

III. Conditional Approval Form

EPA issued a notice, published in the **Federal Register** of February 15, 2006 (71 FR 7954) (FRL-7761-5), which announced that Jabb of the Carolinas, P.O. Box 310, Pine Level, NC 27568, had submitted an application to conditionally register the pesticide products, *Beauveria bassiana* HF23 Technical, insecticide (EPA File Symbol 70787-1), containing the fungal active ingredient at 95 percent, an active ingredient not included in any previously registered product.

Listed below are the applications conditionally approved on December 27, 2006 for an end-use product and a technical.

1. EPA File Symbol 70787-1:

Beauveria bassiana HF23 Technical at 95 percent for use as a Manufacturing product for insecticides. Manufacturer: Jabb of the Carolinas, P.O. Box 310, Pine Level, NC 27568. The registrant must provide analyses of five production batches of this Technical Grade Active Ingredient which is to be used for manufacture of other End-use Products.

2. EPA File Symbol 70787-2: End-use Product (EP) balEnce containing 1.18 percent of *Beauveria bassiana* HF23 Technical for treatment of poultry houses to control house fly in chicken manure.

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: February 28, 2007.

Janet L. Andersen,

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

[FR Doc. E7-4275 Filed 3-13-07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2007-0212; FRL-8287-6]

Notice of Availability of the External Review Draft of an Interim Guidance for Microarray-Based Assays

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of document availability for public comment.

SUMMARY: The U.S. Environmental Protection Agency is announcing a 45 day public comment period for the External Review Draft of the "Interim Guidance for Microarray-Based Assays: Data Submission, Quality, Analysis, Management and Training Considerations." EPA is releasing this

draft document solely for the purpose of seeking public comment prior to external peer review. The contractor-lead external expert peer review will be conducted by letter and closed teleconference in the May 2007 timeframe. All comments received, submitted in accordance with this notice, will be shared with the external peer review panel for their consideration. Comments received after the close of the comment period may be considered by EPA when it finalizes the document. This document has not been formally disseminated by EPA. This draft interim guidance does not represent and should not be construed to represent any EPA policy, viewpoint, or determination. Members of the public may obtain the draft interim guidance from www.regulations.gov; or www.epa.gov/osa/spc/genomicguidance.htm; or from Dr. Kathryn Gallagher via the contact information below.

This draft Interim Guidance for Microarray-Based Assays outlines recommendations for: (1) What data to submit to the Agency for microarray studies, (2) performance approach considerations regarding quality assessment parameters, (3) data analysis approaches that should be considered; and (4) data management and storage issues for data submitted to or used by the Agency. The guidance applies to both human health and ecological DNA microarray data. The draft document was developed to provide information to the regulated community and other interested parties about submitting microarray data to the Agency and to provide guidance for EPA staff in evaluating such data and/or information.

DATES: All comments received by April 30, 2007 will be shared with the external peer review panel for their consideration. Comments received beyond that time may be considered by EPA when it finalizes the document.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-ORD-2007-0212, by one of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting comments.
- E-mail: ORD.Docket@epa.gov.
- Mail: ORD Docket, Environmental Protection Agency, Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- Hand Delivery: EPA Docket Center (EPA/DC), Room 3334, EPA West Building, 1301 Constitution Avenue, NW., Washington, DC 20460, Attention Docket ID No. EPA-HQ-ORD-2007-

0212. Deliveries are only accepted from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-ORD-2007-0212. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected by statute through www.regulations.gov or e-mail. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA, without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the ORD Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the ORD Docket is (202) 566-1752.

FOR FURTHER INFORMATION CONTACT: Dr. Kathryn Gallagher, Office of the Science Advisor, Mail Code 8105-R, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: (202) 564-1398; fax number: (202) 564-2070, E-mail: Gallagher.kathryn@epa.gov.

SUPPLEMENTARY INFORMATION: The mapping of diverse animal, plant, and microbial species genomes using molecular technologies has significantly affected research across all areas of the life sciences. The current understanding of biological systems is rapidly changing in ways previously unimagined and novel applications of this technology have already been commercialized. These advances in genomics are likely to have significant implications for risk assessment policies and regulatory decision making. In 2002, EPA issued its Interim Policy on Genomics (available at <http://www.epa.gov/osa/spc/genomics.htm>) that communicated the Agency's initial approach to using genomics information in risk assessment and decision making. The Interim Policy described genomics as the study of all the genes of a cell or tissue, at the DNA (genotype), mRNA (transcriptome), or protein (proteome) level. While noting that the understanding of genomics is far from established, the Agency stated that such data may be considered in the decision making process, but that these data alone were insufficient as a basis for decisions.

