Commandant Instruction M16475.1D, and determined that this proposed rule will not significantly affect the quality of the human environment. The ''Environmental Assessment'' and ''Finding of No Significant Impact'' is available in the docket where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 100 as follows:

PART 100—MARINE EVENTS

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46.

2. § 100.525 is added to read as follows:

§ 100.525 Western Branch, Elizabeth River, Portsmouth, Virginia.

(a) *Definitions*—(1) *Coast Guard Patrol Commander.* The Coast Guard Patrol Commander is a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the Commander, Coast Guard Group Hampton Roads.

(2) *Official Patrol.* The Official Patrol is any vessel assigned or approved by Commander, Coast Guard Group Hampton Roads with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

(3) *Regulated Area.* The regulated area includes all waters of the Western Branch, Elizabeth River bounded by a line connecting the following points:

Latitude	*Longitude*
36°50′18″ North	076°23′ 10″ West, to
36°50′18″ North	076°21′42″ West, to
36°50′12″ North	076°217prime;42″ West, to
36°50′12″ North	076°23′10″ West, to
36°50′18″ North	076°23′10″ West

All coordinates reference Datum NAD 1983.

(b) *Special Local Regulations.* (1) Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area.

(2) The operator of any vessel in this area shall:

(i) Stop the vessel immediately when directed to do so by any Official Patrol, including any commissioned, warrant, or petty officer on board a vessel displaying a Coast Guard ensign; and

(ii) Proceed as directed by any Official Patrol, including any commissioned, warrant, or petty officer on board a vessel displaying a Coast Guard ensign.

(c) *Effective Dates.* This section is effective annually from 6 a.m. to 6 p.m. local time on the fourth Friday and fourth Saturday in March, the fourth Friday and fourth Saturday in April, the second Friday and second Saturday in May, and the second Saturday and second Sunday in October.

Dated: December 11, 2001.

Thad W. Allen,

Vice Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 02–545 Filed 1–8–02; 8:45 am]

BILLING CODE 4910–15–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 725

[OPPTS–50645; FRL–6809–2]

RIN 2070–AD43

Burkholderia Cepacia Complex; Proposed Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for *Burkholderia cepacia* complex (Bcc), a group of naturally-occurring microorganisms. Bcc microorganisms, when encountered in sufficient numbers through an appropriate route of exposure by a member of a sensitive population, such as a cystic fibrosis (CF) patient, have the potential to cause a severe infection, resulting in significantly increased rates of mortality. This proposed rule would require persons who intend to manufacture, import, or process Bcc for a significant new use to notify EPA at least 90 days before commencing the manufacturing(including import) or processing of Bcc for a use designated by this SNUR as a significant new use. The required notice would provide EPA with the opportunity to evaluate the intended new use and associated activities and, if necessary, to prohibit or limit that activity before it occurs.

DATES: Comments, identified by docket control number OPPTS–50645, must be received on or before March 11, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS–50645 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Barbara Cunningham, Director, Office of Program Management and Evaluation, 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, Office of Pollution Prevention and Toxics (7405M), 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?

You may be potentially affected by this action if you manufacture (including import), process, or use products that contain living microorganisms subject to jurisdiction under TSCA, especially if you know that your products contain or may contain Bcc. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of Potentially Affected Entities
Chemical manufacturers	325	Persons manufacturing, importing, or processing products for commercial purposes containing Bcc for biofertilizers; biosensors; biotechnology reagents; commodity or specialty chemical production; energy applications; and other TSCA uses
Waste management and remediation	562	Waste treatment or pollutant degradation

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 the table in this unit could also be affected. To determine whether you or your business is affected by this action, you should carefully examine the list of substances excluded by TSCA section (3)(2)(B), and the applicability provisions at 40 CFR 725.105(c) for SNUR related obligations. 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/. A frequently updated electronic version of 40 CFR part 725 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr725_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPPTS–50645. 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.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS–50645 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Document Control Office (7407), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: OPPT Document Control Office (DCO) in EPA East Building Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930.

3. *Electronically*. You may submit your comments electronically by e-mail to: oppt.ncic@epa.gov, or mail your computer disk to the address identified above. Do not submit any information electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on standard disks in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPPTS–50645. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI Information That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the technical person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

We invite you to provide your views on the various options we propose, new approaches we have not considered, the potential impacts of the various options (including possible unintended consequences), and any data or information that you would like the Agency to consider during the development of the final action. You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the proposed rule or collection activity.

