Commodity	Parts per million
Vegetable, root and tuber, group 1, except sugar beet	0.40
* * * * *	
Watercress	3.5
Wax jambu	1.0
* * * * *	

[1] There are no U.S. registration as of June 13, 2003 for use on banana.

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[FR Doc. 03–14880 Filed 6–12–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 725

[OPPT–2002–0041; FRL–7200–3]

RIN 2070–AD43

Burkholderia Cepacia Complex; Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing 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 rule would require persons who intend to manufacture, import, or process any individual member of 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: This final rule is effective on August 12, 2003.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Barbara Cunningham, Director, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; 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 20460–0001; 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 members of Bcc. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers (NAICS 325), e.g., 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 (NAICS 562), e.g., 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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the list of substances excluded by TSCA section (3)(2)(B), and the applicability provisions in 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 Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPPT–2002–0041. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566–0280.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. The OPPTS harmonized test guideline referenced in this document is available at http:/www.epa.gov/opptsfrs/home/guidelin.htm. 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.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket identification number.

II. Background

A. What Action is the Agency Taking?

This SNUR will require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of any member 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 rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the 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) or TSCA Experimental Release Applications(TERAs) 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 or TERA, 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 or TERA. 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 Final Rule

A. Final Rule

On July 31, 2001, the Cystic Fibrosis Foundation (CFF) 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.'' 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. On January 9, 2002 (67 FR 1179) (FRL–6809–2) EPA proposed a SNUR for Bcc, where the significant new use for Bcc was designated as any use other than research and development in the degradation of chemicals via injection into subsurface groundwater. EPA received comments regarding the proposed SNUR only from CFF. EPA's response to those comments is contained in the next paragraph. No one identified any other ongoing commercial uses of Bcc other than those identified by EPA. In addition, no new data were submitted or identified that would change EPA's findings regarding the SNUR for Bcc. Therefore, EPA is issuing the SNUR as proposed. This final rule requires persons who intend to manufacture, import, or process Bcc for any use other than research and development in the degradation of chemicals via injection into subsurface groundwater notify EPA at least 90 days before commencing such activity.

B. Response to Comments

As noted earlier, the only comments submitted on the proposed SNUR were from CFF. CFF did not challenge or object to any of the provisions proposed by the Agency in the proposed SNUR, but instead suggested that the final rule should be expanded beyond what was proposed in two ways. First, CFF stated that EPA should designate as a significant new use all research and development activities that result in potential environmental release of Bcc. Second, CFF stated that EPA should require manufacturers of microoganisms that may contain Bcc to test their products for the presence of Bcc. Leaving aside the fact that these comments go beyond the scope of the proposed SNUR, the changes proposed by CFF are not appropriate for inclusion in a Significant New Use Rule under section 5 of TSCA.

As to CFF's first comment, CFF asks the Agency to require notification even for ''research and development in the degradation of chemicals via injection into subsurface groundwater.'' In the proposed SNUR, EPA identified ''research and development in the degradation of chemicals via injection into subsurface groundwater'' as an existing use. CFF did not present any information to suggest that this particular use is not an existing use, or that new research and development activities would be significantly different in kind or quantity than existing activities. Under the

circumstances, the Agency continues to believe that the particular research and development activities excluded from the proposed SNUR constitute an ongoing use of Bcc, and therefore do not constitute a ''significant new use'' for purposes of section 5(a)(2) of TSCA. Only significant new uses may be included in a Significant New Use Rule.

As to CFF's request that the SNUR require manufacturers of microorganisms to test their products to determine whether they contain Bcc. EPA concurs that manufacturers of microorganisms are responsible for knowing whether their products contain Bcc and EPA encourages manufacturers to test their products if they are uncertain whether the products contain Bcc. EPA's regulations exempt ''chemical'' impurities from SNUR reporting requirements (40 CFR 721.45(d)), but those regulations do not provide a similar exemption for ''microorganisms'' produced as impurities (see 40 CFR 725.912). When this SNUR becomes a final effective rule, all commercial uses of Bcc, except research and development in the degradation of chemicals via injection into subsurface groundwater, will require notification to EPA at least 90 days before commencing the manufacturing (including import) or processing of Bcc. Any manufacturer, importer, or processor of microorganisms that actually contain Bcc, even if the Bcc is present unintentionally as an impurity, will be required to submit a notification before commencing activities subject to this final SNUR. However, the Agency does not believe that a requirement to test products is appropriate for inclusion in a SNUR under section 5 of TSCA.

If a manufacturer, importer, or processor does decide to test its products, the Agency encourages conformity with OPPTS Product Analysis Test Guideline 885.1100 for product identity. Because identification of members of the Bcc may be difficult due to complexities of the taxonomy of this group, EPA believes it advisable to consult experts in this matter prior to testing. EPA encourages any manufacturer, importer, or processor considering such testing to consult the Agency for further guidance or questions.

