

### *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 microorganisms 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