7. Make sure to submit your comments by the deadline in this document.

8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background

A. What Action is the Agency Taking?

This proposed rule would require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of Bcc, a group of naturally occurring microorganisms, for any use other than research and development in the degradation of chemicals via injection into subsurface groundwater.

B. What is the Agency's Authority for Taking this Action?

TSCA section 5(a)(2) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' See also, 40 CFR part 725, Subparts L–M. EPA must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2) of TSCA. Section 5(a)(2) of TSCA lists the following as potentially relevant factors for EPA to consider: (A) the projected volume of manufacturing and processing of a chemical substance, (B) the extent to which a use changes

the type or form of exposure to human beings or the environment to a chemical substance, (C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and (D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

Once EPA promulgates a rule designating ''significant new uses'' for a given chemical substance, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the substance for that use. The mechanism for reporting under this requirement is established under 40 CFR 725.105(c).

EPA has interpreted the TSCA section 3(2) definition of ''chemical substance'' as authorizing EPA to regulate microorganisms under TSCA. See the **Federal Register** of April 11, 1997 (62 FR 17910 and 17913) (FRL–5577–2). Microorganisms that are not intergeneric are implicitly included on the TSCA Inventory, which would include naturally-occurring microorganisms such as Bcc (40 CFR 725.8(b)). Thus, such microorganisms are only subject to TSCA section 5 notification requirements upon promulgation of a SNUR, pursuant to TSCA section 5(a)(2).

C. Which General Provisions Apply?

General provisions for SNURs appear under subpart L of 40 CFR part 725. These provisions describe persons subject to the proposed rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the proposed rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700. Persons subject to this SNUR must comply with the same notice requirements and EPA regulatory procedures as submitters of Microbial Commercial Activity Notices (MCANs) under section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the conditions necessary to qualify for the exemptions under TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), as codified in the regulations at 40 CFR part 725. In contrast to the provisions of 40 CFR part 721, under 40 CFR part 725, EPA has adopted a narrow interpretation of the TSCA section 5(h)(3) exemption for small quantities used in research. Under 40 CFR 725.3, EPA has defined small quantities solely for research and development as ''quantities of a microorganism manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that meet the requirements of § 725.234.'' Any other research and development activity of a microorganism subject to a SNUR must comply with the section 5(a)(1)(A) notification requirements unless that activity has been excluded from coverage under the SNUR. See, 40 CFR 725.3, Subparts E and F of 40 CFR part 725, and the **Federal Register** of April 11, 1997 (62 FR 17921–17926).

Once EPA receives an MCAN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities on which it has received the MCAN notice. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707. Persons who intend to import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, which are codified at 19 CFR 12.118 through 12.127 and 127.28. Such persons must certify that they are in compliance with SNUR requirements. The EPA policy addressing the import certification appears at 40 CFR part 707.

III. Summary of the Proposed Rule

On July 31, 2001, The Cystic Fibrosis Foundation submitted a petition under section 21 of TSCA which requested EPA to ''establish regulations prohibiting the manufacture, processing, distribution in commerce, use, and improper disposal of bacterial species within the *Burkholderia cepacia* complex.'' The Bcc was defined by the petitioner as nine species including *B. cepacia*, *B. multivorans*, *B. stabilis*, *B. vietnamiensis*, *B. ambifaria*, *B. pyrrocinia*, and three as yet unnamed species referred to as *B. cepacia* genomovars III, VI, and VIII. The petitioner stated that ''exposure of individuals with CF to Bcc frequently results in life-threatening infections'' and ''these actions are necessary to address the significant threat that these microorganisms pose to individuals with CF and other diseases that compromise the immune system.'' On November 6, 2001 (66 FR 56105) (FRL–6808–7) EPA published in the **Federal Register** a notice denying that petition. EPA also stated in the notice that it intended to issue a SNUR for Bcc.

It is well established that when encountered in sufficient numbers through an appropriate route of exposure by a member of a sensitive population, such as a CF patient, Bcc has the potential to cause a severe infection, resulting in significantly increased rates of mortality. There is also the possibility of increased exposure from several potential commercial uses especially for bioremediation where EPA has identified environmental research and development of Bcc that has already occurred. EPA believes that there is currently no general commercial use of Bcc. Therefore, EPA is proposing to designate any use of Bcc other than research and development in the degradation of chemicals via injection into subsurface groundwater as a significant new use.

