federal register

Wednesday
November 26, 1980

Part V

Environmental Protection Agency

N-Methanesulfonyl-P-Toluenesulfonamide; Determination of Significant New Uses

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[OPTS-50013 FRL 1558-1]

N-Methanesulfonyl-P-Toluenesulfonamide; Determination of Significant New Uses for a Chemical Substance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing that certain uses of the chemical substance N-methanesulfonyl-p-toluene sulfonamide be designated as "significant new uses" under section 5(a)(2) of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2604). This substance was the subject of a premanufacture notice (PMN) submitted on September 5, 1979 by National Starch and Chemical Corporation. Under Section 5(a)(1)(B) of TSCA, any person who intends to manufacture, import, or process the substance for a "significant new use" must submit a notice to EPA at least 90 days prior to manufacture, import, or processing for that use.

DATES: Written comments should be submitted on or before January 12, 1981.

ADDRESS: Written comments should bear the document number OPTS 50013 and should be submitted in triplicate to the Document Control Officer, Office of Pesticides and Toxic Substances (TS-793), Environmental Protection Agency, Rm. E-447, 401 M St. SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: John B. Ritch, Jr., Director, Industry Assistance Office (TS-799), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-429, 401 M St., SW., Washington, DC 20460; toll free: (800-424-9065); in Washington, D.C. (554-1404).

SUPPLEMENTARY INFORMATION: Section 5(a)(2) of the Toxic Substances Control Act (TSCA) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by a rule, promulgated after consideration of all relevant factors, including those enumerated in section 5(a)(2)(A) through (D). Once a use is determined to be a "significant new use," persons who intend to manufacture or process the substance for that use must, under section 5(a)(1)(B), submit a notice at least 90 days proir to manufacture or processing for that use. The section 5(a)(1)(B) notice is subject to the same general statutory requirements and procedures as a premanufacture notice (PMN) submitted under section 5(a)(1)(A). In particular these include the information submittal requirements of section 5(d)(1) and section 5(b), the exemptions authorized by section 5(h), and the regulatory authorities of section 5(e) and section 5(f).

In this notice, EPA is proposing a significant new use rule (SNUR) which would apply to a particular chemical substance for which a premanufacture notice (PMN) was submitted under section 5(a)(1) of TSCA. This action is one of several approaches under TSCA to follow up on new chemical substances and to obtain additional data on selected Inventory substances.

First, OPTS will continue to issue section 5(a)(2) significant new use rules on a case-by-case basis for new chemical substances of concern. Second, because use of the section 5(a)(2) and other reporting authorities on a purely case-by-case basis would impose a heavy burden on OPTS's limited resources, OPTS will develop model rules suitable for most situations when follow up of new substances is necessary. These model follow-up rules, establishing general requirements and procedures, would allow EPA to promulgate rules more efficiently and frequently than if it relied strictly upon case-by-case rulemaking. After the development of model follow-up rules, case-by-case follow-up will be used when the model rules do not suffice. Finally, in the future EPA will issue significant new use rules on Inventory substances or categories of substances.

PMN Substance of Concern: N-Methanesulfonyl-P-Toluenesulfonamide; PMN #5AHQ-0979-0016

On September 5, 1979, National Starch and Chemical corporation ("National Starch") submitted a PMN for N-methanesulfonyl-p-toluenesulfonamide. According to information supplied by National Starch, the company intends to manufacture annually approximately 400 pounds of the substance for the only known use. National Starch claimed that this use of the chemical was confidential business information ("CBI"), and EPA accepted this claim. When asked by EPA for the maximum potential production volume, National Starch indicated that production would not exceed 1,000 pounds per year.

During its assessment of the potential risks associated with the substance, the Agency found that to the best of its knowledge no reliable toxicity data exists for the subject compound nor for any close structural analogs. Therefore the Agency was unable to evaluate the toxicity of N-methanesulfonyl-p-toluenesulfonamide.

With regard to potential exposure, the Agency determined that exposure would be relatively low taking into consideration the following information supplied by National Starch and conclusions made regarding the substance from the properties of close structural and use analogs:

1. Limited production volume: between 400 and 600 pounds per year.
2. The substance is a crystalline solid with a low vapor pressure.
3. The substance is not likely to be metabolized by the body but rather will pass through the body in its original state.
4. The substance is to be produced in probably two to three "batches" per year; each production cycle requiring less than 48 hours.
5. Approximately five to six workers would be exposed to the substance during manufacture and processing.
6. The substance would be used in low concentrations.
7. The segment of the population using the substance is experienced in using substances of this nature and thus would know how to handle the material appropriately.
8. The product containing the substance carries instructions for porper handling and use.
9. The manner of application of the final product (confidential) is such as to minimize exposure.

For the reasons stated above, EPA determined that it was not necessary to regulate the substance for the use and exposure conditions described in the PMN. As a result, EPA did not extend the notice period, which expired on December 4, 1979. National Starch has been free to commence production since that time. The company submitted a Notice of Commencement of Manufacture, and the substance was added to the Inventory during July 1980, published in the Federal Register of August 26, 1980 (45 FR 56909). Therefore, until this rule becomes effective, the substance may be produced without restrictions under TSCA.

EPA Concerns

EPA's decision not to regulate the substance under section 5(e) or 5(f) does not indicate a lack of concern about the substance. In fact, the Agency remains concerned about this substance because of the lack of any information or test data that would allow the Agency reliably to determine or estimate its degree of toxicity. EPA does not presume that this substance is extremely toxic. Similarly, EPA is unable to conclude that it is not toxic. Rather, the

Agency has no knowledge about the substance's toxicity whatsoever.

