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Diana Esher,

Acting Director, Chesapeake Bay Program Office.

[FR Doc. 01-27834 Filed 11-5-01; 8:45 am]

BILLING CODE 6560-50-M

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-211046A; FRL-6808-7]

TSCA Section 21 Petition; Response to Citizen's Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On August 2, 2001, EPA received a petition under section 21 of the Toxic Substances Control Act (TSCA) from the Cystic Fibrosis Foundation. The petition requests that EPA initiate a rulemaking under TSCA section 6(a)(1)(A) to prohibit the manufacture processing, distribution in commerce, use, and improper disposal of *Burkholderia Cepacia* Complex (Bcc), a group of naturally occurring microorganisms in order to "address the significant threat that these microorganisms pose to individuals with cystic fibrosis (CF) and other diseases that compromise the immune system." For the reasons set forth in this notice, EPA has denied the petition to initiate rulemaking. However, based on EPA's review of Bcc's commercial status, and in light of the seriousness of the potential hazard presented to CF patients, EPA intends to initiate a rulemaking to issue a Significant New Use Rule (SNUR) under TSCA section 5(a)(2).

FOR FURTHER INFORMATION CONTACT: *For general information contact:* Barbara Cunningham, Acting Director, Environmental Assistance Division, Office of Pollution Prevention and Toxics (7401), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: James Alwood, Chemical Control Division (7405), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564-8974; e-mail address: alwood.jim@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to manufacturers (including importers), processors, and users of products that contain living microorganisms subject to jurisdiction under TSCA, especially if that entity knows that its products contain or may contain Bcc. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPPTS-211046A. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, North East Mall Rm. B-607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Center is (202) 260-7099.

II. Background

A. What is a TSCA Section 21 Petition?

Section 21 of TSCA allows citizens to petition EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule under TSCA section 4, 5(a)(2), or 6, or an order under TSCA section 5(e) or 6(b)(2). A TSCA section 21 petition must set forth facts which the petitioner believes establish the need for the action requested. EPA is required to grant or deny the petition within 90 days of its receipt. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the **Federal Register**. Within 60 days of denial or no action, petitioners may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking. When reviewing a petition for a new rule, as in this case, the court must provide an opportunity for de novo review of the petition. Pursuant to TSCA section 21(b)(4)(B)(ii), "if the petitioner demonstrates to the satisfaction of the court by a preponderance of evidence that ... there is a reasonable basis to conclude that the issuance of such [TSCA section 6(a)(1)(A) rule] is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment" the court can order EPA to initiate the requested action.

B. What Action is Requested Under this TSCA Section 21 Petition?

On August 2, 2001, EPA received a petition under TSCA section 21 from the Cystic Fibrosis Foundation. The petition requests that EPA initiate rulemaking under TSCA section 6(a)(1)(A) to prohibit the manufacture, processing, distribution in commerce, use, and improper disposal of Bcc, a group of naturally occurring microorganisms in order to "address the significant threat that these microorganisms pose to individuals with CF and other diseases that compromise the immune system."

III. Disposition of Petition

The petitioners submitted extensive information on the potential hazard Bcc microorganisms may present to CF patients. EPA agrees that Bcc microorganisms, when encountered in sufficient numbers through an appropriate route of exposure by a member of a sensitive population, such as a CF patient, have the potential to cause a severe infection, resulting in significantly increased rates of mortality. The petition claims that Bcc is likely used in products and services

that involve drain cleaning, bioremediation, biomonitoring of hazardous wastes, biomass conversion, production of specialty chemicals, oil recovery, wastewater treatment, bio-mining, and desulfurization of oil and coal. The petition claims to document these potential uses. However, the petition contains no evidence that Bcc is currently used in existing commercial industrial products to which a sensitive individual might be exposed.

In order to gauge the scope of commercial use of Bcc, EPA conducted a survey of over 100 firms, associations, and researchers. In sum, EPA was able to discover no evidence that Bcc is contained in a commercial product currently available for use in the United States. The only potential TSCA uses of Bcc for which information is available are field demonstration studies of Bcc in the biodegradation of chlorinated solvents in groundwater. (See Commercial Uses of *Burkholderia Cepacia* Complex, USEPA, October 2001.) Specifically, one company has injected a strain of Bcc into aquifers in New Jersey to demonstrate its ability to degrade trichloroethylene and a consulting firm carried out a pilot study in Wichita, KS, to verify the effectiveness and overall feasibility of using *Burkholderia Cepacia* PR1₃₀₁ to degrade chlorinated aliphatic hydrocarbons. However, none of these strains is currently available in an existing commercial industrial product.