This proposed rule, when finalized, would require persons, who intend to manufacture, import, or process Bcc for a significant new use to notify EPA, through submission of an MCAN or TSCA Experimental Release Application (TERA), at least 90 days before commencing the manufacture or importation of any of these microorganisms for any use other than research and development in the degradation of chemicals via injection into subsurface groundwater. The required notice would provide EPA with the opportunity to evaluate the intended use, and, if necessary, to prohibit or limit that use before it occurs.

IV. Hazard and Exposure of Bcc

A. Defining Bcc

B. cepacia complex is comprised of former *Pseudomonas* species (*P. cepacia* and *P. pyrrocinia*), existing *Burkholderia* species newly allied with Bcc (*B. vietnamiensis*), newly named *Burkholderia* species split off from *Burkholderia cepacia* (*B. multivorans*, *B. stabilis*, and *B. ambifaria*), and the three as yet unnamed genomovars (genomovars III, VI, and VIII). Of these nine components, only seven appear generally accepted as members of the Bcc in the current literature. Most current literature and reports refer to seven genomovars/species in the Bcc. One of these components, *B. pyrrocinia* had not been universally associated with Bcc until recently, but new information appears to move *B. pyrrocinia* from a unique species to part of a new genomovar of the Bcc. Additionally, recent information indicates that a publication is in

preparation which will establish a new genomovar (VIII). Acceptance of these two additional genomovars may be a function of the time needed for common usage by the research community (Ref. 1).

For purposes of this proposed rule EPA is defining Bcc as including all nine species. EPA is also proposing to use the provisional name, *Burkholderia cepacia* genomovars III, VI, and VIII, for the three unnamed genomovars, in the codified text and to replace these names with species designations via an administrative amendment when the species names are accepted by the scientific community. If in the future the composition of the Bcc is modified to include new species equivalents, or existing Bcc members are removed from that group, EPA will consider whether an additional rulemaking is warranted to revise the definition of Bcc in this proposed rule.

B. Bcc Hazard Assessment

Although *B. cepacia* is not a frank pathogen for humans, it is an important opportunistic pathogen for patients with CF and other diseases resulting in immune defects (Refs. 2 and 3). CF is an autosomal recessive disorder resulting in the dysfunction of the cystic fibrosis transmembrane regulator (CFTR), that actively transports chloride ions across the plasma membrane of mammalian cells (Ref. 3). This defect results in high salt concentrations in epithelial secretions and a production of a thick mucus within the airways of the CF lung. The airway mucus impairs normal mucocilliary clearance mechanisms, thus promoting infection with a variety of microbial pathogens.

CF patients suffer from a variety of health problems including infection, intestinal obstruction, pancreatic insufficiency, reproductive problems, and malnutrition (Ref. 4). These result in symptoms such as gastrointestinal pain, diarrhea, fatigue, weight loss, and wheezing. These problems are the result of mutations in the CFTR gene (Ref. 5). There have been more than 600 different mutations of this gene documented (Ref. 6). Different mutations have resulted in different phenotypes of the disease. Thus, CF is not an ''all or none'' disease, and the spectrum of CF disease can vary from very mild to very severe (Ref. 7).

Bacterial colonization and associated inflammation are the major causes of morbidity and mortality in patients with CF (Ref. 3). Surprisingly, the spectrum of bacteria that are routinely isolated from CF sputum is narrow (Ref. 3). Characteristically, infant CF patients are infected with *Staphylococcus aureus* and *Haemophilus influenzae*. In adolescent and adult CF patients, the prevalence of pulmonary infection with *Pseudomonas aeruginosa* (80–90% in most CF adults) exceeds that of all other pathogens. Other organisms isolated from CF patients include *Stenotrophomonas maltophilia*, *Alcaligenes xylosoxidans*, *Aspergillus* species, *Ralstonia pickettii*, and *Bordetella*.

