

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