Sunshine Act Meetings

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This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

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SECURITIES AND EXCHANGE COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCENENT: [To be published]

STATUS: Open/close meetings.

PLACE: 450 Fifth Street, NW., Washington, DC.

DATE PREVIOUSLY ANNOUNCED: Thursday, April 10, 1986.

CHANGE IN THE MEETING: Deletion/ additional items.

An open meeting scheduled for Thursday, April 17, 1986, at 2:30 p.m. was cancelled.

Oral argument on appeals by Rooney Pace, Inc., a registered broker-dealer, Randolph K. Pace, its president, and the Commission's Division of enforcement, from an administrative law judge's initial decision. For further information, please contact R. Moshe Simon at (202) 272–7400.

A closed meeting scheduled for Thursday, April 17, 1986, following the 2:30 p.m. open meeting, was cancelled.

Post oral argument discussion.

The following item will be considered at an open meeting scheduled for Thursday, Aapril 22, 1986, at 2:30 p.m.

The Commission will consider accounting for oil price declines. For further information, please contact Howard Hodges at (202) 272–2553.

Commission Peters, as Duty Officer, determined that Commission business required the above changes and that not earlier notice thereof was possible.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Kathryn Natale at, (202) 272–3195.

Dated: April 18, 1986.

John Wheeler,

Secretary.

[FR Doc. 86–9043– Filed 4–18–86; 12:49 pm]

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federal register

Tuesday
April 22, 1986

Part II

Environmental Protection Agency

40 CFR Part 720

Toxic Substances; Revisions of Premanufacture Notification Regulations; Final Rule

40 CFR Part 721

Toxic Substances; Significant New Use Rules; Proposed Amendments to General Provisions and Individual Rules; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 720

[OPTS-50002L; FRL 2959-8]

Toxic Substances; Revisions of Premanufacture Notification Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule revises certain premanufacture regulations that, under the Toxic Substances Control Act (TSCA), require any person who intends to manufacture or import a new chemical substance to notify EPA at least 90 days before manufacture or import begins. The revisions clarify and eliminate ambiguities in the stayed provisions of the rule (48 FR 41132; September 13, 1983), particularly the exemption for research and development, and they revise certain language in the rule to simplify the provisions affecting compliance and enforcement.

DATES: This rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time on May 6, 1986. This rule is effective June 5, 1986.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, DC 20460, Toll-free: (800-424-9065). In Washington, DC: (202-554-1404). Outside the USA: (Operator 202-554-1404).

SUPPLEMENTARY INFORMATION: EPA is revising certain provisions in 40 CFR Part 720 concerning premanufacture notification requirements, most notably the exemption for research and development.

I. Background

Under section 5 of TSCA, any person who intends to manufacture or import a new chemical substance for commercial purposes must notify EPA at least 90 days before manufacture or import begins. This requirement has been in effect since July 1, 1979. Since then, EPA has received and reviewed more than 6,000 notices on such new substances.

EPA promulgated a final premanufacture notice (PMN) rule in the **Federal Register** of May 13, 1983 (48 FR 21722). After receiving comments from the public, EPA postponed the effective date of the rule so that it could review several provisions. In the **Federal Register** of September 13, 1983 (48 FR 41132), EPA stated that the rule would become effective on October 26, 1983, with the exception of four provisions: (1) § 720.3(y) (the definition of "possession or control"); (2) § 720.36 (procedural requirements concerning new chemical substances manufactured under the section 5(h)(3) exemption for R&D); (3) § 720.78(b) (recordkeeping requirements for R&D); and (4) § 720.50(c) (data requirements on related chemicals). It also issued a non-substantive amendment to § 720.102(b)(1) (timing of submission of the notice of commencement of manufacture). On December 27, 1984, EPA proposed modifications of the stayed provisions in the **Federal Register** (49 FR 50201), and proposed a modified definition of "manufacture solely for export" (§ 720.3(s)). EPA is now issuing these provisions as a final rule. It is also issuing a non-substantive amendment to § 720.102(a) to further clarify the timing of submission of the notification of commencement of manufacture.