Although *Pseudomonas aeruginosa* is the dominant pathogen for the CF patient, *B. cepacia* has been isolated with increasing frequency over the last 15 years (Ref. 3). According to the Cystic Fibrosis Foundation, 3.5% of all people with CF receiving care at CF Foundation-accredited Care Centers in 1988 were infected with *B. cepacia*. An adult CF infection rate of 6% has been reported (Ref. 6). The clinical outcome for CF patients can vary considerably. Some patients have only transient infection or are chronically infected without impact. Infection in other patients results in a more rapid deterioration of lung function. In about 20% of CF patients infected with *B. cepacia*, colonization results in the so-called ''cepacia syndrome,'' which is characterized by fever, pneumonia, and ultimately a fatal clinical decline.

B. cepacia causes pulmonary infections in CF patients. Respiratory tract infections, in general, are mainly caused by invasion of the mucus membranes lining the respiratory tract (Ref. 8). Thus, inhalation exposure would be the most relevant route of exposure for *B. cepacia* risk assessment. The level of exposure needed to cause infection is not known (Ref. 9).

B. cepacia is a pathogen in other immunocompromised patients as well. For example, patients with chronic granulomatous disease (CGD) are at a high risk of invasive *B. cepacia* infection (Ref. 10). This can result in fatal pneumonia in these patients. CGD is an inherited disorder of the immune system that leaves patients vulnerable to bacterial and fungal infections.

The virulence factors that allow *B. cepacia* to cause disease are only beginning to be defined (Ref. 11). Several virulence factors have been proposed for *B. cepacia* infecting CF patients. These include *B. cepacia* lipopolysaccharide catalase, a hemolysin, lipases, proteases, siderophores, and a so-called giant cable pilus. However, it is difficult to determine if the virulence traits identified actually contribute to pathogenicity in CF patients. This is partly due to animal models that do not reproduce the human CF phenotype with high fidelity.

Ascertaining the virulence factors important for *B. cepacia* infection would help in determining the relative pathogenicity of each distinct *B. cepacia* genomovar. Formerly a member of the genus *Pseudomonas*, *B. cepacia* is now known to be a complex of bacteria (*B. cepacia* complex) consisting of nine distinct species or genomovars (Ref. 3). Currently, it is not known if all genomovars of the *B. cepacia* complex are human pathogens. Based on analyses of isolates associated with human disease, genomovar III appears to be the most pathogenic for CF patients (Ref. 11). Some of the other genomovars are only rarely encountered in a clinical setting, and their ability to cause disease in CF patients is unknown. Thus far, however, no *B. cepacia* strains can currently be determined to be free from the potential to cause disease in CF patients (Ref. 12).

Ascertaining the virulence factors important for *B. cepacia* infection would also help in determining the source of all the infections that cause disease in CF patients. For example, epidemic transmission of *B. cepacia* is most commonly seen with genomovar III (Ref. 11). However, CF patients can also be infected by non-epidemic strains of *B. cepacia* (Refs. 2, 4, and 11). The source of all the infections that cause disease in CF patients is unknown. Potential infection sources could include: a) humans, b) hospital/treatment centers (nosocomial), c) food, or d) the environment (soil, water, plants). Thus far, only patient to patient transmission has been demonstrated to be an infection source (Ref. 13). Importantly, environmental isolates of *B. cepacia* cannot thus far be distinguished from human pathogenic strains (Ref. 11).

The therapy for *B. cepacia* remains a challenge (Ref. 11). *B. cepacia* is highly resistant to antibiotic drugs, and there is poor penetration of antibiotics into respiratory secretions. There have been reports of bacterial isolates for which no single anti-bacterial agent is effective *in vitro*. According to one author (Ref. 14), the most effective reagents appear to be carbapenems, extended-spectrum β-lactam drugs, and trimethoprim-sulfamethoxazole.

C. Potential Uses of Bcc

Studies suggest that Bcc microorganisms may be useful in a variety of TSCA applications, including bioremediation (degradation of toxic chemicals, as well as degradation of grease in drains), turf management, and specialty chemicals production. 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 U.S. The only potential TSCA uses of Bcc for which information is available are field studies of Bcc in the biodegradation of chlorinated solvents in groundwater. 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, Kansas to verify the effectiveness and overall feasibility of injecting *Burkholderia cepacia* $PR1_{301}$ into groundwater to degrade chlorinated aliphatic hydrocarbons. The conclusion to the pilot study report suggests that the use of *Burkholderia cepacia* $PR1_{301}$ was quite successful and should reduce clean-up time and costs at many other sites. However, none of these strains is currently available for general commercial use.

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 presence of Bcc.