No companies indicated that Bcc was currently used for the degradation of grease (typically in drain cleaners) or for turf management (typically in thatch reduction), although researchers and firms cautioned that even the companies that produce such products may be unaware of the specific presence of Bcc.

One respondent indicated that lipases harvested from Bcc are used in the production of specialty chemicals. One company's web site, lists seven lipases derived from Bcc species available for sale under their brand names. However, when this company was contacted, it indicated that it purchases the lipases from an overseas firm, and does not work with Bcc microorganisms; no more information was available.

Many respondents indicated a knowledge of Bcc and its possible applications, but very few had any knowledge that it was actually being used. Some contacts indicated that Bcc's known potential for opportunistic pathogenicity had led them to discount it for use in their products. Thus, the information available to EPA indicates that there is no current commercial use of Bcc in the United States, although demonstration studies of its

effectiveness in degrading chlorinated solvents in groundwater have been reported.

At this time EPA is unable to identify any existing commercial use of products containing Bcc, other than demonstration studies. Based on this information, EPA finds that issuing a ban of Bcc under TSCA 6(a)(1)(A) is not the appropriate mechanism under TSCA to prevent an unreasonable risk of injury to health. However, based on EPA's review of Bcc's commercial status, and in light of the seriousness of the potential hazard presented to CF patients, EPA intends to initiate a rulemaking to issue a Significant New Use Rule (SNUR) under TSCA section 5(a)(2). As the only identified commercial uses of Bcc are demonstration studies, the SNUR when issued, would require manufacturers, importers, and processors of Bcc to notify EPA at least 90 days before any use of Bcc, other than such demonstration studies, occurs. The notice would provide EPA with an opportunity to evaluate the intended new use and associated activities and, if necessary, to prohibit or limit that activity before it occurs.

IV. Comments Received

EPA received no comments in response to the **Federal Register** notice published September 5, 2001 (66 FR 46459) (FRL-6800-5) announcing EPA's receipt of this TSCA section 21 petition.

List of Subjects

Environmental protection, *Burkholderia Cepacia* Complex (Bcc), Cystic fibrosis, Hazardous substances.

Dated: October 30, 2001.

Stephen L. Johnson,

Assistant Administrator, Office of Pesticides, Prevention and Toxic Substances.

[FR Doc. 01-27840 Filed 11-5-01; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[FRL-7099-3]

Notice of Availability of National Management Measures to Protect and Restore Wetlands and Riparian Areas for the Abatement of Nonpoint Source Pollution and Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability and request for comment.

SUMMARY: EPA has developed and is requesting comment on draft technical

guidance for protecting and restoring wetlands and riparian areas from sources of nonpoint pollution and using vegetated treatment systems (vegetative filter strips and constructed wetlands) for controlling nonpoint source pollution. This guidance is intended to provide technical assistance to state program managers and others on the best available, economically achievable means of protecting and restoring wetlands and riparian areas from nonpoint source pollution. Additionally, this guidance provides technical assistance for state program managers on the use of vegetated treatment systems to control nonpoint source pollution. The guidance provides background information about nonpoint source pollution, including where it comes from and how it enters the Nation's waters. It also presents many examples of how to protect and restore the many functions of wetlands and riparian areas from the impacts of nonpoint source pollution. The guidance concludes with a variety of illustrations for using vegetated treatment systems to control sources of nonpoint pollution.

Reviewers should note that the draft technical guidance is entirely consistent with the Guidance Specifying Management Measures for Sources of Nonpoint Pollution in Coastal Water (EPA 840-B-92-002), which EPA published in January 1993 under the authority of section 6217(g) of the Coastal Zone Act Reauthorization Amendments of 1990 (CZARA). The draft document does not supplant or replace the requirements of the 1993 document. It enhances the technical information contained in the 1993 coastal guidance to include inland as well as coastal context and to provide updated technical information based on current understanding and implementation of best management practices (BMP) controls. It does not set new or additional standards for either CZARA section 6217 or Clean Water Act section 319 programs.

EPA will consider comments on this draft guidance and will then issue final guidance.

DATES: Written comments should be addressed to the person listed directly below by February 4, 2002.

ADDRESSES: Comments should be sent to Chris Solloway, Assessment and Watershed Protection Division (4503-F), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Non-US Postal Service comments should be sent to Chris Solloway, Assessment and Watershed Protection Division, U.S.