance from the animal was projected to occur in 23 days. In a single 24 hour dermal exposure of two grams of the technical powder, erythema and edema were observed in 30% of the animals. These symptoms cleared in 1-7 days and indicated that the material was a moderate dermal irritant. These results were classified as Toxicity Category IV. A bovine corneal opacity and permeability assay was conducted to project the potential irritancy of the technical powder. The results indicated that the technical powder might be a slight irritant. The results of a primary eye irritation study confirmed that the technical powder was a slight irritant to the eye (Toxicity Category III). A study was conducted in the rat in which the animals were exposed by intraperitoneal injection to 10^7 CFU of the material (MRID 43294201). The animals were unaffected by the test material during the 29 day observation period. In a rat intratracheal toxicity study, rats were exposed to 10^7 CFU per animal. There were small tan nodules in the lungs of the test animals following exposure. These lesions reversed as the study progressed and the author opined that they would be totally reversible if more time were allowed. Total clearance of *Beauveria bassiana* occurred within 15 days. There were no effects on survival and the test material was not found in any tissue outside the lungs. The organism was not considered toxic or pathogenic in this test animal.

D. Aggregate Exposure

1. *Dietary exposure— Food.* Troy Biosciences has requested an exemption from the requirement for a tolerance, based on the well-documented instability of the conidia of *Beauveria bassiana* outside its natural environment, the soil. Residues should not be present because Troy Biosciences has requested a waiver of the requirement for a tolerance, based on the well-documented instability of the conidia of *Beauveria bassiana* outside its natural environment, the soil. Residues should not be present because spores are not viable 96 hours following application.

2. *Drinking water.* Use of Naturalis L in agriculture could result in the entry of the active ingredient into surface waters via drift from the agricultural application or run-off from treated

foliage during rainfall events. It is unlikely that the organism, because of its short half-life, would survive more than 1-2 days in this environment and would be unlikely to contaminate drinking water. Further, the organism is not a known human pathogen.

3. *Non-dietary exposure*. The only non-dietary exposures are expected to be to applicators and other pesticide handlers working with the product, including those workers involved at the manufacturing facility. Use of the product according to the directions for use on the label is not expected to result in any risk of adverse health effects. Exposure to the active ingredient in the manufacturing process is minimized by engineering controls. There may also be limited dermal exposure as a result of the turf use of the product (homes, schools, other public areas). Adults and children could contact treated foliage; however, these residues are not pathogenic in humans and the residues degrade rapidly over time after application.

E. Cumulative Exposure

Beauveria bassiana is a naturally occuring, soil-borne microorganism which is found throughout the World. Over 400 different strains have been identified, with concentrations varying from region to region depending on soil type and climatic conditions. Factors such as sunlight, temperature and humidity affect the persistence of this organism in the environment. Data from the past experimental use program indicate residues of this organism are not present on treated crops 96 hours after application.

Optimum growth for *Beauveria bassiana* occurs between 28-32°C, with no growth occurring at temperatures above 35°C. From a biological viewpoint the human body does not have the specific surface factors nor proper temperature to stimulate spore germination and infection hindering the organism's ability to cause systemic disease. This is corroborated by additional biological data from animal testing via oral, intraperitoneal, intratracheal, and dermal exposure. These studies indicate both a lack of systemic toxicity and non-pathogenicity. In addition, clearance of the test animals occurs within a relatively short time (<21 days).

Beauveria bassiana is effective by infecting target insects. In this respect, it shares a common mode of action with many other registered biological pesticides, including another strain of *Beauveria bassiana*. The lack of infectivity in humans and other non-insect species, combined with low toxicity indicates that there is likely to be no appreciable cumulative effect from application of several pesticides with this mode of action. Moreover, because both products have similar target pests (whiteflies, aphids and thrips) and the product labels state that 7 to 9 days at a minimum are needed to observe control, it is unlikely that both products would be used within the 96-hour effective period on the foliage. Consequently, there would be no accumulation of residues.

F. Safety Determination

1. *U.S. population*. *Beauveria bassiana* is a ubiquitous soil microorganism which is susceptible to sunlight, temperature and humidity. Data generated during the experimental use program (1992-1994) indicate that, once applied to raw agricultural commodities, *Beauveria bassiana* does not persist. Exposure to the general public from treated foods will be negligible. Biological data previously cited indicate the organism does not persist in the mammalian body, is not pathogenic and clearance from the body occurs within 21 days.

Troy Biosciences' *Beauveria bassiana* and its formulated product, Naturalis L, are carefully monitored under a rigorous quality control program. The active ingredient is screened for bacterial contaminants, including human pathogens, and for the presence of beauvericin and aflatoxins, metabolites of potential concern. Raw materials used for the formulated product also are subject to quality control screens and meet all applicable EPA and FDA quality standards. To further assure the safety of the formulated product, each batch is monitored and must meet rigorous quality control standards.

2. *Infants and children*. Based upon the lack of persistence, favorable biological data and quality control procedures no adverse effects would be expected for infants and children. Residues of *Beauveria bassiana* would not be present on commodities used for the production of foods or formulae for infants and children.

G. Effects on the Immune and Endocrine Systems

Beauveria bassiana ATCC # 74040 (TBI#1) is a naturally-occurring, living, fungal organism that is not pathogenic to humans. It is unlikely that exposure to this organism would result in an effect on the human endocrine or immune systems. There are no reports of any estrogenic or other adverse effects to human population as a result of the use of *Beauveria bassiana* in the field. Based on this information, combined with its low mammalian toxicity, it is concluded that there is a reasonable certainty that no adverse endocrine effects nor immune system effects will result from the use of *Beauveria bassiana* as an insecticide.

H. Existing Tolerances

No maximum residue level has been established for this organism by the Codex Alimentarius Commission.

[FR Doc. 98–15325 Filed 6–9–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6109–8]

Public Notice of Draft NPDES General Permits for Wastewater Lagoon Systems Located On Indian Reservations in Montana, North Dakota, South Dakota, Utah, and Wyoming

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of intent to issue NPDES general permits.

SUMMARY: Region VIII of EPA is hereby giving notice of its tentative determination to issue National Pollutant Discharge Elimination System (NPDES) general permits for wastewater lagoon systems located on Indian Reservations in the States of MT, ND, SD, UT, and WY and treating primarily domestic wastewater. The use of wastewater lagoon systems is the most common method of treating municipal wastewater and domestic wastewater from isolated housing developments, schools, etc., on the Indian Reservations in those states. Region VIII is proposing to use general permits instead of individual permits for permitting the discharges from such facilities in order to reduce the Region's administrative burden of issuing separate individual permits. The administrative burden for the regulated sources is expected to be about the same under the general permits as with individual permits, but it will be much quicker to obtain permit coverage with general permits than with individual permits. The discharge requirements would be essentially the same with an individual permit or under the general permit. A separate general permit is proposed to cover the aforementioned facilities within the exterior boundaries of a single reservation.

DATES: Public comments on this proposal must be received, in writing, on or before August 10, 1998.