II. Provisions of Final Rule

A. Exemption for Research and Development

1. *Summary of rule.* Section 5(h)(3) of TSCA exempts the manufacture or import of small quantities of new chemical substances produced solely for research and development (R&D) from the PMN requirements if the manufacturer or importer notifies persons engaged in R&D of any health risks that the company or EPA has reason to believe may be associated with the chemical substance.

The provisions promulgated in this notice, together with §§ 720.3(cc) and 720.3(ee), promulgated on May 13, 1983, define the scope of the R&D exemption and establish the requirements associated with it. Section 720.3(cc) defines the phrase "small quantities" as those quantities no greater than necessary for R&D purposes, and § 720.3(ee) provides a definition of the "technically qualified individual" who must supervise the R&D. Sections 720.36 and 720.78(b), issued as part of the rule published with this notice, clarify specific requirements associated with the section 5(h)(3) exemption for R&D.

Under § 720.36, manufacturers and importers must evaluate information in their possession or control to determine whether a new chemical substance manufactured under the section 5(h)(3) exemption poses a risk to health, and they must notify employees who are exposed to the substance of the risks associated with it. However, § 720.36(b)(2) exempts R&D conducted entirely in laboratories under prudent laboratory practices from the requirement for risk evaluation. Section 720.36(c)(2) provides that, if manufacturers and importers distribute an R&D substance to other persons, they must provide those persons with written notification of known hazards and of the requirement that the substance be used solely for R&D. Section 720.36(d) prohibits the processing, use, sale, or distribution for non-R&D uses of R&D substances and mixtures containing R&D substances without submission of a PMN and completion of PMN review. Sections 720.36 (d) and (e) do permit, however, the sale of articles containing the R&D substance and chemical substances containing the R&D substance as an impurity, disposal of the substance, and certain forms of commercial recycling, assuming that other requirements of the R&D exemption are met.

Section 720.78(b) establishes recordkeeping requirements for manufacturers and importers taking advantage of the R&D exemption.

The R&D exemption of section 5(h)(3) also applies to persons who manufacture, import, or process a chemical substance for a significant new use designated in a rule under section 5(a)(2). Section 5(a)(1)(B) requires submission of a notice to EPA at least 90 days before a person manufactures, imports, or processes a substance for a designated significant new use. However, section 5(h)(3) exempts the person if the substance is manufactured, imported, or processed in small quantities solely for R&D. Thus, such persons can conduct R&D concerning a significant new use without submitting a notice. Pending promulgation of the revisions of §§ 720.36 and 720.78(b), EPA did not promulgate specific rules applicable to the R&D exemption for significant new use rules (SNUR's) because EPA intended to make the R&D provisions for SNUR's as similar as possible to those for PMN's. Accordingly, now that §§ 720.36 and 720.78(b) have been revised, EPA intends to amend 40 CFR Part 721, Subpart A (the general provisions for SNUR's) to incorporate provisions similar to §§ 720.36 and 720.78(b). These provisions would cover manufacturers, importers, and processors of substances for significant new uses and would be altered as necessary to address the SNUR situation. EPA is soliciting comment on any modifications that may be needed to accommodate §§ 720.36 and 720.78(b) to R&D for SNUR's.

On December 31, 1984, EPA published a proposed policy regarding certain microbial products, focusing on the

products of genetic engineering (49 FR 50880). In that proposed policy EPA discussed the need to alter the definition of "small quantities" for R&D to address the problem of release of microorganisms to the environment as part of R&D (field testing). EPA is still considering the need to amend the definition in § 720.3(cc), as well as the provisions of §§ 720.36 and 720.78(b), to meet the concerns about R&D activities conducted with microorganisms. These concerns have not been taken into account in promulgating §§ 720.36 and 720.78(b). Any such amendments to address R&D with microorganisms will be the subject of a future proposal with an opportunity for public comment.

2. *Scope of R&D.* a. *Definition.* In its notice of December 27, 1984, EPA proposed retaining the qualitative approach to defining "small quantities" solely for research and development used in § 720.2(cc) of the PMN Rule. EPA stated that there is no single quantitative limit that would allow for the variety of research taking place in the chemical industry, and commenters on the rule unanimously agreed. Therefore, this rule does not amend the definition of "small quantities" solely for R&D.