EPA's concerns based on a lack of toxicity data were mitigated by the fact that according to the information provided by the submitter, the probability and magnitude of exposure during manufacturing, processing, and use are relatively low. However, since the substance is on the Inventory, any person can make the substance under any conditions of manufacture, processing, and use. Moreover, the PMN submitter itself is not bound to the conditions specified in the PMN, and is free to change the use, volume, or manufacture of the substance. (However, the submitter is bound at the time of submission to provide EPA the information required for a PMN, and any intentional falsification or withholding of required information could result in prosecution under 18 U.S.C. 1001 or appropriate enforcement action under TSCA.) In the absence of further action by EPA, the submitter or anyone else may produce the substance for any use without further notifying EPA.

EPA has no information to predict that uses, other than the use described in the PMN, will be developed or that such new qualitative uses will result in changes in exposure conditions. Further, in addition to new qualitative uses, there might be increases in production volume for the use described in the PMN, either by the submitter or by other companies.

The risk that a substance presents to humans or the environment is a function of toxicity and exposure. In this case we know nothing about toxicity, and anticipated exposures for the activities described in the PMN are relatively low. However, if exposures increase in the future, the substance may present risks that cannot be evaluated (by either industry or EPA because there are no toxicity data. EPA has a responsibility to evaluate any risks that might result in the event that this substance is toxic. In particular, EPA believes that consistent with the purposes of TSCA section 5, if exposures increase for this substance, the Agency should either review any additional toxicity data which may have been developed for this substance or analogous substances, or consider whether the substance should be controlled until toxicity data are developed. To accomplish this purpose, EPA proposes to designate as "significant new uses" certain uses of this substance that would result in new or increased exposures.

Proposed Significant New Uses

EPA believes that in general, there are a variety of different ways to define significant new uses pursuant to section 5(a)(2) of TSCA. In deciding what will constitute a significant new use for a particular substance, the Agency will consider all relevant information about the actual or predicted toxicity of the substance and the exposures associated with its proposed and potential uses. In this notice, EPA proposes to define each of the following as a significant new use of this chemical substance: (1) manufacture and processing of the substance for any "qualitative" use other than that described in the PMN; (2) and manufacture or processing of more than 1,000 pounds of the substance for the use described in the PMN. These determinations of significant new uses are intended to apply to this chemical substance only; they do not establish a fixed policy with regard to the reporting triggers which may be utilized in future SNURs. The Agency's bases for each of these "significant new use" determinations in this case are explained below.

(1) *Change in "Qualitative" Use of the Substance.* EPA is proposing to require that any person intending to manufacture or process the PMN substance for a "qualitative new use" submit a "significant new use" notice under § 721.7. A "qualitative new use" is defined in proposed § 721.3 as: the use of a substance, defined by its function and particular commerical or technical application, without regard to the quantity of a substance for that use. EPA has determined that such qualitative new uses are significant because they could present a potential for risk based upon the unknown toxicity of the substance and the new or additional exposures which would be associated with new qualitative uses. Submittal of a significant new use notice would provide the Agency with an opportunity to examine proposed new qualitative uses of this substance, and decide if action should be taken under TSCA section 5 to prohibit the manufacturing and/or processing of the substance for this use.

As discussed above, EPA has evaluated the potential exposures to the PMN substance which would result from the qualitative use intended by the submitter, and the exposures which would occur during manufacture of the substance by the submitter. The Agency determined that these exposures would be relatively low. Based upon this assessment, EPA decided during the PMN review period that regulatory action was not warranted at that time, although the Agency knew nothing about the toxicity of the substance.

During the PMN review period, EPA did not evaluate any other qualitative uses of the substance, because no other uses were claimed by the submitter, and none were known to the Agency. However, now that this substance has been added to the Inventory, there is a possibility that new qualitative uses may develop which were not anticipated by the submitter or EPA. These new qualitative uses may result in exposures which present new potential risks to health and the environment. Considering the factors set out in section 5(a)(2) of TSCA. First, the new uses may result in a substantial increase in production volume. The volumes estimated in the PMN for the third year of production are relatively low (400–600 lbs.), and it is quite possible that a new qualitative use will require production in excess of these amounts. At a minimum, a significant increase in production would increase the exposures which the Agency anticipated in its PMN review of the substance. Second, a new qualitative use may present new exposure problems not presented by the qualitative use assessed during the Agency's PMN review of the substance. Although only short term dermal exposure is expected for the submitter's intended qualitative use, other qualitative uses involving this substance may result in higher exposures; exposures by different routes, and exposures which occur more frequently or for longer periods of time. Such changes in exposure could occur if a new qualitative use of the substance resulted in changes in the manner and methods of manufacture, processing, distribution in commerce, use, and disposal. In sum, one or more of the changes in exposure which could result from the new use would result in both the chemical industry and EPA needing to know more about the substance's toxicity to adequately evaluate risks and make informed judgments about the need to take control actions.