One respondent indicated that lipases harvested from Bcc are used in the production of specialty chemicals. One company 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 imports 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 potential for opportunistic pathogenicity had led them to disregard it for use in their products. Thus, the information available to EPA indicates that the only existing TSCA use of Bcc in the U.S. are the demonstration studies of its effectiveness in degrading chlorinated solvents in groundwater. EPA considers these studies to fall under the description of research and development (Ref. 15).

D. Exposures

Bcc is a naturally occurring microorganism which is found in a wide range of habitats but especially in high populations in the soil. While Bcc is not known to be in general commercial use at this time, the potential uses identified could give rise to exposures in different ways. To produce microorganisms on a commercial scale, they first are cultured in large commercial fermentation facilities to obtain adequate amounts for a potential use. If used for specialty chemical manufacture the microorganisms are cultured first then killed after harvesting the chemical substance to be manufactured. EPA has identified potential dermal and inhalation exposures as well as environmental release from manufacture of microorganisms. These exposures could occur for any potential use of microorganisms. Sources of potential environmental release include exhaust gas from the fermentor and wastes from cleanup of equipment. Potential exposures result from laboratory propogation of cells, sampling, equipment cleaning/maintenance, and from cell recovery. Estimates of potential inhalation exposure were derived from area monitoring data in fermentation facilities. Estimates of potential dermal exposure were derived from laboratory experiments involving liquids which measured the retention on the hands for various types of exposures.

In addition to exposure from fermentation, there is also potential for dermal and inhalation exposures as well as environmental release from uses in bioremediation, turf builders, and drain cleaners. The primary source of potential release and dermal exposure is from the intended injection or application of the material. Application of turf builders would be spray applications resulting in increased inhalation exposures. Other release sources include air releases from off-gassing of aerated shipping containers and residue left in the shipping containers. Exposure to bioaerosols may occur from the aerated shipping containers. Although there is no evidence that Bcc specifically is used in the turf building or drain cleaning applications, there are commercially available products that contain microbials. (Ref. 16)

V. Objectives and Rationale of the Proposed Rule

In determining what would constitute a significant new use for the microorganisms that are the subject of this proposed SNUR, EPA considered relevant information on the toxicity of the microorganisms, likely exposures associated with potential uses, information provided by industry sources, and the relevant factors listed in TSCA section 5(a)(2) and Unit II.B. of this document. Based on these considerations, EPA has determined that all uses other than research and development in the degradation of chemicals via injection into subsurface groundwater, are significant new uses.

EPA's considerations under each of the relevant factors are discussed below:

1. *Projected volume of manufacturing and processing of a chemical substance.* Microorganisms may reproduce and increase beyond the number initially introduced and may spread beyond the site of manufacture or use. Thus, what begins as a small localized population of microorganisms may become a large widespread population which could contribute to increased exposure potential for Bcc beyond that which occurs naturally. These facts complicate the Agency's ability to project the potential volume and processing of Bcc.

2. *Extent to which a use changes the type, form, magnitude, and duration of exposure to human beings or the environment to a chemical substance.* EPA has not currently identified any general commercial use of Bcc. EPA has identified field studies of Bcc in the biodegradation of chlorinated solvents in groundwater. All other research and development activities, other than such field studies involving injection into groundwater, that do not meet the definition of small quantities for research and development would require reporting under 40 CFR 725.105(c) if included in a final SNUR. EPA is specifically soliciting comments on whether all other research and development activities should be captured under the SNUR or whether the SNUR should be limited to general commercial use of Bcc.

EPA expects only limited exposures from the identified field studies of Bcc as only technically qualified individuals are growing and injecting Bcc directly into groundwater. The potential uses identified in Unit IV.C. of this document, which include bioremediation (degradation of toxic chemicals, as well as degradation of grease in drains), turf management, and specialty chemicals production, could significantly increase dermal and inhalation exposures of Bcc to humans. In some cases these exposures could be higher than typically found in nature and more likely to be encountered by a member of a sensitive population. These exposures would significantly increase the type, form, magnitude, and duration of exposures to human beings from known uses of Bcc.

EPA wants to achieve the following objectives with regard to the significant new uses that are designated in this proposed rule. EPA wants to ensure that:

1. EPA will receive notice of any company's intent to manufacture, import, or process Bcc for a significant new use before that activity begins.