EPA has previously published considerable guidance on the scope of activities that fall within R&D, most recently in the notice in the **Federal Register** of December 27, 1984 (49 FR 50202). The Agency understands R&D activities to include tests of the physical, chemical, production, and performance characteristics of a chemical substance. The substance must be used directly by, or under the supervision of, a technically qualified individual, who must carefully monitor the tests and measure or assess their results. Chemical substances produced for R&D may be distributed in commerce, as long as the buyer uses them solely for purposes of R&D. However, distribution of a chemical substance to consumers removes it from the category of R&D.

EPA and TSCA also differentiate R&D from test marketing activities. The latter usually involve limited sale or distribution of a substance within a predetermined period of time to determine its competitive value when its market is uncertain. Test marketing activities require a manufacturer or importer to submit a PMN or an application for a test market exemption under § 720.38 of the PMN Rule.

EPA intends to summarize guidance on the definition of R&D in an information bulletin to be issued in the near future.

b. *Residual R&D material.* EPA recognizes that in some cases manufacturers and importers will have a surplus of a material produced for R&D after the R&D activities are complete. Section 720.36(d) of this rule prohibits the non-R&D commercial use or sale of this substance or of mixtures containing this substance before a PMN has been submitted and reviewed. If the manufacturer or importer intends to manufacture or import further quantities of the substance for non-R&D purposes, it can submit a PMN, a polymer exemption PMN under 40 CFR 723.250, or a low volume exemption notice under 40 CFR 723.500, as appropriate. Unless EPA acts to prevent manufacture or import, the manufacturer or importer would be free, upon completion of the relevant review period, to use the surplus R&D material for non-R&D purposes, as well as any additional quantities manufactured or imported afterwards.

In some situations, the manufacturer or importer does not intend to manufacture or import any additional quantities of the substance for non-R&D purposes. Rather, it seeks only to use up the material already produced during the R&D activities. Several commenters requested that EPA develop an expedited review procedure under section 5(h)(4) for such one-time use of R&D substances. EPA is not developing such a rule at this time because it believes that is not possible to make for all activities involving such R&D substances the "will not present an unreasonable risk" finding necessary for an exemption under section 5(h)(4). However, EPA has concluded that it is appropriate to allow manufacturers and importers in such situations to submit a PMN, a polymer exemption PMN, or a low volume exemption notice, as appropriate, to allow EPA to review the intended activities. If necessary, EPA could use its authority under section 5(e) or (f), or under the terms of the exemption rules, to prevent the intended activities if they may present an unreasonable risk. Substances described in such PMN's or exemption notices would not go on the inventory because they would not be manufactured or imported for nonexempt commercial purposes (see unit II.E. below for discussion of notice of commencement of manufacture or import).

Although persons conducting R&D may not sell or use R&D substances or mixtures for non-R&D purposes, § 720.36(d) permits the non-R&D use or sale of substances containing the R&D material as an impurity. For example, an R&D substance tested for its effectiveness as a process aid (e.g., a catalyst or a reagent) or an intermediate may exist as an impurity in the final product resulting from the R&D. If the final product is an existing chemical, it may be used for non-exempt commercial purposes without a PMN being submitted on the R&D substance, as long as the product was produced in the course of legitimate R&D, and the manufacturer or importer meets all the requirements of the exemption for R&D and the PMN rule. If the final product is not on the TSCA inventory, a PMN is necessary for that quantity of the substance before it can be sold or used in commerce, but no PMN is necessary for the R&D intermediate unless further non-R&D production is required.