As indicated, the proposal would require manufacturers and processors to submit a PMN notice for any qualitative new use. The Agency recognizes that this requirement may result in the submittal of a PMN notice for new qualitative use which the Agency may conclude presents less risk than the National Starch qualitative use. The Agency, however, was unable to devise a formula which would identify adequately any such new qualitative uses and exclude them from the PMN submittal requirement. The Agency was unable to do so because the toxicity of the PMN substance is unknown and unpredictable, and because the Agency's decision not to act on the

National Starch PMN involved judgments which could not be reduced to a formula. The Agency expressly solicits comment on whether such a formula can be devised, including any suggestions for "cut off" formulas which commentors believe will adequately accomplish the Agency's objectives. However, the Agency notes that the consequences of having no "cut off" formula are less severe than the consequences of an inadequate cut-off formula—the entrance on the market place of new qualitative uses posing significant risk concerns without necessary Agency review. If the Agency is correct that an adequate cut-off formula cannot be devised, it has no doubt that it has authority to impose a broad PMN reporting requirement such as the one included in the proposal. To conclude otherwise would effectively prevent the Agency from imposing PMN requirements on new qualitative uses in cases where industry failure to develop sufficient data have prevented the Agency from developing a "cut off" formula. Congress intended industry to bear the burden of developing data to access TSCA chemicals, not the Agency. An implicit corollary of the TSCA burden of proof concept is that the industry—and not the Agency and the public—bear the consequences of failing to meet this burden.

(2) *Increase in Volume of Production for the Use Described in the PMN.* EPA proposes to designate production by any one person of more than 1,000 pounds of the substance per year for use in the manner described in the PMN as a "significant new use" of the substance. In the PMN, the submitter stated that he would manufacture a total of approximately 400 to 600 pounds per year of the substance by the third year. The submitter subsequently indicated to EPA that 1,000 pounds per year was its most optimistic estimate of total production for any year. Therefore, because it would be approximately twice the submitter's best third-year projection and would exceed his most optimistic long-run production estimate, production of over 1,000 pounds in any one year would represent a significant expansion in volume.

Congress intended production volume to be a major factor in the determination of what is a significant new use for a substance. Projected volume of manufacture and processing is one of the relevant factors listed in section 5(a)(2) that EPA must consider in making its findings that a use is a "significant new" use. Further, while section 5(a)(2) states that all relevant factors are to be considered in making a significant new use determination, the legislative history indicates that a change in a single factor could be enough. In this regard, the Conference Report stated that "a significant increase in the projected volume * * *, a significant change in the type or form of human exposure * * *, or a significant increase in the magnitude * * * could be the basis for determining that a use is a significant new use." [1] Finally, use of production volume in this manner is consistent with the intent of section 5(a)(2), because and increase in volume usually will correlate with increased exposure to humans or the environment, and increased exposure is the primary consideration in making a finding of a "significant new use." Especially where there is no information about toxicity, as in this case, exposure factors such as production volume are the focus of EPA's SNUR decisionmaking.

With regard to this substance, the PMN submitter's intended use will result in some exposure to workers at the projected production volumes. An increase in the quantity manufactured for this particular use very likely will increase either the number of workers exposed to the substance in the final product at the same level, or the total numbers of hours the product is used, resulting in greater frequency of exposure to the present number of persons. In either case, it is reasonable to anticipate that there would be increased exposure of humans to the substance.

An expansion in production volume for this use may increase exposure in another way. Conditions of manufacture and processing of the substance could change if production volume expands significantly. This is because the initial production equipment and processes may not, for technical and economic reasons, be the best ones for producing the substance in higher volumes. Thus, if these changes occur in how the substance is produced and handled, the types and levels of exposure also may change, including possible increases in exposure.

Not all increases in production volume are "significant" from the standpoint of increased exposures. Also, it is impossible to predict in quantitative terms the specific changes in exposure that will result from increased production. Generally, it may not be appropriate to require submission of SNUR notices to EPA for marginal changes in volume. Rather, the notices should reflect "significant" changes, and one measure of "significance" is the submitter's own estimates of production volume. Presumably, maximum or "outside" estimates represent the submitter's own best estimates of potential market demand, and thus production volume, for the new substance. Anything exceeding this would be unanticipated by the submitter in making his technical, commercial, and industrial hygiene plans, i.e. it would be "significant" to him in several respects. If it also could lead to significant new exposures, then it may be the basis for a finding of a "significant new use," particularly when there is no information about toxicity.

In this case, the submitter's ultimate production estimate of 1,000 pounds per year is a maximum figure—a range of 400 to 600 pounds is projected as being realistic and most probably for the third year. To allow for moderate increases in volume consistent with the manufacturer's own plans for production and commercialization, EPA proposes to use the 1,000 pound figure as a basis for a finding that a significant change in production occurs. As noted above, in this case increase in production will likely correlate with increase in exposure, so that the selection of the 1,000 pound figure accounts both for the normal growth of the product and increased risks to humans.

EPA proposes that this 1,000 pounds per year amount be applied on a per-person basis—that is, under the proposed SNUR more than 1,000 pounds of the substance could be produced, if several companies manufacture the substance, each making no more than 1,000 pounds per year. The Agency considered making the 1,000 pounds figure an aggregate one, so that total U.S. poduction in any one year could not exceed 1,000 pounds without notification to EPA. However, EPA is not proposing this requirement for three reasons:

1. To implement such a rule EPA might need to develop some type of "allocation" or "rationing" system, requiring some manufacturers to submit a notice based on the cumulative production of the substance by a number of different persons. Although such an approach may be appropriate for some production volume SNURs, it is neither necessary nor appropriate to do so here, particularly in light of the next two points.

2. Based upon information gathered during EPA's review of the PMN it is likely that this company will be the only producer of the PMN substance fot his use.