IV. Objectives and Rationale of the Rule

In determining what would constitute a significant new use for the microorganisms that are the subject of this 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. 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.* At present there is little manufacturing and processing of Bcc, so almost all exposure to Bcc today is from its presence in the natural environment. Any new use of Bcc could result in a significant increase in manufacturing and processing of the compound, and of exposure to it. Microorganisms may reproduce and increase beyond the number initially introduced and may spread beyond the site of manufacture or processing. 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. However, Bcc is typically found in the environment in soils at a concentration of 10^2 to 10^4 colony forming units (cfu)/g. Manufacture of Bcc would result in production of batches of 10^{16} cfu of Bcc. Depending on the type and duration of use these batches could be even larger. (See Reference 16, 67 FR 1185, January 9, 2002 (FRL–6809–2))

2. *Extent to which a use changes the type or form of exposure to human beings or the environment to a chemical substance.* Currently, human beings are exposed to Bcc because of its presence in soil, where it is found at concentrations significantly lower than might be seen if it is cultivated for commercial use. In addition to the fact that these uses would likely involve much higher concentrations of Bcc than are naturally found in the environment, some of the potential uses identified for Bcc, including bioremediation (degradation of toxic chemicals), degradation of grease in drains, turf management, and specialty chemicals production, could also significantly increase direct dermal and inhalation exposures of Bcc to human beings and release of Bcc to the environment. (See Reference 16, 67 FR 1185, January 9, 2002). This would be especially true for individuals involved directly in or near the manufacturing or application of formulations containing Bcc. These are types and forms of exposures to which human beings and the environment are exposed on a limited basis during field studies of Bcc in the biodegradation of chlorinated solvents in groundwater.

3. *Extent to which a use changes the magnitude and duration of exposure to human beings or the environment to a chemical substance.* Currently, human beings are exposed to Bcc because of its presence in soil, where it is found at concentrations significantly lower than might be seen if it is cultivated for commercial use. In addition to the fact that these uses would likely involve much higher concentrations of Bcc than are naturally found in the environment, some of the potential uses identified for Bcc, including bioremediation (degradation of toxic chemicals), degradation of grease in drains, turf management, and specialty chemicals production, could also significantly increase direct dermal and inhalation exposures of Bcc to human beings and release of Bcc to the environment. Releases from typical manufacturing could result in releases to surface waters of 10^9 to 10^{13} cfu in water and 10^5 cfu in the air. Inhalation exposures of 450 cfu and dermal exposures of 10^{11} cfu to exposed workers could also result from typical manufacturing. (See Reference 16, 67 FR 1185, January 9, 2002) Exposures from various uses would be the same or higher depending on the method of application. For example, if spray-applied, the potential for inhalation exposure would be higher due to potential inhalation of mist. All Bcc produced for uses such as bioremediation (degradation of toxic chemicals), degradation of grease in drains, and turf management would eventually be released to the environment. New uses could also significantly increase the duration of exposure. Use in bioremediation for research and development could be limited to a few days/yr. In instances where manufacturing and application of formulations containing Bcc are repeated or continuous this increased level of exposure could occur on a daily basis throughout the year. In addition, repeated or continuous applications of formulations containing Bcc at the same location would increase the likelihood that a small localized population could become a larger and more widespread population. All of these factors would contribute to a change in the magnitude and duration of exposure to which human beings and the environment are not currently exposed.

4. *The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of 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. (See Reference 15, 67 FR 1185, January 9, 2002) 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. Other potential uses identified for Bcc which include bioremediation (degradation of toxic chemicals), degradation of grease in drains, turf management, and specialty chemicals production, could significantly increase dermal and inhalation exposures of Bcc to human beings as well as releases to the environment. Currently, there are no exposures to human beings and no releases to the environment from these uses. In most cases these exposures would be higher than typically found in nature and more likely to be encountered by a member of a sensitive population.

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

- EPA will receive notice of any company's intent to manufacture, import, or process Bcc for a significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in an MCAN or TERA before the notice submitter begins manufacturing, importing, or processing Bcc for a significant new use.
- 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 (5)(f).

V. Alternatives

Before issuing 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 SNUR will allow the Agency to address the potential risks associated with any intended significant new use of Bcc.

VI. 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 TSCA Experimental Release Application (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).

VII. Applicability of 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.

Any person who, after publication of the proposed SNUR, began commercial manufacture, import, or processing of Bcc, for the significant new use in this SNUR, must stop such 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 began commercial manufacture or import of Bcc for a significant new use between the proposal and the effective date of the final SNUR met 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.

VIII. 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 SNUR. The

Agency's economic analysis is available in the public docket for this rule.

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 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.

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, import, or processing of Bcc for any use other than research and development in the degradation of chemicals via injection into subsurface groundwater. 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., 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 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.

EPA is unable to estimate the total number of TSCA section 12(b) notifications that will be received as a result of this 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 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.

IX. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

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 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.

B. Paperwork Reduction Act

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 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 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act

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 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 or TERA, 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 1000 SNURs, the Agency receives fewer than 10 SNUNs per year. 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 VIII.A.) are minimal regardless of the size of the firm. Therefore, EPA believes that the potential economic impact of complying with this SNUR is 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.

D. Unfunded Mandates Reform Act

Based on EPA's experience with 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) (Public Law 104–4).

E. Executive Order 13132: Federalism

This action will not 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).

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This 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 rule.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

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.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This 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.

I. National Technology Transfer Advancement Act

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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

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).

K. Executive Order 12630: Governmental Actions and Interference with Constitutionally Protected Property Rights

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 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.

L. Executive Order 12988: Civil Justice Reform

In issuing this 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).

M. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 725

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

Dated: June 6, 2003.

Charles M. Auer,

Director, Office of Pollution Prevention and Toxics.

■ Therefore, 40 CFR part 725 is amended as follows:

PART 725—[AMENDED]

■ 1. The authority citation for part 725 continues 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*, *Burkholderia cepacia* genomovar VIII (*Burkholderia anthina*), and *Burkholderia cepacia* genomovars III and VI 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]

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