In addition, § 720.36(d) permits manufacturers or importers to use or sell articles incorporating an R&D chemical substance without the submission of a PMN, as long as the article was produced in the course of legitimate R&D. EPA has received questions about the interpretation of the term "article," as defined in § 720.3(c). The Agency considers an item to meet the definition of an "article" if it is manufactured in a specified shape or design for a particular end-use application, and this design is maintained as an essential feature in the finished product. The item must have no change of chemical composition during its end-use, or only incidental changes. If an item is manufactured in a particular shape for the purpose of shipping convenience and the shape of the item has no function in the end-use, it would not be viewed as an article. Therefore, the category of articles includes an automobile painted with a coating containing an R&D pigment, and a moldable plastic sheet which incorporates an R&D stabilizer, but it does not include substances distributed in containers, e.g., paint containing an R&D pigment in a can, or such items as ingots, billets and blooms. Manufacturers and importers who use or sell articles produced for R&D should assess these activities for potential risks in accordance with the risk evaluation provision of § 720.36(b)(1). In addition, they must keep appropriate records of the disposition of R&D chemicals in articles, as required by § 720.78(b)(2).

Section 720.36(d) of the proposed rule, which specified commercial methods of recycling and disposal permissible under the R&D exemption, caused some confusion among commenters. EPA has reorganized the section and created § 720.36(e) to state more clearly that the rule does not prohibit disposal of wastes from R&D activities, and that it allows certain commercial uses of surplus R&D substances. However, all forms of disposal of waste from research and development activities must follow

local, state, and Federal regulations, and those wastes which meet the criteria for hazardous wastes under the Resource Conservation and Recovery Act must follow the procedures it requires. In addition, § 720.36(e) identifies other permissible commercial uses of surplus R&D substances: (1) Burning them as fuel, and (2) reacting or processing them to form other chemical substances.

Several commenters on the proposal raised specific questions about permissible methods of recycling or disposal of surplus R&D substances, including the recycling of small amounts of R&D substances into refinery feedstocks and the thermal oxidation of R&D substances to form commercially valuable substances. EPA has already clarified that small quantities of R&D fuels can be disposed of by blending small amounts into refinery streams without triggering PMN requirements (48 FR 7636). This constitutes disposal exempt under § 720.36(e)(1). In addition, EPA has modified the proposed rule to broaden the range of methods by which manufacturers may process chemical substances which remain after R&D activities are complete. In contrast to the proposal, which limited processing to extraction, the final rule, in addition, allows manufacturers and importers to react or otherwise process residual R&D substances to form other chemical substances for commercial use.

c. *Pesticides and pesticide intermediates.* In the Federal Register of December 27, 1984 (49 FR 50201), EPA stated that it considered chemical substances that were in the process of R&D as pesticides to be subject to TSCA, and therefore subject to the R&D rule. It referred to the Comment and Response Document accompanying the Inventory Reporting Requirements of December 23, 1977 (42 FR 64572), which stated the presumption that these chemical substances are subject to TSCA until their manufacturers or importers demonstrate intent to create a pesticide by submitting an application for an experimental use permit (EUP) or an application for registration under the Federal Insecticide, Fungicide, Rodenticide, and Insecticide Act (FIFRA).

Public comments on the R&D revision argued that FIFRA defines a pesticide as any chemical substance intended for pest control, and contended that R&D devoted solely to such pest control constituted evidence of intent to create a substance for pesticidal use. In addition, the comments indicated that it was unreasonable to subject pesticide R&D activities to TSCA R&D requirements when the final product would not be subject to TSCA.