3. The other proposed SNUR "trigger"—requiring a notice prior to manufacture for any other qualitative

[1] H.R. Rep. 94-1679, 94th Cong., 2d Sess. 66.

use—provides assurance that other possible exposures will not occur without prior notice to EPA. By taking a comprehensive approach to this SNUR, in terms of the possible exposures that are covered, EPA can set production volume limits at the maximum levels projected by the PMN submitter and still ensure that significant increases in exposure will not take place before EPA has reviewed them. Under the proposed rule, a person would be required to sumbit a notice at least 90 days before manufacturing or processing the substance for the significant new use. In the case of the production volume trigger, this would mean the notice must be filed at least 90 days prior to the point when the 1,000 pound trigger would be exceeded, and the 1,000 pound level could not be exceeded until the SNUR notice period expired.

In EPA's proposed rule, the calculation of when a person would exceed the 1,000 pound level is made for each calendar year on an individual basis, without regard to the production for previous years. However, EPA is also considering substituting a moving two-year average for the calculation made on a year-by-year basis. Under this method a person would average his production for the current year with that of the previous year, and would only be subject to the reporting requirement at least 90 days prior to the time when the average of the current year and the preceding year exceed 1,000 pounds. For example, a person could produce 1,500 pounds of the substance in 1983 if his production had been 500 pounds or less in 1982.

Use of a two-year average might more closely approximate the realities of production of low-volume specialty chemicals. Fluctuations in annual production levels that result in an occasionally very high or very low annual figure seem to be common. Thus, depending on inventory levels, cost and availability of feedstocks, or availability of production equipment, a single year's production can be much greater or less than previous or succeeding years. However, such changes may not signal significant growth.

EPA can foresee two possible disadvantages to a production volume trigger based on a two-year moving average. First, some significant growth scenarios would be identified only one year after the growth had actually exceeded the 1,000 pound level. For example, if production equalled 200 pounds in 1981, and 1,700 pounds in 1982 as part of planned significant growth, EPA might not receive a notice until 1983. A second concern is that a two-year average may pose some difficulty in enforcement actions. EPA requests comment on these problems, and the overall utility of the two-year average in cases like this one.

Persons Subject To Section 5(a)(1)(B)

Section 5(a)(1)(B) states that no person shall manufacture or process a substance for a significant new use unless that person submits a notice in accordance with section 5(a). This suggests that any significant new use rule applies automatically to both manufacturers and processors. However, EPA does not interpret this provision in this manner; instead, the Agency believes that it has authority to and should adjust the coverage of manufacturers and processors in the rule in order to eliminate duplication, or reduce unnecessary burdens, where it has a reasonable basis for doing so.

In this case, EPA is proposing that both manufacturers and processors be required to give notice of significant new uses as defined in proposed § 721.75(a), that is, for qualitative new uses. Both manufacturers and processors are capable of initiating, either singly or in concert, the actions which may result in significant new exposures in conjunction with manufacturing or processing the substances for qualitative new uses. For example, if a person manufactures the substance, and sells it to a person who processes it for a qualitative new use, increased exposures may result from the independent actions of either the manufacturer or processor at their respective stages of the chemical's life cycle. In this case, the reporting responsibility should fall on both persons, who may submit either separate notices reflecting forthcoming changed exposures at each stage, or a combined notice reflecting all stages of the substance's life-cycle.

EPA is proposing that only the persons who intend to manufacture in excess of 1,000 pounds per annum of the substance for the use proposed in the PMN be required to submit a notice. Under this proposal, it would theoretically be possible for a single person to process more than 1,000 pounds of the substance for the originally proposed use without notifying EPA. He could do this by purchasing the substance from two or more different manufacturers, each of whom manufactured less than the 1,000 pounds which would trigger significant new use reporting. However, this eventuality is unlikely; in addition, once a given amount of the substance has been manufactured, the fact that processing occurs at one site rather than several does not significantly affect total exposure. EPA requests comment on whether the 1,000 pound trigger should be applied to processors as indirect means of limiting aggregate manufacture of the substance.

Required Information

As indicated in § 721.7, EPA is not at this time proposing any notice form or other special information requirements for notices submitted under this Part. Instead, the Agency is proposing that any such notices comply with the explicit requirements of section 5 of TSCA. In particular, this includes the requirement to submit the information and data described in section 5(d)(1). EPA's policy with regard to what test or other health and safety data a person should include in a notice is discussed in the next section of this notice; other issues concerning information submittal requirements under section 5(d)(1) are discussed immediately below.

EPA previously has proposed forms and other requirements which will be applicable to notices for new chemical substances, submitted under section 5(a)(1)(A) published in the Federal Register of January 10, 1979 (44 FR 64572), reproposed in the Federal Register of October 16, 1979 (44 FR 59764). EPA at this time is not proposing similar detailed rules for notices of significant new uses for several reasons. The Agency still believes that forms and rules for reporting under section 5 are useful and necessary, in the long run. EPA has been receiving PMN's for new chemical substances since July 1979 under an Interim Policy published in the Federal Register of May 15, 1979 (44 FR 28564). Experience under this policy, which among other things stated that the PMNs should include information and data required by the law, has been mixed. A few notices have been quite complete; others, while meeting the statutory minimums, have been so brief and informative as to hamper EPA's initial review, although in almost all cases the submitters later were willing to supplement the PMN to some degree in response to specific questions posed by the Agency. In short, the past few months have generally reinforced EPA's original view that an efficient and effective section 5 premanufacture notification review program, especially one that may have to process a significantly greater number of notices than it has in this early phase, needs rules and forms to standardize the submittal of information. In line with this determination, EPA is continuing with efforts to develop a form or forms for significant new use notification, as one of the many facets of developing

general rules and procedures for "follow-up" of new chemical substances. When these rules are proposed, the Agency also will propose that the information requirements extend to any significant new use rules for individual substances which are in effect at that time. However, EPA will not be prepared to propose these rules until 1981.