Following the release of the Interim Policy, EPA's Science Policy Council (SPC) created a cross-EPA Genomics Task Force and charged it with examining the broader implications genomics is likely to have on EPA programs and policies. The Genomics Task Force developed a Genomics White Paper entitled "Potential Implications of Genomics for Regulatory and Risk Assessment Applications at EPA" (available at <http://www.epa.gov/osa/genomics.htm>). That document identified four areas likely to be influenced by the generation of genomics information within EPA and the submission of such information to EPA: (1) Prioritization of contaminants and contaminated sites; (2) monitoring; (3) reporting provisions; and (4) risk assessment. The Task Force identified the establishment of a framework for analysis and acceptance criteria for genomics information for scientific and regulatory purposes as a critical need. The Task Force recommended that the Agency charge a workgroup to establish such a framework and in doing so consider the performance of assays

across genomic platforms (e.g., reproducibility, sensitivity, pathway analysis tools) and the criteria for accepting genomics data for use in a risk assessment (e.g., assay validity, biologically meaningful response).

In 2004, EPA's Genomics Technical Framework and Training Workgroups were formed with the responsibility to ensure that the technical framework and training activities build upon the Agency's Interim Policy on Genomics while continuing to engage other interested parties. Information developed by these workgroups is intended for use by the EPA program offices and regions to determine the applicability of specific genomics information to the evaluation of risks under various statutes.

To this end, EPA's Genomics Technical Workgroup considered all of the "omics" technologies and applications and decided that an interim guidance document on the use of data generated by DNA microarray technology would be most beneficial to the Agency and regulated community at this time. Consequently, this document describes data submission, quality, analysis, management and training considerations for microarray-based assays. It is important to note that microarray technology is rapidly changing, such that methodologies for generating such data and ensuring its quality will likely change; however the need to ensure consistency and quality in generating, analyzing and using the data will not. As the state of the science develops, EPA plans to revisit this guidance as necessary.

EPA will consider all peer review and public comments in finalizing its Interim Guidance for Microarray-Based Assays. To obtain additional information, visit: <http://www.epa.gov/osa/spc/genomicsguidance.htm>

Dated: March 9, 2007.

Elizabeth Lee Hofmann,
Acting Chief Scientist, Office of the Science Advisor.

[FR Doc. E7-4650 Filed 3-13-07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-8287-5]

Notice of Approval of Revisions to Delaware's National Pollutant Discharge Elimination System (NPDES) Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of approval.

SUMMARY: Notice is hereby given of approval of the submittal by the State of Delaware of its new and revised NPDES regulations to maintain consistency with the requirements of the Clean Water Act and its implementing regulations at 40 CFR 122, 123 and 124, as amended.

DATES: EPA's approval is effective on March 14, 2007.

FOR FURTHER INFORMATION CONTACT: Evelyn MacKnight, U.S. EPA, Region 3, 1650 Arch Street, Philadelphia, PA 19103, or telephone her at (215) 814-5717. Copies of materials considered by EPA in its decision are available for review by appointment at U.S. EPA, Region 3, 1650 Arch Street, Philadelphia, PA 19103. Appointments may be made by calling Ms. MacKnight.

SUPPLEMENTARY INFORMATION: Section 402 of the Federal Clean Water Act (CWA) created the NPDES program under which the Administrator of EPA may issue permits for the discharge of pollutants into waters of the United States when consistent with the CWA. Section 402(b) allows States to assume NPDES program responsibilities upon approval by EPA. On April 1, 1974, Delaware was authorized by EPA to administer the NPDES program; the State also received the authority to administer the General Permits program on October 23, 1992.

EPA has established a regulation at 40 CFR Part 123 that establishes the requirements for NPDES State Programs. Section 123.62 establishes procedures for the revision of authorized NPDES State Programs. Pursuant to § 123.62(a), a State may initiate a program revision and must keep EPA informed of any proposed modifications to its regulatory authority. On July 28, 2003, the State of Delaware submitted to EPA for review and approval revisions to the regulations implementing the State's NPDES program. The State made significant revisions to sections 1 through 8 and sections 10 through 14 of its Department of Natural Resources and Environmental Control's (DNREC) March 15, 1974 Regulations Governing the Control of Water Pollution, which EPA has determined constituted a substantial revision to Delaware's authorized NPDES program. EPA determined that the State's submittal was complete on November 19, 2003, with the submittal of a statement from the State's Attorney General's office which certified that the regulations were duly adopted pursuant to State law. EPA solicited public comments as to whether it should approve or disapprove the revisions on February 10, 2004 (69 FR 6289) pursuant to