EPA believes that the interpretation embodied in comment responses for the inventory reporting rule remains valid and that pesticide R&D activities are generally subject to TSCA jurisdiction until submission of an application for an EUP or a registration. While EPA recognizes that other activities may also evidence the "intent" to make a pesticide, it is very difficult to define such activities. Further, such activities take place after the substance is first manufactured—the event that triggers an obligation under section 5. However, EPA recognizes that requiring persons conducting strictly pesticide-oriented R&D to comply with §§ 720.36 and 720.78(b) for the period of time until an application for an EUP or a registration is submitted, but not after, may place an unnecessary burden on such activities. In general EPA believes that persons engaged in exclusively pesticide R&D activities are aware of the potential toxicity of the substances and that applying the specific requirements §§ 720.36 and 720.78(b) will not provide any additional protection. Further, the alternative to complying with the requirements of the rule would be the submission of a PMN. But in the case of a substance undergoing R&D for ultimate development of a pesticide, a PMN would be contradictory. Accordingly, EPA has decided, as a matter of policy, to exclude from the application of §§ 720.36 and 720.78(b) manufacture of a new chemical substance where the exclusive intention of the subsequent R&D activities of the person manufacturing the new substance and conducting the R&D activities is to develop the substance as a pesticide. This would apply even if the potential properties of the substance as a pesticide are unknown at the time it is first manufactured—a likely situation. The Agency considers the existence of a patent relating to use as a pesticide or the manufacture of the substance by a company or a laboratory wholly devoted to pesticide R&D and marketing as evidence of exclusive pesticide intent. In contrast, exclusive pesticide intent would not be conveyed by the manufacture of a substance by a company or in a laboratory whose R&D and marketing efforts ranged beyond pest control, unless the manufacturer or importer could present other positive evidence of express and exclusive pesticide intent for the substance. In such non-exclusive cases, R&D activities for the substance would be subject to §§ 720.36 and 720.78(b) until the submission of an application for an EUP or registration under FIFRA, or other activities begin which provide evidence of exclusive pesticide intent. Thus any R&D activities would be conducted in accordance with § 720.36 until the event evidencing exclusive pesticide intent occurs.

The other provisions of TSCA still apply to pesticide-oriented R&D activities, in particular the provisions of section 8(e) which require notice to EPA of information concerning substantial risks of such substances.

In addition, EPA has received several inquiries about the relevance of the R&D exemption to intermediates and inerts used in the production of pesticides. These chemical substances fall within the jurisdiction of TSCA and are eligible for the R&D exemption. A new chemical substance used in small quantities as a pesticide intermediate or inert is eligible for an R&D exemption (1) if research and development is conducted on the intermediate or inert substance itself, or (2) if the substance is used to produce a pesticide which is used only for R&D. In the latter case, the R&D status of the pesticide intermediate or inert depends on the commercial purpose of the pesticide it is used to produce.

If manufacturers or importers produce the final pesticide in small quantities, solely for purposes of R&D, the intermediate qualifies for the R&D exemption. If the pesticide falls outside the TSCA definition of R&D, EPA requires a PMN for the intermediates involved in its manufacture (unless, of course, the intermediates themselves are the subject of R&D activities).

In reaching a decision on whether a pesticide is manufactured for R&D purposes only, the manufacturer must consider the specifics of the use. Submission of an application for an experimental use permit on a pesticide does not automatically mean that the pesticide remains within the scope of R&D or has gone beyond it for TSCA purposes. If the purpose of the experimental use is to determine customer acceptance or economic viability, or if the pesticide is distributed to consumers, the pesticide would fall outside the scope of R&D under TSCA.

d. *Research for non-commercial purposes.* As EPA proposed on December 27, 1984, research conducted for non-commercial purposes, as described in § 720.30(i), lies outside the scope of section 5 and is not subject to the requirements of the R&D exemption. EPA considers non-commercial purposes to be research activities conducted by academic, government, or independent not-for-profit research organizations, unless the activity is

intended for commercial use. If the research is funded by contract, joint venture, or other financial arrangement with the purpose of eventually producing a commercial product, the organization is not exempt from the requirements of section 5 for that substance. For example, research conducted under a research contract between a company and a university, where patent rights or trade secrets are held by the company, would be considered commercial R&D. In contrast, research funded by an outright gift from a company to a university, with no limitations on either the purpose for which the funds are to be used or the use to be made of the results of the research conducted, would be considered non-commercial R&D.

3. *Requirements.* a. *Evaluation and notification of risks.* Section 720.36(a)(2) of the proposed rule would have required manufacturers and importers to perform a risk evaluation of substances used for R&D, and to notify persons engaged in the R&D of any risks identified. Companies reviewing risks would have to consider information in their possession or control (see discussion in unit II.C.) and all proposed or final rules issued under sections 4, 5, or 6 of TSCA. EPA has retained this provision in the final rule, with one modification: Manufacturers are not required to consider proposed rules in their evaluation of risks. EPA has revised this provision because of the tentative nature of many proposals, and because of the difficulty manufacturers may have in ascertaining whether a specific substance is the subject of a proposal. However, those manufacturing chemical substances under the exemption for R&D should nevertheless consider all available information on potential health and environmental risks, including information accompanying proposed EPA rules and advanced notices of proposed rulemaking.