EPA believes that, with an exhaustive examination of significant new use information requirements pending, it is not necessary or useful to devote resources to a detailed consideration of these requirements in the context of a SNUR for a single chemical substance. The number of notices likely to be submitted under this rule should be rather low, and therefore assessing notices which are not in a standard format, or which EPA must request the submitter to supplement to some degree, should not constitute a serious burden on the program.

Pending development of detailed reporting rules for notices submitted under SNURs, EPA believes persons should submit notices on the basis of EPA's Interim Policy for Premanufacture Notices published in the Federal Register of May 15, 1979 (44 FR 28564). Although the Interim Policy document was not drafted specifically to include significant new use notices, EPA has reviewed the Interim Policy and determined that the guidance it provides is generally applicable. However, for the purposes of this proposed SNUR, EPA is supplementing the Interim Policy with the following additional guidance.

First, persons would not be required to submit information and data that were included in the original PMN. For example, if a person submits a SNUR notice because he intends to manufacture 2,000 pounds of the substance for the use described in the PMN, he would focus on the volume increase and need not provide further deatiled descriptions of the use. However, to the extent that the estimated exposures differed significantly from those in the PMN, this information must be corrected and updated.

Second, EPA would urge persons to submit more specific and detailed information on the human exposures and environmental release that result from any significant new use of the substance. Information on these topics will allow EPA to focus on these new uses at a level of detail consistent with its conclusion that they are "significant."

EPA requests comments on additional guidance which the Agency should provide when this rule is promulgated.

Health and Safety Studies

In addition to submitting information required by section 5(d)(1)(B) and (C) of the Act concerning the submittal of data related to health and environmental effects, these sections require the submittal of health and environmental effects data that are known to or reasonably ascertainable by the submitter but do not require the submitter to perform additional testing. EPA has proposed its interpretation of these requirements under proposed 40 CFR 720.23 published in the Federal Register January 10, 1979 (44 FR 2270), and the Agency's final rules on this subject would apply to any section 5(a)(1)(B) notices submitted under this SNUR.

Any notice submitted under this rule would describe a proposed use of this substance that involves signficant exposure to humans or the environment. As discussed above, at this time EPA is unable to conclude anything about the substance's toxic properties, and this lack of information is one of the reasons for issuing this SNUR. If exposures change or increase, so will possible risks, and it is this possibility that is the basis for EPA's concerns about production and use of the chemical.

Because of these potential risks from the increased exposures indicated by the proposed SNUR triggers, EPA strongly encourages any person who submits a notice under this SNUR to include information on the substance's toxic properties. EPA is planning to publish premanufacture testing guidance in the near future. Persons subject to this SNUR are urged to refer to the testing guidance for EPA's recommendations concerning data needed for assessment of risk presented by new chemicals or significant new uses of existing chemicals.

Procedures for Filing SNUR Notices

EPA is not, in this notice, proposing any procedures for the processing of notices which may be submitted under this rule. Instead, the proposed rule focuses only on the most essential elements of this SNUR, including definition of significant new uses, description of types of persons subject to the requirements, and special exemption procedures. As discussed above, EPA has begun to develop general rules on the subject of "follow-up," under the authorities of section 5(a)(2) and section 8(a). This rulemaking will parallel the initial PMN rulemaking, addressing any overall procedural issues in the implementation of SNUR requirements and review of notices. When these rules are proposed, EPA will indicate that certain portions of them—including information requirements, disposition procedures, etc.—would apply to any SNURs promulgated on a case-by-case basis prior to the effective date of the general follow-up rules. (The general rules would also apply to subsequent case-by-case significant new use rules unless the individual rule specifically stated otherwise.)

Pending completion of that rulemaking, persons submitting SNUR notices should rely on EPA's Interim Policy for guidance. The present PMN Interim Policy (44 FR 28564) addresses a variety of topics including submitter identification, notice certification, section 5(d)(2) Federal Register notices and procedures for asserting confidentiality claims. EPA is considering supplementing and modifying this policy, based on experience with PMNs thus far. EPA requests comments on any special procedures that should be developed for significant new use notices.

Procedures for Informing Persons of the Existence of This Significant New Use Rule

One practical problem that EPA must confront in implementing this proposed rule is the task of informing persons that certain uses of the substance are subject to a significant new use rule. A discussion of the Agency's proposed methods follows. EPA requests suggestions for additional methods of disseminating this information.

EPA will follow the formal mechanisms for notice that a new regulation has come into effect. First, the final rule will be published in the Federal Register. Second, because the rule is one of continuing applicability and effect, it will be codified in Title 40 of Code of Federal Regulations (CFR), which is revised annually.

In addition to these formal notice mechanisms, EPA is exploring the possibility of using the Inventory of existing chemical substances or associated documents to inform persons of the existence of this SNUR. The Agency contemplates placing a footnote on the Inventory by the chemical identity of this substance. This footnote could refer the user to a statement that the substance was subject to a SNUR; this would notify the person of the requirement, and lead him to contact EPA for further information. In the alternative, the footnote could refer the user to an Inventory Appendix which would give a Federal Register or CFR citation of the rule.