2. EPA will have an opportunity to review and evaluate data submitted in an MCAN before the notice submitter begins manufacturing, importing, or processing Bcc for a significant new use.

3. EPA would be able to regulate prospective manufacturers, importers, or processors of Bcc before a significant new use occurs, provided such regulation is warranted pursuant to TSCA section 5(e) or section (f).

VI. Alternatives

Before proposing this SNUR, EPA considered the following alternative regulatory actions for Bcc. In addition, EPA determined that Bcc is currently not subject to Federal notification requirements.

1. *Promulgate a TSCA section 8(a) reporting rule for Bcc.* Under a TSCA section 8(a) rule, EPA could require any person to report information to the Agency when they intend to manufacture or import Bcc. However, the use of TSCA section 8(a) rather than the SNUR authority, would not provide the opportunity for EPA to review human and environmental hazards and exposures associated with the new uses of these substances and, if necessary, to take immediate regulatory action under TSCA section 5(e) or section 5(f) to prohibit or limit the activity before it begins. In addition, EPA may not receive important information from small businesses, because those firms generally are exempt from TSCA section 8(a) reporting requirements. In view of EPA's concerns about Bcc and its interest in having the opportunity to review these substances and regulate them as appropriate, pending the development of exposure and/or hazard information should a significant new use be initiated, the Agency believes that a TSCA section 8(a) rule for Bcc would not meet all of EPA's regulatory objectives.

2. *Regulate Bcc under TSCA section 6.* EPA must regulate under TSCA section 6 if there is a reasonable basis to conclude that the manufacture, import, processing, distribution in commerce, use, or disposal of a chemical substance or mixture ''presents or will present'' an unreasonable risk of injury to human health or the environment. Based on EPA's findings that there is currently no general commercial use of Bcc, EPA concluded that risk management action under TSCA section 6 is not necessary at this time. This proposed SNUR would allow the Agency to address the potential risks associated with any intended significant new use of Bcc. If EPA is notified of any additional existing commercial uses, EPA may reconsider the decision and pursue additional regulatory action as appropriate.

VII. Test Data and Other Information

EPA recognizes that section 5 of TSCA does not require the development of any particular test data before submission of a MCAN or TERA. Persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 725.160).

However, in view of the potential health risks posed by the significant new uses of Bcc, EPA requests that potential MCAN or TERA submitters include data that would permit a reasoned evaluation of risks posed by Bcc when used for an intended significant new use. EPA also requests that potential MCAN or TERA submitters include data that demonstrate that the bacteria which would be the subject of the MCAN or TERA are in fact in the Bcc. EPA encourages persons to consult with the Agency before submitting an MCAN or TERA for Bcc. As part of this optional pre-notice consultation, EPA will discuss specific data it believes are necessary to evaluate a significant new use of Bcc. EPA urges MCAN or TERA submitters to provide detailed information on human and environmental exposures that would result or could reasonably be anticipated to result from the significant new uses of Bcc. In addition, EPA encourages persons to submit information on risks posed by Bcc compared to risks posed by possible substitutes. An MCAN or TERA submitted without sufficient data to reasonably evaluate risks posed by a significant new use of Bcc may increase the likelihood that EPA will take action under TSCA section 5(e).

VIII. Applicability of Proposed Rule to Uses Occurring Before Effective Date of the Final Rule

EPA believes that the intent of section 5(a)(1)(B) of TSCA is best served by designating a use as a significant new use as of the proposal date of the SNUR, rather than as of the effective date of the final rule. If uses begun after publication of the proposed SNUR were considered to be ongoing, rather than new, it would be difficult for EPA to establish notification requirements, because any person could defeat the SNUR by initiating the proposed significant new use before the proposed rule became final, and then argue that the use was ongoing.

Persons who begin commercial manufacture, import, or processing of Bcc, for the significant new use in this proposed SNUR, after the proposal has been published must stop that activity before the effective date of the final rule. To resume commercial manufacture, import or processing of Bcc, those persons will have to meet all applicable MCAN or TERA requirements and wait until the notice review period, including all extensions, expires before engaging in any commercial manufacture, import, or processing of Bcc for a significant new use. If, however, persons who begin commercial manufacture or import of Bcc for a significant new use between the proposal and the effective date of the final SNUR meet the conditions of advance compliance as codified at 40 CFR 725.912, those persons would be considered to have met the requirements of the final SNUR for those activities.