Section 720.36(b)(2) of this rule, like the proposal, exempts manufacturers of chemical substances used solely in laboratories operating according to prudent laboratory practices from the requirement to evaluate risks. EPA has defined the term laboratory for the purposes of this rule as a contained research facility where relatively small quantities of chemical substances are used on a non-production basis, and where activities involve the use of containers for reactions, transfers, and other handling of substances designed to be easily manipulated by a single individual. The Agency discussed the nature of prudent laboratory practices in the **Federal Register** notice of December 27, 1984 (49 FR 50204).

Several commenters on the proposed rule have asked about the application of this definition to particular circumstances. The definition emphasizes the controlled use of small quantities, and certainly applies to laboratory work conducted by a team of researchers using prudent laboratory practices. The definition does not apply to R&D conducted in pilot plants, because such activities involve relatively large quantities of new chemical substances in situations where workers may operate under reduced controls. Some commenters have inquired as to whether the definition of laboratory and the exclusion from risk assessment include the activities of workers who dispose of the chemical substance for a laboratory. In that case, no chemical-specific risk assessment is necessary, but disposal must follow prudent laboratory practice.

Other commenters asked EPA to clarify whether R&D substances transferred from one laboratory to another were subject to the requirement for risk evaluation. As long as the substance is transferred to a laboratory operating under prudent laboratory practices, no chemical-specific risk evaluation is required. However, the distributing laboratory is required, in accordance with § 720.36(c)(2), to notify the person receiving the R&D substance that the substance is to be used only for purposes of R&D.

b. *Recordkeeping.* In the **Federal Register** of December 27, 1984, EPA proposed a two-tiered system for recordkeeping to document compliance with the requirements of the exemption for R&D. It has decided to retain the proposed system, which divides the equired records into two categories: those which must be kept for all new substances produced for R&D, and those which must be kept for chemical substances produced in larger volumes. It has, however, modified the requirements to reduce the burden of recordkeeping as much as possible while still ensuring effective documentation of compliance. EPA also retains the requirement that manufacturers or importers keep the specified records for 5 years, a period consistent with other PMN requirements and necessary for the Agency to monitor compliance effectively.

All persons producing chemical substances under the exemption for R&D, regardless of the amount, must document compliance with requirements for evaluation and notification of risks. The proposed regulation would have required manufacturers and importers to maintain copies of information reviewed and evaluated, but the final rule allows them to keep citations to this information, such as references to internal files or unpublished data, and to keep a record of the nature and method of the notifications given to workers. Those manufacturers or importers who use chemical substances in laboratories must document the prudent laboratory practices that excuse them from the requirements for risk evaluation. EPA considers the use and presence of codes of laboratory standards or handbooks such as those cited in the **Federal Register** of December 27, 1984 (49 FR 50201) to constitute evidence of prudent laboratory practices. Finally, if a manufacturer or importer distributes a chemical substance for purposes of R&D to another person in any quantity, EPA requires a record of the identity of the substance to the extent known, the names and addresses of persons to whom the substance is distributed, documentation of the quantities distributed, and copies of the notifications required under § 720.36(c)(2).

EPA has restructured the second set of records required from certain manufacturers or importers of an R&D substance. If the total quantity of the R&D substance produced in a year exceeds 100 kg, the manufacturer or importer must record the identity of the substance to the extent known, the volumes produced, and the disposition of the substance.

In the proposed rule, companies were required to keep records of the "identity" of R&D substances, unless less than 100 kg per year were produced or the substances were distributed to other persons. Several commenters pointed out that in certain circumstances manufacturers or processors may not know the specific identity of an R&D substance. To address this concern, EPA has modified the recordkeeping provision to require that the identity of the substance be kept to the extent it is known. Where the specific substance of the substance is not known, the company may identify it by company code, generic name, or some other indicator or they are in the articles or products.