EPA believes that use of the Inventory in this manner would be an effective

way of informing persons about the rule. Any person who intends to manufacture a substance which he has not manufactured before should check the Inventory to determine if the substance is listed, in order to determine whether or not to file a PMN for a new chemical substance. If he does find the substance on the Inventory, but it is subject to a SNUR, he will be put on notice of this fact, and can take further actions to determine whether he would be subject to the section 5(a)(1)(B) reporting requirement.

Finally, to help ensure that all persons potentially subject to the rule are put on notice, EPA is considering imposing on the original manufacturer the duty of informing persons purchasing the substance from him of the existence of the significant new use rule. The requirement to give notice could also be extended to other situations in which the original manufacturer becomes aware that another person intends to manufacture, process, or use the substance— especially situations in which the original manufacturer has a commercial interest in the new use, as in sale of production rights or production technology.

EPA authority to impose such a requirement would be based on the terms of the SNUR, which make it unlawful to manufacture or process a substance for a significant new use as defined by the Agency. Inherent in this requirement is the responsibility of a manufacturer or processor to know something about the uses being made of a substance, or at least to inform persons for whom the substance is being manufactured or processed that certain uses are subject to a SNUR.

Confidentiality of Proposed Use

In its PMN, the manufacturer asserted a claim of confidentiality with respect to the qualitative use of the new chemical substance, and EPA has acquiesced in this claim. The confidentiality of the use poses significant problems for the implementation of this rule, in which significant new uses of the substance are at least partially defined by the use proposed in the PMN. EPA's proposed resolution of the problem, and alternative approaches which were considered are discussed below.

EPA is proposing that the confidential description of the use not be published in the final rule, § 721.75. Instead, under § 721.11 of the proposal, a person who intends to manufacture or process the substance (the chemical identity of which is not confidential) for any use may ask EPA if that use is the same as the existing one. However, EPA will provide this information only if the requester indicates that he has a *bona fide* intent to manufacture or process the substance for that purpose. The proposed rule sets out the information EPA would require a person to submit in order to establish *bona fide* intent. Use of this procedure will prevent fishing expeditions by competitors, while allowing persons with legitimate intentions to determine whether a section 5(a)(1)(B) notice is required. On the other hand, use of such an approach does moderately increase the burden on persons intending to manufacture or process the substance. This approach for responding to inquiries concerning use description is similar to the procedure utilized in the Inventory Rules (40 CFR 710.7(g)) to enable EPA to respond to *bona fide* inquiries concerning the identities of confidential substances on the Inventory.

EPA examined the alternative of using the authorities of section 14(a) to disclose the proposed use of the substance for the purposes of this rulemaking and in the final rule itself. The Agency believes such a disclosure could be based on the authority of section 14(a)(4), which states that otherwise confidential information "may be disclosed when relevant in any proceeding" under the Act. This rulemaking is clearly such a "proceeding" and the qualitative use description, an essential part of the rule, is clearly "relevant." However, EPA is not proposing to disclose specific use information in this case. Section 14(a)(4) qualifies the Agency's rights to disclose by stating that disclosure "shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding." EPA's tentative conclusion is that, because the identity of the substance is not confidential, maintaining confidentiality in this case except where *bona fide* intent to manufacture is shown may not unduly hamper the ability of persons to participate in this rulemaking or to comply with the rule when promulgated. This determination, however, is based on the facts of this particular case; the Agency is not proposing a general policy of maintaining confidentiality for essential elements of section 5 rulemaking, and believes that on different facts section 14(a)(4) would justify broader disclosure. EPA specifically requests comments on how it should handle confidentiality issues in this and future SNURs.

EPA Review of Notice

EPA intends to process and review any section 5(a)(1)(B) notices submitted under this proposed rule in a manner similar to premanufacture notices for new chemical substance. When a notice is received, EPA will publish a summary in the Federal Register in accordance with 5(d)(2). The review period for the notice will run 90 days from EPA receipt of the notice; under section 5(c) this period may be extended up to an additional 90 days for "good cause." The submitter may not manufacture or process the substance for the significant new use until the review period, including extensions, has expired. As with a PMN for a new chemical substance, EPA will use the notice as a point of departure for assessment, supplementing the information submitted with it with other available data to the extent necessary and possible.

The Agency has a variety of means of addressing concerns raised by such a notice. Section 5(e) specifically provides for EPA to regulate the substance, under certain conditions, pending the development of information necessary to evaluate the health and environmental effects of the substance. In addition, section 5(f) provides authority for EPA to control exposures which result in an unreasonable risk to health or the environment. EPA may also refer the information to other EPA offices and other Federal agencies, if these offices would be helpful in evaluating new uses of chemical substances and controlling them when appropriate.

Section 5(g) is the only part of section 5 which mandates special treatment of SNUR notices. This provision states that, at the end of the notification period for a significant new use, EPA must publish in the Federal Register a statement of the reasons for not initiating an action under section 6 or section 7 to control the substance. EPA has not determined the appropriate contents or level of detail for this notice, and requests public comment on the purposes this notice should serve.

Modification of Reporting Requirement Based on Notices

EPA is not proposing, and does not believe it would be appropriate to proposed, a sunset provision that would terminate, on the basis of passage of time alone, the signficant new use reporting requirement. On the other hand, the Agency believes that there may be several circumstances, arising from the submittal of notices, which will lead to modification of the requirements proposed today.

