

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

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. The mechanism for reporting under this requirement is established under 40 CFR 721.5.

### *C. Applicability of General Provisions*

General provisions for SNURs appear under subpart A of 40 CFR part 721. 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 PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUR notice, 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 SNUR 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 chemical 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 appear 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 in support of the import certification appears at 40 CFR part 707.

### **III. Substances Subject to this Rule**

EPA is establishing significant new use and recordkeeping requirements for the following chemical substances under 40 CFR part 721, subpart E. In this unit, EPA provides a brief description for each chemical substance, including its PMN number, chemical name (generic name if the specific name is claimed as CBI), CAS number (if assigned for non-confidential chemical identities), basis for the action taken by EPA in the TSCA section 5(e) consent order or as a non-section 5(e) SNUR for the chemical substance (including the statutory citation and specific finding), toxicity concern, and the CFR citation assigned in the regulatory text section of this rule. The specific uses which are designated as significant new uses are cited in the regulatory text section of this document by reference to 40 CFR part 721, subpart E where the significant new uses are described in detail. Certain new uses, including production limits and other uses designated in the rule are claimed as CBI. The procedure for obtaining confidential information is set out in Unit VII.

Where the underlying TSCA section 5(e) consent order prohibits the PMN submitter from exceeding a specified production limit without performing specific tests to determine the health or environmental effects of a chemical substance, the tests are described in this unit. As explained further in Unit VI., the SNUR for such chemical substances contains the same production limit, and exceeding the production limit is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a significant new use notice (SNUN) at least 90 days in advance. In addition, this unit describes tests that are recommended by EPA to provide sufficient information to evaluate the chemical substance, but for which no production limit has been established in the TSCA section 5(e) consent order. Descriptions of recommended tests are provided for informational purposes.

Data on potential exposures or releases of the chemical substances, testing other than that specified in the TSCA section 5(e) consent order for the chemical substances, or studies on analogous chemical substances, which may demonstrate that the significant new uses being reported do not present an unreasonable risk, may be included with significant new use notification. Persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs, as

stated in 40 CFR 721.1(c), including submission of test data on health and environmental effects as described in 40 CFR 720.50.

EPA is not publishing SNURs for PMNs 99-255, 99-314, 99-350/351/352/353, 99-534, 99-848, 00-277/278/280, 00-281-285, 00-286-292, 00-502/503/504, 00-574/575/576/577/608, 00-901, 00-1085, 00-1093, 01-558, 01-584, 01-629, 01-728, 01-757, 01-776, 02-16, 02-195, 02-415, 02-536, 02-609, and 02-700, which are subject to a final TSCA section 5(e) consent order. The TSCA section 5(e) consent orders for these chemical substances are derived from an exposure finding based solely on substantial production volume and significant or substantial human exposure and/or release to the environment of substantial quantities. For these cases there were limited or no toxicity data available for the PMN substances. In such cases, EPA regulates the new chemical substances under TSCA section 5(e) by requiring certain toxicity tests. For instance, chemical substances with potentially substantial releases to surface waters would be subject to toxicity testing of aquatic organisms and chemicals with potentially substantial human exposures would be subject to health effects testing for mutagenicity, acute effects, and subchronic effects. However, for these chemical substances, the short-term toxicity testing required by the TSCA section 5(e) consent order is usually completed within 1 to 2 years of notice of commencement (NOC). EPA's experience with exposure-based SNURs requiring short-term testing is that the SNUR is often revoked within 1 to 2 years when the test results are received. Rather than issue and revoke SNURs in such a short span of time, EPA will defer publication of exposure-based SNURs until either a NOC or data demonstrating risk are received unless the toxicity testing required is long-term. EPA is issuing this explanation and notification as required in 40 CFR 721.160(a)(2) as it has determined that SNURs are not needed at this time for these chemical substances which are subject to a final section 5(e) consent order under TSCA.

#### **PMN Number P-97-1108**

*Chemical name:* (generic)

Polycarboxylic acid ester.

*CAS number:* Not available.

*Basis for action:* The PMN substance will be used as a plasticizer. Based on structural analogy to esters, EPA is concerned that toxicity to aquatic organisms may occur at a concentration as low as 1 part per billion (ppb) of the PMN substance in surface waters. Since