The provision in the proposed rule that manufacturers and importers record the "method of disposal" of substances used for R&D led to some confusion. To clarify its intent, EPA has modified the final rule to require records of the "disposition" of R&D substances, rather than of their "methods of disposal." Companies are responsible for

documenting their own activities. They are not required by this rule to maintain records documenting what becomes of an R&D substance after their own activities are complete and they no longer have control of the substance.

The provision that manufacturers retain specific records when an R&D substance is distributed to other persons does not apply if the substance is incorporated into an article or exists in a final product as an impurity. If an R&D substance produced at more than 100 kg per year is incorporated into articles in the course of R&D or is included in a product as an impurity, manufacturers must record the disposition of the substance in the article or the final product (assuming the substance is produced at more than 100 kg per year), but they are not specifically required to document the disposition of the articles or products themselves, or the names and addresses of the persons to whom they are distributed. In addition, the specific quantities involved are not subject to the notification requirements of § 720.36(c)(2).

Beyond the specific records required by the rule, manufacturers and importers who conclude they are exempt from PMN requirements for a chemical substance used for purposes of R&D should be prepared to justify the nature and scope of their activities. EPA notes here that, although the final rule does not require manufacturers and importers of R&D substances to maintain records demonstrating that their activities constitute legitimate R&D, the burden of proving eligibility for the R&D exemption, as for any specific exemption from an otherwise applicable general statutory requirement, rests with the person claiming the exemption. EPA advises manufacturers and importers of R&D substances to be prepared to meet this responsibility should a question arise concerning their compliance with the general requirements for PMN or the exemption for R&D.

B. Data on Related Chemicals

EPA has reexamined the proposed requirement in § 720.50(c), published in the **Federal Register** notice of December 27, 1984 (49 FR 50209), that persons submitting a PMN provide the Agency with unpublished data on the health and environmental effects of chemicals, such as byproducts and feedstocks, which are related in the course of production to the new chemical substance which is the focus of the PMN. While section 5(d)(1)(B) and (C) of TSCA grants the EPA broad authority to require such data, EPA finds that it is not necessary to exercise this authority in the case of every new chemical substance. For most reviews of new substances, published data on the health and environmental effects of related substances and data submitted under section 8(e) will suffice to enable EPA to evaluate risks.

Should the Agency determine that data on related chemicals are essential to its review of a particular new chemical substance, it will request the additional data from the submitter, a procedure recommended by the Chemical Manufacturers Association (CMA). In a comment on the proposed rule, CMA wrote that in the event EPA required unpublished data on related chemicals, "EPA could ask the PMN submitter to search for the data the Agency needed to complete its review. If such data are available, the PMN submitter could provide them to EPA on request." This approach will provide a flexible method of securing information necessary to conduct premanufacture reviews. Accordingly, the requirements of § 720.50(c) have been deleted. EPA points out, however, that it is in the interest of submitters to provide the Agency with a full description of all available data relevant to a risk assessment of the chemical substance that is the focus of the PMN. Failure to provide this information, where it is important to assessing risk, may unnecessarily delay review of the PMN, potentially leading to extension of the review period and possible action.

EPA also reminds manufacturers and importers that existing provisions of the PMN rule still require them to submit certain information about related chemicals. Under § 720.45 of the PMN rule, paragraph (b) requires reporting of the identity and volume of impurities, and paragraph (d) requires descriptions of byproducts resulting from the manufacture, processing, and use of the new chemical substance. In addition, section 8(e) of TSCA requires manufacturers and importers to provide EPA with any information which they obtain which supports the conclusion that a substance or mixture presents a substantial risk to health or the environment.