First, when a notice is submitted which describes a significant new use, EPA will be able to review the use to determine whether any control

measures are necessary. Once the Agency has had its review opportunity, the use reported would arguably not be "new" any longer, and EPA believes that in general, the requirement to submit PMNs for such specific new uses should be lifted once the submitter begins to manufacture or process for that particular use. In these cases, the Agency proposes that the significant new use rule itself be modified or annotated automatically—that is, without following rulemaking procedures. The justification for such an approach is simple. Addition of a particular use to a list of existing uses would not be a discretionary activity. Rather, it would be akin to the automatic addition to the Inventory of a new chemical substance upon EPA's receipt of a Notice of Commencement of Manufacture. This would mean essentially that for each substance subject to a SNUR there would be a list of uses not subject to the SNUR which EPA would supplement automatically as new uses were reviewed, unless EPA acted to prohibit the use. However, establishing a list of non-SNUR uses may not be necessary in all cases, depending on how the reporting triggers are defined.

While the Agency would not have discretion to prevent a new use from being added to the list of "existing" uses, in some cases it might want to propose that certain changes in that use themselves be considered as significant. For example, EPA might not be concerned if a person proposed to manufacture 1,500 pounds of the substance for qualitative new use X, but might wish to review the use in the future if the total production rose to 10,000 pounds, or if some aspect of that use changed. The requirement to report these changes could result from a narrow description of the qualitative use added to the existing use list, e.g., "manufacture of 1,500 lbs. for qualitative use X." In other cases, further rulemaking under section 5(a)(2) might be appropriate. In addition to modifying the SNUR, EPA may follow up on particular new uses in other ways, including issuance of section 8 reporting rules.

Of course, submittal of a section 5 notice for a significant new use may result in a more substantial modification of the significant new use rule. If, for example, a notice contains information sufficient to show that a substance is of very low toxicity, the class of "significant" new uses subject to reporting may be narrowed to very high exposure situations, or eliminated entirely.

Cost Analysis

According to the manufacturer of the PMN chemical, its production (or processing) of the PMN chemical is not expected to exceed the "trigger" level stated in the SNUR. Therefore, the manufacturer is not required to do anything at this time, and should not incur any direct costs as a result of this SNUR.

However, in the event that production (or processing) of the chemical is intended to exceed the "trigger" level, then the manufacturer or processor will be required to submit the information included in section 5(d)(1) in accordance with EPA's Interim PMN Policy. The cost of submitting a notice under EPA's Interim Policy has not been determined. However, the Agency did propose a PMN form in October 1979, and the cost of filling out and submitting that form was estimated to range from $1,155 to $8,900. EPA believes the cost of submitting a notice under the Interim Policy has in most cases been in the lower part of this range.

The cost estimate for completing the revised PMN form cited above did not include the cost for asserting and substantiating confidentiality claims. The costs for claiming and substantiating confidentiality claims on EPA's proposed form estimated by EPA's contractor ranged from $900–$6,400. Although EPA has not prepared an assessment of the cost PMN submitters have actually been incurring in asserting and substantiating confidentiality claims under the Interim Policy for PMNs, EPA believes it has been only a small percentage of the costs estimated for the Agency's October 16, 1979 reproposed form.

EPA has not estimated the costs a submitter might incur in developing test or other data on the substance subject to SNUR notice. Although the SNUR does not require that the person perform additional testing EPA expects that some level of additional information, which may include testing will be generated. However, it is impossible for EPA to estimate the level of costs which may result.

The cost also does not include any indirect costs that may result from the imposition of the SNUR. These indirect costs may result from business decisions against the use of the PMN chemical due to increased uncertainties about the economic viability of the chemical for levels of production (or processing) exceeding the trigger level, and the uncertainty of using a chemical that may be subject to future Agency requirements, i.e., testing requirements or regulatory controls, under section 5(e) and (f) of TSCA. These uncertainties may affect the total market for the PMN chemical. While the Agency acknowledges that these indirect costs may exist, it also realizes that it is extremely difficult (if not impossible) to estimate the extent of these costs and their possible impacts at this time.

Rulemaking Record

The following documents constitute the administrative record of this rule (docket number OPTS 50013). Except to the extent that confidential business information has been masked, all documents are available to the public in the OPTS Reading Room, 8:00 a.m. to 4:00 p.m. Monday through Friday, except legal holidays, Room E-447, 401 M St., SW, Washington, D.C. 20460. This record includes basic information considered by the Agency in developing the proposed rule. EPA will supplement the record with additional information as it is received. The record includes the following categories of information:

1. The PMN submitted by National Starch, and other supplementary written materials.
2. The Federal Register notice of receipt of the PMN.
3. Records of all communications and meetings between EPA personnel and National Starch.
4. Any factual information the Agency considered in developing this rule.
5. Comments received on this notice.

EPA will identify the complete rulemaking record on or before the date of promulgation, as prescribed by section 19(a)(3) of TSCA, and will accept additional materials for inclusion in the record at any time between this notice and that designation. The final rule will also permit persons to point out any errors or omissions in the record.

Regulatory Analysis

EPA has determined that this document does not contain a proposal for which the Agency is required to conduct a Regulatory Analysis under Executive Order 12044.

Regulatory Development

EPA has determined that the proposal contained in this document is a specialized regulation. Specialized regulations are not subject to the procedural requirements of E.O. 12044, and are not subject to the uniform regulation development procedures promulgated by EPA and published in the Federal Register of May 29, 1979 (44 FR 30988).

Dated: November 18, 1980.

Douglas M. Costle,

Administrator.

It is proposed that a new Part 721 be added to Chapter I of Title 40 as follows:

PART 721—SIGNIFICANT NEW CHEMICAL USE

Subpart A—General Provisions

Subpart B—New Uses for Specific Chemical Substances

Authority: Sec. 5 of the Toxic Substances Control Act, Public Law 94-469 (90 Stat. 2003 (15 U.S.C. 2601 *et seq.*)).