IX. Economic Considerations

EPA has evaluated the potential costs of establishing a SNUR for potential manufacturers, importers, and processors of Bcc. These potential costs are related to the submission of MCANs, TERAs, and the export notification requirements of TSCA section 12(b). EPA notes that, the costs of submission of MCANs or TERAs will not be incurred by any company unless that company decides to pursue a significant new use as defined in this proposed SNUR.

A. MCANs and TERAs

Because of uncertainties related to predicting the number of MCANs or TERAs that will be submitted as a result of this proposed SNUR, EPA is unable to calculate the total annual cost of compliance with the final rule. However, EPA estimates that the cost for preparation and submission of an MCAN ranges from approximately $7,582 to $42,736, which includes the $2,500 user fee required by the Agency. EPA notes that small businesses with annual sales of less than $40 million are subject to a reduced user fee of $100. The cost of a TERA is estimated to range from $6,905 to $73,562 (Ref. 17).

Based on past experience with SNURs and the low number of Significant New Use Notices (SNUNs) which are submitted on an annual basis, EPA believes that there would be few, if any, MCANs or TERAs submitted as a result of this SNUR. Furthermore, no company is required to submit an MCAN or TERA for Bcc unless the company decides to

begin manufacture or importation of Bcc. As a result, EPA expects that companies would be able to determine if the burden of submitting an MCAN or TERA would be likely to create significant adverse economic impacts for the company prior to incurring MCAN/TERA-related costs.

B. Export Notification

As noted in Unit II.C. of this document, persons who intend to export a microorganism identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)). These provisions require that a company notify EPA of the first shipment to a particular country of an affected microorganism. The estimated cost of the TSCA section 12(b)(1) export notification, which would be required for the first export to a particular country of a microorganism subject to this proposed rule, is estimated to be $158.35 for the first time that an exporter must comply with TSCA section 12(b)(1) export notification requirements, and $14.43 for each subsequent export notification submitted by that exporter (Ref. 17).

EPA is unable to estimate the total number of TSCA section 12(b) notifications that will be received as a result of this proposed SNUR, or the total number of companies that will file these notices. However, EPA expects that the total cost of complying with the export notification provisions of TSCA section 12(b) will be limited based on historical experience with TSCA section 12(b) notifications and the fact that no companies have currently been identified that currently market Bcc commercially. If companies were to manufacture the microorganisms covered by this proposed SNUR for export only, these companies would incur costs associated with export notification even if these companies decided to forgo any domestic significant new use. EPA is not aware of any companies in this situation, and expects that any potential impact would be limited to the small burden of export notification.

X. References

These references have been placed in the official record that was established under docket control number OPPTS–50645 for this document as indicated in Unit I.B.2. of this document.

1. Risk Assessment for TSCA Section 21 Petition on Bacteria in the *Burkholderia cepacia* complex, USEPA, November 2001.

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4. Buchwald, M.., Clin Invest Med 1996; 19 (5): 304.

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7. Bush, A., and Wallis, C., Ped. Pulmonology 30, 2000, 139.

8. Davies, S.S., Advanced Drug Delivery Reviews 51, 2001, 21.

9. FIFRA SAP Report # 99–04, Sept. 30, 1999.

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11. Parke, J. L., Gurian-Sherman, D., Ann. Rev. Phytopath. 39, 2001, 225.

12. FIFRA SAP report (1999). Risk Assessment of *Burkholderia cepacia* - based biopesticides and other bacteria related to opportunistic human infections.

13. Speert, D. P., Infect. Med., 18, 2001,49.

14. Parke, J.J., The Plant Health Instructor, 10, 2000, 1094.

15. Commercial Uses of *Burkholderia cepacia* complex, USEPA, October 2001.

16. Assessment of Potential Worker Exposure and Environmental Releases From Commercial Uses of *Burkholderia cepacia* complex, USEPA, October 2001.

17. Economic Analysis to Support the Proposed SNUR for *Burkholderia cepacia* complex, USEPA, October 15, 2001.

XI. Regulatory Assessment Requirements

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that proposed or final SNURs are not a ''significant regulatory action'' subject to review by OMB, because they do not meet the criteria in section 3(f) of the Executive Order.

