

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