Subpart A—General Provisions

§ 721.1 Scope.

This Part identifies activities with respect to certain chemical substances which EPA has determined are "significant new uses" under the authority of section 5(a)(2) of the Toxic Substances Control Act (TSCA). In addition, it specifies the persons subject to the reporting requirements, procedures for exclusions in certain cases, and the information to be reported in a notice.

§ 721.3 Definitions.

The definitions in section 3 of TSCA, 15 U.S.C. section 2602, apply for this rule. In addition, the following terms are defined:

(a) "EPA" means the U.S. Environmental Protection Agency.

(b) "Importer" or "person who intends to import" means anyone who intends to import any chemical substance, in pure form or as part of a mixture or article, into the customs territory of the U.S. and includes:

(1) The person liable for the payment of any duties on the merchandise, or any authorized agent on his behalf (as defined in 19 CFR 1.11).

(2) The consignee.

(3) The importer of record.

(4) The actual owner if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR Part 141.20.

(5) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with Subpart C of 19 CFR Part 144. For the purpose of this definition the Customs territory of the U.S. consists of the 50 states, Puerto Rico, and the District of Columbia.

(c) "Manufacture for commercial purposes" means to import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer and include(s), among other things, such "manufacture" of any amount of a chemcial substance or mixture:

(1) For commercial distribution, including for test marketing.

(2) For use by the manufacturer including use for product research and development, or as an intermediate.

Manufacture for commercial purposes also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts that are separated from that other substance or mixture. Such byproducts and impurities may, or may not in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemcial product for a commercial purpose.

(d) "Qualitative use" means the use of a substance, defined by its function and particular commercial or technical application, without regard to the quantity of the substance for that use.

(e) "Person" means any natural person, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity, and State or political subdivision thereof, any municipality, and interstate body, and any department, agency, or instrumentality of the Federal Government.

(f) "Process for commercial purposes" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing any amount of a chemical substance or mixture is included. If a chemical or mixture containing impurities is processed for commercial purposes, then those impurities are also processed for commercial purposes.

§ 721.5 Persons who must report.

(a) *General.* The following persons must submit a notice under the provisions of section 5(a)(1)(B) of TSCA and of this Part:

(1) Any person who intends to manufacture in the United States for commercial purposes any chemcial substance listed in Subpart B of this Part, for any significant new use of that substance specified in Subpart B of this Part.

(2) Any person who intends to import into the United States for commercial purposes, other than as part of an article, any chemical substance listed in Subpart B of this Part, for any significant new use of that substance specified in Subpart B of this Part.

(3) Any person who intends to process in the United States for commercial purposes any substance listed in Subpart B of this Part for any significant new use of that substance specified in Subpart B of this Part.

(b) [Reserved]

§ 721.7 Notice requirements and procedures.

Each person who is required to submit a significant new use notice under this Part must submit the notice at least 90 calendar days before commencing an activity specified in § 721.5 with respect to that use. The submitter must comply with any applicable requirement of section 5(b) of TSCA, and shall include the information and data specified in section 5(d)(1).

§ 721.11 Information for persons demonstrating a bona fide intent to manufacture, import, or process.

(a) If an important factor in the description of a use determined to be a significant new use is subject to confidential treatment, a person who intends to manufacture, import, or process that substance may ask EPA whether his intended use of the substance is subject to this Part. If the answer to the inquiry would require EPA to reveal otherwise confidential information, EPA will answer such an inquiry only if the Agency determines that the person has a *bona fide* intent to manufacture, import, or process the substance for the use with regard to which inquiry is made.

(b) If inquiry is made concerning the particular use or uses of the substance, to establish the *bona fide* intent the person must submit to EPA:

(1) A signed statement that the person intends to manufacture, import, or process the substance for the indicated purposes.

(2) A description of the research and development activities he has conducted to date.

(c) EPA will compare the use information submitted with information on existing uses and will inform the submitter whether a notice of significant new use is required if the person intends to manufacture, import, or process the substance for that purpose.

(d) A disclosure of the use description of a substance to a person with a *bona fide* intent to manufacture, import, or process a particular chemical substance for that particular use will not be considered a disclosure of confidential information.

(e) EPA will provide a final response to an inquiry under these procedures within 45 days after the Agency's receipt of a complete submission under paragraph (b) of this section.

§ 721.15 Exemptions and exclusions.

The exemptions and exemption authorities of sec. 5(h) of TSCA apply without modification to any significant new uses defined in this Part.

Subpart B—New Uses For Specific Chemical Substances

§ 721.175 N-methanesulfonyl-p-toluenesulfonamide.

EPA has determined that the following are "significant new uses" of the chemical substance N-methanesulfonyl-p-toluenesulfonamide:

(a) Use of the substance as other than confidential qualitative use, unless the new qualitative use is excluded under § 721.15.

(b) Manufacture or import of an amount of the substance in excess of 1,000 pounds per annum for use as a confidential qualitative use.

[FR Doc. 80-36898 Filed 11-25-80; 8:45]

BILLING CODE 6560-31-M

United States
Environmental Protection
Agency TS 799

Washington DC 20460

Official Business
Penalty for Private Use
$300

First-Class Mail
Postage and Fees Paid
EPA
Permit No. G-35

05372
DOUG [illegible]
PACE TEXTILES
987 COMMERCIAL ST
SAN CARLOS CA 94070

KMX 01157