

substance for a significant new use before that activity begins.

2. EPA will have an opportunity to review and evaluate data submitted in a SNUR notice before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for a significant new use.

3. When necessary, to prevent unreasonable risks, EPA will be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before a significant new use of that substance occurs.

4. All manufacturers, importers, and processors of the same chemical substance which is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the substance is listed on the TSCA Inventory. Manufacturers, importers, and processors are responsible for ensuring that a new chemical substance subject to a final SNUR is listed on the TSCA Inventory.

#### V. Direct Final Procedures

EPA is issuing these SNURs as a direct final rule, as described in 40 CFR 721.160(c)(3) and 721.170(d)(4). In accordance with 40 CFR 721.160(c)(3)(ii), this rule will be effective May 27, 2003, unless EPA receives a written notice by April 28, 2003 that someone wishes to make adverse or critical comments on EPA's action. If EPA receives such a notice, EPA will publish a document to withdraw the direct final SNUR for the specific substance to which the adverse or critical comments apply. EPA will then propose a SNUR for the specific substance providing a 30-day comment period.

This action establishes SNURs for a number of chemical substances. Any person who submits a notice of intent to submit adverse or critical comments must identify the substance and the new use to which it applies. EPA will not withdraw a SNUR for a substance not identified in a notice.

#### VI. Test Data and Other Information

EPA recognizes that section 5 of TSCA does not require developing any particular test data before submission of a SNUN. 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. In cases where a TSCA section 5(e) consent order requires or recommends certain testing, Unit III. lists those recommended tests.

However, EPA has established production limits in the TSCA section

5(e) consent orders for several of the substances regulated under this rule, in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the substances. These production limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these substances. Under recent consent orders, each PMN submitter is required to submit each study at least 14 weeks (earlier consent orders required submissions at least 12 weeks) before reaching the specified production limit. Listings of the tests specified in the TSCA section 5(e) consent orders are included in Unit III. The SNURs contain the same production volume limits as the consent orders. Exceeding these production limits is defined as a significant new use.

The recommended studies may not be the only means of addressing the potential risks of the substance. However, SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on:

1. Human exposure and environmental release that may result from the significant new use of the chemical substances.
2. Potential benefits of the substances.
3. Information on risks posed by the substances compared to risks posed by potential substitutes.

#### VII. Procedural Determinations

EPA is establishing through this rule some significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2. EPA is required to keep this information confidential to protect the CBI of the original PMN submitter. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI. This procedure appears in 40 CFR 721.1725(b)(1) and is similar to that in § 721.11 for situations where the chemical identity of the substance subject to a SNUR is CBI. This procedure is cross-referenced in each of these SNURs.

A manufacturer or importer may request EPA to determine whether a

proposed use would be a significant new use under this rule. Under the procedure incorporated from § 721.1725(b)(1), a manufacturer or importer must show that it has a *bona fide* intent to manufacture or import the substance and must identify the specific use for which it intends to manufacture or import the substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or import the substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in § 721.1725(b)(1) with that under § 721.11 into a single step.

If a manufacturer or importer is told that the production volume identified in the *bona fide* submission would not be a significant new use, i.e. it is below the level that would be a significant new use, that person can manufacture or import the substance as long as the aggregate amount does not exceed that identified in the *bona fide* submission to EPA. If the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use. EPA is considering whether to adopt a special procedure for use when CBI production volume is designated as a significant new use. Under such a procedure, a person showing a *bona fide* intent to manufacture or import the substance, under the procedure described in § 721.11, would automatically be informed of the production volume that would be a significant new use. Thus, the person would not have to make multiple *bona fide* submissions to EPA for the same substance to remain in compliance with the SNUR, as could be the case under the procedures in § 721.1725(b)(1).

#### VIII. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

To establish a significant "new" use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have recently undergone premanufacture review. TSCA section 5(e) consent orders have been issued for 3 substances and notice submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which EPA is designating as significant new uses. In cases where EPA has not received an NOC and the substance has not been