Based on EPA's experience with proposing and finalizing SNURs, State, local, and tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or tribal government will be impacted by this rulemaking. As such, EPA has determined that this regulatory action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This proposed rule does not have tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This does not significantly or uniquely affect the communities of Indian tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), which took effect on January 6, 2001 do not apply to this proposed rule. Nor will this action have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999).

In issuing this proposed rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988, entitled *Civil Justice Reform* (61 FR 4729, February 7, 1996).

EPA has complied with Executive Order 12630, entitled *Governmental Actions and Interference with Constitutionally Protected Property Rights* (53 FR 8859, March 15, 1988), by examining the takings implications of this proposed rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the Executive Order.

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

In addition, since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. 104–113, section

12(d) (15 U.S.C. 272 note), does not apply to this action.

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of this proposed SNUR will not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows. A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a ''significant new use.'' By definition of the word ''new,'' and based on all information currently available to EPA, it appears that no small or large entities presently engage in such activity. Since a SNUR only requires that any person who intends to engage in such activity in the future must first notify EPA by submitting an MCAN, no economic impact will even occur until someone decides to engage in those activities. Although some small entities may decide to conduct such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of over 900 SNURs, the Agency has received fewer than 25 SNUNs. Of those SNUNs submitted, none appear to be from small entities in response to any SNUR. In addition, the estimated reporting cost for submission of an MCAN or TERA (see Unit IX.A. of this document) are minimal regardless of the size of the firm. Therefore, EPA believes that the potential economic impact of complying with this proposed SNUR are not expected to be significant or adversely impact a substantial number of small entities. This rationale has been provided to the Chief Counsel for Advocacy of the Small Business Administration.

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial display in the preamble of the final rule and in addition to its display on any related collection instrument, are listed in 40 CFR part 9.

The information collection requirements related to this action have already been approved by OMB pursuant to the PRA under OMB control number 2070–0012 (EPA ICR No. 1188.06). This action does not impose any burden requiring additional OMB approval. If an entity were to submit an MCAN or TERA to the Agency, the annual burden is estimated to average between 98.96 and 118.92 hours per response at an estimated reporting cost between $5,957 and $7,192 per MCAN. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review and submit the required MCAN or TERA. This burden estimate does not include the $2,500 user fee submission of an MCAN ($100 for businesses with less than $40 million in annual sales).

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, OP Regulatory Information Division (2137), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

This proposed 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) because it is not a significant regulatory action under Executive Order 12866.

List of Subjects in 40 CFR Part 725

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: December 21, 2001.

William H. Sanders, III

Office Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 725 be amended as follows:

PART 725—[AMENDED]

1. The authority citation for part 725 would continue to read as follows:

Authority: 15 U.S.C. 2604, 2607, 2613, and 2625.

2. By adding new § 725.1075 to subpart M to read as follows:

§ 725.1075 Burkholderia cepacia complex.

(a) *Microorganism and significant new uses subject to reporting.*(1) The microorganisms identified as the *Burkholderia cepacia* complex defined as containing the following nine species, *Burkholderia cepacia*, *Burkholderia multivorans*, *Burkholderia stabilis*, *Burkholderia vietnamiensis*, *Burkholderia ambifaria*, *Burkholderia pyrrocinia*, and *Burkholderia cepacia* genomovars III, VI, and VIII are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new use is any use other than research and development in the degradation of chemicals via injection into subsurface groundwater.

(b) [Reserved]

[FR Doc. 02–513 Filed 1–8–02; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[I.D. 123101B]

Pacific Fishery Management Council; Public Meetings and Hearings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability of reports; public meetings and hearings.

SUMMARY: The Pacific Fishery Management Council (Council) has begun its annual preseason management process for the 2002 ocean salmon fisheries. This document announces the availability of Council documents as well as the dates and locations of Council meetings and public hearings comprising the Council's complete schedule of events for determining the annual proposed and final modifications to ocean salmon fishery management measures. The agendas for the March and April Council meetings will be published in subsequent Federal Register documents prior to the actual meetings.

DATES: Written comments on the salmon management options must be received by April 2, 2002, at 4:30 p.m. Pacific Time.

ADDRESSES: Documents will be available from and written comments should be sent to Dr. Hans Radtke, Chairman, Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, Oregon 97220, facsimile 503–326–6831. For specific meeting and hearing locations, see **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Mr. Chuck Tracy, telephone 503–326–6352.

SUPPLEMENTARY INFORMATION: