

**ENVIRONMENTAL PROTECTION
AGENCY**

40 CFR Parts 9 and 721

[OPPTS-50617A; FRL 5396-6]

RIN 2070-AA58

**Benzidine-Based Chemical
Substances; Significant New Uses of
Certain Chemical Substances**

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating a significant new use rule (SNUR) under section 5(a) of the Toxic Substances Control Act (TSCA) which requires persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of certain benzidine-based chemical substances for any significant new use as described in this rule. EPA believes that this action is necessary because benzidine-based chemical substances may be hazardous to human health and that the uses governed by this rule may result in significant exposure to workers handling those substances. The required notice provides EPA with the opportunity to evaluate any intended new uses and associated activities before the benzidine-based chemical substances can be introduced into the marketplace for a significant new use, and an opportunity to protect against potentially adverse exposure before it occurs.

EFFECTIVE DATE: This rule becomes effective on November 20, 1996. Persons who begin commercial manufacture, importation, or processing of listed benzidine-based chemical substances for any significant new use listed in this rule between August 30, 1995, and November 20, 1996 must comply with the requirements of this final SNUR. See Unit VII of this preamble for more information. In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time on October 21, 1996.

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SUPPLEMENTARY INFORMATION: This
SNUR requires persons to notify EPA at

least 90 days before commencing the manufacture, import, or processing of the benzidine-based chemical substances listed in this rule for any significant new use as described in § 721.1660(a)(2). The SNUR does not apply to uses of benzidine-based substances in existence when this SNUR was proposed which include uses as: A reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; and also for Colour Index (C.I.) Direct Red 28 (Congo Red, CAS No. 573-58-0) as an indicator dye. The required notification will provide EPA with information needed to evaluate the new use and associated activities, and an opportunity to protect against potentially adverse exposure to the chemical substance before it can occur. This rule was proposed on August 30, 1995 (60 FR 45119) (FRL-4762-4).

Regulated entities. Entities potentially regulated by this action are those which manufacture, import, or process the benzidine-based chemical substances listed in the rule for any use other than those listed in § 721.1660(a)(2). Regulated categories and entities include:

| Category | Examples of regulated entities |
|----------|---|
| Industry | Manufacturers, importers, and processors of cyclic organic crudes and intermediates, and organic dyes. |
| Industry | Entities which plan to use the listed dyes in conjunction with apparel and other finished products made from fabrics, leather, and similar materials. |
| Industry | Entities which plan to use the listed dyes in conjunction with paper and allied products. |
| Industry | Manufacturers, importers, and processors of printing ink. |

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your business is regulated by this action, carefully examine the applicability criteria set forth in § 721.1660 of this

rule. For questions regarding the applicability of this action to a particular entity, see "FOR FURTHER INFORMATION CONTACT" at the beginning of this document.

I. Authority

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." The Agency must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Section 5(a)(2) factors generally relate to the extent that a use changes the volume of a chemical substance's production or the type, form, magnitude, or duration of exposure to it. Once EPA determines by rule that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before manufacturing, importing, or processing the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)).

Persons subject to this SNUR must comply with the same notice requirements and EPA regulatory procedures as submitters of premanufacture notices (PMNs) under section 5(a)(1)(A) of TSCA (15 U.S.C. 2604(a)(1)(A)). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and (d)(1), the exemptions authorized by TSCA section 5 (b)(1), (2), (3), and (5), and the regulations at 40 CFR part 720. If during its review, EPA identifies concerns, regulatory action may be taken under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received a SNUN (15 U.S.C. 2604 (e), (f), 2605, 2606). If EPA does not take action, section 5(g) of TSCA requires EPA to explain in the *Federal Register* its reasons for not taking action (15 U.S.C. 2604(g)).

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) (15 U.S.C. 2611(b)). The regulations that interpret 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 (15 U.S.C. 2612) import certification requirements, and to the regulations codified at 19 CFR 12.118 through 12.127 and 12.128. Such persons must certify that they are in compliance with TSCA requirements. The EPA rule in support of import certification appears at 40 CFR part 707.

II. Applicability of General Provisions

General regulatory provisions applicable to SNURs are codified at 40 CFR part 721, subpart A. In the *Federal Register* of August 17, 1988 (53 FR 31252), EPA promulgated a "User Fee Rule" (40 CFR part 700) under the authority of TSCA section 26(b) (15 U.S.C. 2625(b)). Provisions requiring persons submitting SNUNs to submit certain fees to EPA are discussed in detail in the *Federal Register* document. Interested persons should refer to 40 CFR parts 700 and 721 and the August 17, 1988 *Federal Register* document for further information.

III. Introduction

A. Summary

The chemical substances that are the subjects of this SNUR are certain benzidine-based chemical substance as listed in table 1 of § 721.1660.

EPA has determined that there is no ongoing manufacture, import, or processing, of the listed benzidine-based chemical substances, except for the ongoing uses of such substances in small amounts for a few, limited purposes (identified in § 721.1660(a)(2) of this rule). Because the listed benzidine-based chemical substances are currently only used for these limited purposes, EPA is concerned that any new use beyond the current ongoing limited uses would increase production volume resulting in increased potential for exposure to workers which would be significant because of their potential carcinogenicity. Therefore, under TSCA section 5(a)(2), EPA is designating any use of the listed benzidine-based chemical substances as a significant new use, other than the following ongoing uses of such chemical substances: As a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; and also for C. I. Direct Red 28 as an indicator dye.

Except for the ongoing uses listed above, this rule requires persons who intend to manufacture, import, or process the benzidine-based chemical substances listed in table 1 of § 721.1660 of this rule to notify EPA through the submission of a SNUN, at least 90 days before commencing the manufacture, importation, or processing of any of these substances for the significant new uses designated in this SNUR. The required notice provides EPA with the opportunity to evaluate the intended use, and, if necessary, to prohibit or limit that use before it occurs.

B. Final Rule—Changes From the Proposed Rule

The Agency reviewed all comments received on the proposed rule. After consideration of issues raised by the commenters, the Agency has taken the following actions:

1. Some inconsistencies in naming and inaccuracies in CAS numbers in table 1 of 40 CFR 721.1660 have been corrected.
2. Chemical substances not listed on the TSCA Inventory are no longer covered by this rule.
3. The use of C.I. Direct Red 28 (CAS No. 573-58-0) as an indicator dye and the use of benzidine-based chemical substances as an analytical standard were added to the list of uses not designated as significant new uses under this SNUR.

IV. Background Information on Benzidine-Based Chemical Substances

Based upon toxicity information on benzidine and benzidine-based dyes, the Agency is concerned that all the benzidine-based chemical substances listed in this rule may be carcinogens.

The molecule benzidine can only be isolated for commerce or use in the form of a salt. In recognition of this fact, whenever the term "benzidine" is used in this section of the preamble, it refers to the molecule benzidine, CAS No. 92-87-5, as well as to all benzidine salts.

Benzidine is an aromatic amine that has been used as a feedstock for production of man-made dyes since the late 1800's. Dyestuffs were among the first products of the developing chemical industry, and aromatic amines were the first synthetic chemicals found to cause cancer in humans. This was first reported in the last century, when some workers manufacturing dyes developed bladder cancer. Benzidine was subsequently found to be a potent carcinogen in humans and animals.

Several epidemiologic studies of occupationally exposed workers have demonstrated that benzidine exposure is associated with a high risk of developing bladder cancer (Ref. 1). Benzidine is classified by EPA as Group A, a human carcinogen (IRIS, 1996). Benzidine is also classified by the International Agency for Research on Cancer (IARC) as a Group 1 carcinogen, which are chemicals known to cause cancer in humans and animals (Ref. 2).

Originally, only benzidine was considered to be carcinogenic. However, studies found that dyes derived from benzidine release free benzidine via metabolic routes (Ref. 3). The dyes were predicted to be carcinogens based on these findings. Animal bioassays

performed by the National Cancer Institute (NCI) in 1978 confirmed that administration of three different benzidine-based dyes each led to cancer. (Ref. 4)

EPA's hazard analysis (Ref. 5) is based on studies of tested representative benzidine-based dyes, as well as benzidine, from which they are synthesized, and to which they break down or metabolize. The overwhelming health concern for benzidine and benzidine-based dyes is for bladder cancer generally believed to be caused through any route of exposure. As of June 1974, the Occupational Safety and Health Administration (OSHA) requires that manufacture of benzidine be contained within a closed system (29 CFR 1910.1010 Benzidine). In addition, the American Conference of Governmental Industrial Hygienists (ACGIH) has classified benzidine as a "confirmed human carcinogen" with no Threshold Limit Value (TLV) assigned, and has recommended that "all exposure to benzidine should be kept to an absolute minimum" (Ref. 6).

Twelve benzidine-based dyes have been demonstrated to metabolize to benzidine in one or more of four species (Ref. 7). National Toxicology Program (NTP) cancer bioassays by the oral route in rodents using Direct Black 38 (CAS No. 1937-37-7), Direct Blue 6 (CAS No. 2602-46-2), and Direct Brown 95 (CAS No. 16071-86-6), showed statistically significantly elevated tumor incidence of the liver following oral administration. The time to tumor formation was 5 to 13 weeks. No tumors were found in the controls (Ref. 4). In response to these and other data, the National Institute for Occupational Safety and Health (NIOSH) and NCI have jointly recommended that these three dyes be handled in the workplace as if they were human carcinogens, and have suggested guidelines for minimizing employee exposure (Ref. 8).

Bioavailability studies in Rhesus monkeys, rats, and dogs revealed levels of benzidine in the urine, after the administration of the above-mentioned dyes, equivalent to the levels found after administration of a comparable volume of straight benzidine (Refs. 3 and 7). For this reason, IARC has classified these benzidine-based dyes as Group 2A chemicals, which are carcinogenic to animals and probably carcinogenic to humans (Refs. 1, 8, and 9). Given the consistent results from testing these dyes, as well as known mechanistic similarities among benzidine-based dyes, the entire class of benzidine-based dyes are expected to have a similar degree of toxicity. In addition, NIOSH has recommended that all benzidine-

based dyes be recognized as potential human carcinogens, based upon the evaluation of information on the carcinogenicity and metabolism of these dyes (Ref. 10).

There are exposure issues for both the parent amines and the finished dyes. Most available exposure data are for groups of dyes, rather than for individual dyes. Inhalation, skin absorption, and ingestion are possible routes of exposure in a variety of settings where benzidine-based dyes are either manufactured or used. Benzidine and monoacetyl benzidine, a metabolite, have been found in the urine of workers making or using benzidine-based dyes in the paper, textile, leather, and dye manufacturing industries (Ref. 10). The amount of benzidine found in the urine was more than could be accounted for by only benzidine impurities in the dyes.

Exposure estimates for dyes were developed based on the result of a monitoring study conducted collaboratively by EPA and industry (Ref. 11). Using this information, and based on models from EPA and industry, exposure estimates have been calculated for those workers who weigh powder dyes in manufacturing establishments. From these estimates, EPA predicts the highest exposure would occur for workers who would manufacture benzidine-based dyes or who would weigh such dyes, and is also concerned about potential exposures to workers who would operate dyeing machinery (Ref. 11).

V. Rationale and Objectives for the Rule

To determine what would constitute a significant new use of benzidine-based chemical substances, EPA considered relevant information regarding the toxicity of the substances, likely exposure and releases associated with potential uses, and the four factors listed in TSCA section 5(a)(2). The Agency has concerns for bladder cancer in workers which is generally believed to be caused through any route of exposure to benzidine-based chemical substances (Ref. 5). EPA classified benzidine as Group A, a human carcinogen (IRIS, 1996). Benzidine has an IARC classification as a Group 1 carcinogen, which are chemicals known to cause cancer in humans and animals. IARC has also classified several benzidine-based dyes as Group 2A chemicals, which are carcinogenic to animals and probably carcinogenic to humans. The benzidine-based dyes that have not been tested are also suspected carcinogens (e.g., Ref. 10).

EPA has determined that there is no ongoing manufacture, import, or

processing, of the listed benzidine-based chemical substances, except for use in small amounts as a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; and also for C.I. Direct Red 28 as an indicator dye. EPA believes that the use of the subject benzidine-based substances for the uses designated at § 721.1660 would result in increases in production as well as the type, form, magnitude, or duration of exposure to these known or suspected carcinogens. Therefore, EPA is designating the uses at § 721.1660 as significant new uses (Ref. 12).

Based on these considerations, EPA wishes to achieve the following objectives with regard to the significant new uses that are designated in this rule. Specifically, EPA wants to ensure that it:

1. Receives notice of any company's intent to manufacture, import, or process the benzidine-based chemical substances for the significant new uses designated in this rule before that activity begins.
2. Has an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing the listed benzidine-based chemical substances for the significant new uses designated in this rule.
3. Can regulate prospective manufacturers, importers, or processors of the listed benzidine-based chemical substances before any significant new use occurs, provided that the degree of potential health risk is sufficient to warrant such regulation.

For the preceding reasons, EPA is designating any use of the benzidine-based chemical substances listed in § 721.1660, except for those uses listed in § 721.1660(a)(2), as significant new uses.

VI. Alternatives

Before promulgating this SNUR, EPA considered alternative regulatory actions for the listed benzidine-based chemical substances. It determined that the benzidine-based chemical substances listed in this rule are currently not subject to Federal notification requirements nor are they currently subject to any other Federal rules that regulate risks to human health or the environment to a sufficient extent to justify using those regulations as an alternative to this SNUR. EPA also considered the following alternative actions.

1. Promulgate a TSCA section 8(a) reporting rule for these chemical

substances. Under such a rule, EPA could require any person to report information to the Agency when they intend to manufacture, import, or process the listed benzidine-based chemical substances, for a significant new use as listed in this rule (15 U.S.C. 2607). However, in the case of these particular chemical substances, the use of section 8(a) rather than SNUR authority would not provide the opportunity for EPA to review human and environmental risks associated with new uses of a chemical substance and, if necessary, take immediate follow-up regulatory action under TSCA section 5(e) or section 5(f) to prohibit or limit the activity before it begins. In view of the level of health concerns for the listed benzidine-based chemical substances, the Agency believes that a section 8(a) rule for those chemical substances would not meet EPA's regulatory objectives.

2. Regulate the listed benzidine-based chemical substances under section 6 of TSCA. EPA may regulate under section 6 if there is a reasonable basis to conclude that the manufacture, importation, processing, distribution in commerce, use, or disposal of a chemical substance or mixture "presents or will present" an unreasonable risk of injury to human health or the environment. A finding of unreasonable risk indicates a determination that the reduction of health or environmental risk resulting from a potential regulation outweighs the regulatory burden to society.

In the case of this rule, EPA decided that a SNUR was more appropriate than a section 6 rule because the Agency has not determined that the ongoing uses raise sufficient concerns to justify a section 6 regulation. At the same time, EPA's concerns are for potential future uses, and the notification which is required by this SNUR will be sufficient to allow the Agency to make the decisions necessary to protect against such uses.

VII. Applicability to Uses Occurring Before Effective Date of this Final Rule

EPA believes that the intent of section 5(a)(1)(B) is best served by designating a use as a significant new use as of the proposal date of this SNUR rather than as of the effective date of this final rule. If uses begun during the proposal period of a SNUR were considered ongoing, rather than new, as of the effective date, it would be difficult for EPA to establish SNUR notice requirements, because any person could defeat the SNUR by initiating the proposed significant new use before the rule became final, arguing that the use is no longer new.

Persons who began commercial manufacture, importation, or processing of the listed benzidine-based chemical substances for any significant new use listed in this rule between issuance of the proposed rule and the effective date of this SNUR must cease that activity before the effective date of this rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. If, however, persons who began commercial manufacture, importation, or processing of the chemical substances between the issuance of the proposed rule and the effective date of this SNUR meet the conditions of advance compliance as codified at § 721.45(h), those persons will be considered to have met the requirements of this final SNUR for those activities.

VIII. Response to Comments Received on Proposed Rule

The Agency received comments on the proposed rule from two businesses and two trade associations. The Agency reviewed and considered all significant comments received. These comments and EPA's responses follow:

Comment. Some of the dyes listed in the proposed rule are assigned incorrect CAS numbers and nomenclature.

Response. EPA reviewed the list of dyes in the proposed rule. Inconsistencies in naming substances were identified and corrected in table 1 in § 721.1660 of this final rule. Inaccurate CAS numbers were also identified and corrected in table 1 of this final rule for C.I. Direct Blue 2 (CAS No. 2429-73-4), C.I. Direct Brown 6 (CAS No. 2893-80-3), and C.I. Direct Brown 74 (CAS No. 8014-91-3). Additionally, chemical names were added to table 1 of this rule to further identify substances subject to SNUR reporting. These corrections were minor in nature and did not change the types of benzidine-based dyes subject to this final SNUR.

Comment. A majority of the chemical substances listed in the proposed rule are not found on the TSCA Inventory. A SNUR for substances that are not on the TSCA Inventory is unnecessary because the "PMN would serve the same purpose".

Response. EPA conducted a review of the TSCA Inventory. This review revealed that 24 out of 149 benzidine-based chemical substances in the proposed SNUR were on the TSCA Inventory and the remaining substances were not. EPA has removed the substances that are not on the TSCA Inventory from the final list of

substances requiring notification of a significant new use. Those substances continue to be subject to the reporting requirements under TSCA section 5(a)(1) (15 U.S.C. 2604(a)(1)). Section 5(a)(1) requires a person who manufactures a chemical substance that is not on the Inventory, and not otherwise excluded or exempted from the requirements of section 5, to file a premanufacture notification (PMN) with EPA. When EPA proposed the SNUR it based the proposal on certain objectives that it announced in the preamble to the proposed rule (60 FR 45121, August 30, 1995). EPA has concluded that these same objectives can be met through the submission of a PMN for benzidine-based chemical substances that are not on the Inventory and requiring a SNUR in addition is not necessary.

Comment. C.I. Direct Red 28, a benzidine derivative, is used as a mineral acid indicator but was not identified in the proposed rule as an ongoing use. Also, certain uses of benzidine as an analytical laboratory standard, as with EPA Reference Method 8270, are also ongoing. These uses are similar to other ongoing uses identified in the proposed rule.

Response. EPA added the use of C.I. Direct Red 28 (CAS No. 573-58-0) as an indicator dye and the use of benzidine and benzidine-based chemical substances as an analytical standard to the list of ongoing uses based on information from commenters and EPA's Office of Solid Waste and Emergency Response (OSWER) (Benzidine SNUR Memo, 50617A). No additional ongoing uses of benzidine-based chemical substances were identified. Ongoing uses, as identified in § 721.1660(a)(2) of this final rule, are not subject to SNUR reporting. EPA decided to add these two uses because they are similar to other ongoing uses that were originally proposed. Like some of the proposed ongoing uses, the additional uses rely on benzidine-based substances to test for the presence of chemical substances. EPA received no objections to the inclusion of the original uses in this SNUR and has concluded that additional notice is not necessary to add these similar uses.

Comment. There are other benzidine-based dyes on the TSCA Inventory which were not listed in the proposed rule.

Response. EPA's intent is to require notification prior to the manufacture, import, or processing of all benzidine-based chemical substances on the TSCA Inventory for all non-ongoing uses. EPA conducted a thorough search of the TSCA Inventory which revealed that there are additional benzidine-based

chemical substances on the TSCA Inventory that were not included in the proposed SNUR. EPA will propose a SNUR for these additional benzidine-based chemical substances in the near future.

Comment. EPA should exempt all laboratory uses of very small amounts of benzidine-based chemical substances from the SNUR where prudent laboratory practices are employed. Another comment suggested that the SNUR should not apply to laboratory uses of benzidine-based chemical substances.

Response. EPA agrees with the first comment and under existing EPA regulations, a person who manufactures, imports, or processes a listed substance for a significant new use is not subject to SNUR notification requirements if the person is utilizing small quantities for research and development and meets the other safeguards as specified in 40 CFR 721.47. In addition, this SNUR will not cover identified laboratory uses which are ongoing (listed in § 721.1660(a)(2) of this rule). However, EPA does not agree with the second comment that all laboratory uses in general should be excluded. The purpose of the SNUR is to insure that EPA has an opportunity to review human and environmental risks associated with significant new uses of a chemical substance and, if necessary, take further action to protect against those risks. If EPA exempts all laboratory uses without any of the safeguards specified in 40 CFR 721.47, as suggested by the commenter, then persons may engage in those uses without further EPA review of these additional human and environmental exposures. The comment did not provide adequate information to allow EPA to determine the extent or possible consequences of these exposures. Given the potentially hazardous nature of benzidine-based chemical substances, EPA believes it is not appropriate to exempt all laboratory uses from the SNUR. Anyone who wishes to engage in such a new use in the future, however, may submit a significant new use notice and initiate the process for determining whether those uses pose an unreasonable risk.

Comment. The use of benzidine as a laboratory standard or an indicator dye does not constitute manufacturing, importing, or processing for a commercial purpose, i.e., for distribution in commerce. The analytical procedures, of which the benzidine is part, either consume the benzidine or produce by-products which are properly disposed. No benzidine is manufactured or processed

in the course of these uses, nor is it for the purpose of distribution in commerce.

Response. EPA generally agrees with the commenter that a SNUR only regulates manufacturing and processing activities that are undertaken for commercial purposes; however, a laboratory could be engaging in regulated activities when it uses a listed benzidine-based chemical substance. TSCA provides that SNURs apply only to persons who "manufacture or process" subject substances (15 U.S.C. 2604(a)(1)(B)). TSCA also defines the term "manufacture" to include importation of as well as production (15 U.S.C. 2602(7)). TSCA further provides that SNURs only regulate manufacturing, importation, and processing activities if those activities are for "commercial purposes" (15 U.S.C. 5(I)). EPA interprets these provisions broadly to encompass a wide range of activities. TSCA and the SNUR regulations define manufacturing to include any activities associated with the production or importation of substances with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer or importer (40 CFR 720.3(r), defining "manufacture or import for commercial purposes"). Processing for commercial purposes is also defined to encompass a wide range of activities (40 CFR 721.3, defining "process for commercial purposes"). Based upon these regulations, a laboratory could be engaged in regulated activity when it uses a listed benzidine-based substance. Determining whether a laboratory is engaged in a regulated activity is very fact specific and requires an assessment of a variety of the circumstances surrounding the laboratory's activities. The commenter has not provided enough information for EPA to determine whether the activities it describes would be subject to the SNUR. Rather than speculate on hypothetical situations, EPA advises a laboratory that intends to engage in activities involving a significant new use of a listed benzidine-based chemical substance to contact EPA as specified in 40 CFR 721.11 to determine in advance whether it is subject to the SNUR. Additionally, as stated in the previous response to comment, under existing EPA regulations, a person who manufactures, imports, or processes a listed substance for a significant new use is not subject to SNUR notification requirements if the person is utilizing small quantities of research and development and meets the other