C. Possession or Control

Section 5(b)(1)(B) of TSCA and § 720.50 of the PMN rule require manufacturers and importers to submit all health and environmental effects test data on the new chemical substance in their "possession or control." In addition, § 720.36(b)(1)(i) requires manufacturers or importers of R&D substances to evaluate certain information in their "possession or control" to meet the requirements for the exemption for R&D. EPA has made a slight change in the language of § 720.3(y) from the proposed rule to clarify that data in a manufacturer's or importer's possession or control include data in the files of its agents who are engaged in R&D, test marketing, or commercial marketing of the substance to the extent that the files are kept in that person's capacity as an agent. EPA considers these selected groups of individuals, who work under contract or special arrangement for a manufacturer or importer on a specific project, to be under that company's control for the scope of the project. Companies must request that the files of the agents engaged in such work be searched for data on health and environmental effects relevant to the activities they are under contract to pursue. EPA also includes within the scope of data in "possession or control" the files of persons engaged in research, development, test marketing or commercial marketing of a new chemical substance, and who are employed by companies associated with the submitter of the PMN but which are located outside the United States, unless the laws of the foreign nation forbid such a search.

D. Export-Only Chemicals

Section 12(a) of TSCA exempts from PMN new chemical substances which are manufactured or processed for export only and will not be used in the U.S. The proposed revision of § 720.3(s) would have limited processing to activities occurring under the control of the manufacturer or importer. In this final rule, EPA modifies the definition of the term "manufacture solely for export" to include processing which is not under the direct control of a manufacturer or importer, as long as it occurs solely for export. (The rule cross-references the definition of "process solely for export" in 40 CFR 721.3.) However, the manufacturer must know, by means of a contract or some other evidence, that the processing is occurring for export only. For substances to qualify as export-only chemicals, their processing must also be limited to activities which do not involve use. For example, formulating a mixture constitutes a legitimate form of processing for export-only chemicals, but their use as intermediates in chemical production does not.

E. Notification of Commencement of Manufacture

As discussed earlier in this notice, EPA allows a manufacturer or importer to use R&D material for non-R&D commercial purposes only after completion of the PMN review period,

except as described in § 720.36 (d) and (e). EPA has received queries about the timing of notification of commencement of manufacture in cases where PMN review has been completed, but the manufacturer intends to begin non-exempt commercial activities with quantities of the new chemical substance previously produced for purposes of R&D.

EPA requires persons to submit a notification of commencement of manufacture within thirty days of the start of non-exempt commercial manufacture of a new substance. If amounts of the new chemical produced for R&D already exist, a manufacturer or importer may use them for non-exempt commercial purposes as soon as the PMN review is complete, but that person may not submit a notification of commencement of manufacture until actual non-exempt manufacture begins. Section 720.102(a) has been revised to reflect this. In addition, even after the PMN review period ends, the new substance may be manufactured solely for R&D or solely for export. In that case, the manufacturer or importer should submit no notice of commencement of manufacture until non-exempt manufacture occurs.

III. Rulemaking Record

EPA has established a record for this rulemaking (docket number OPTS-50002L), which is available for inspection in Rm. E-107, 401 M St., SW., Washington, DC 20460, from 8 a.m. to 4 p.m. Monday through Friday, except legal holidays. Persons who do not have access to the record in the public reading room should contact Edward A. Klein, Director, TSCA Assistance Office (TS-799), at the above address for assistance.

The record includes information EPA considered in developing this rule. The record includes:

1. This notice and PMN documents cited in this notice.

2. Public comments.

3. Summaries of meetings with trade associations, public interest groups, and other groups.

4. Economic support documents.

5. Survey of research and development activities conducted by chemical firms.

6. All communications between EPA and persons outside the Agency pertaining to the development of the rule.

7. A document responding to public comments.

IV. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must determine whether a rule is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this rule is not major because it would not have an effect of $100 million or more on the economy. The rule will not have a significant effect on competition, costs, or prices. EPA submitted this rule to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has assessed the impact of this rule on small businesses. EPA has determined that since the rulemaking involves relatively minor revisions to the final PMN rule, it will not create additional impacts on small businesses over those already identified in the final PMN rule, 48 FR 21722.

C. Paperwork Reduction Act

The information provisions in this rule are a subset of the information collection requirements of the PMN rule, which has already been cleared by OMB under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* OMB control number is 2070-0012.

List of Subjects in 40 CFR Part 720

Chemicals, Environmental protection, Premanufacture notification, Hazardous materials, Recordkeeping and reporting requirements.

Dated: April 7, 1986.

Lee M. Thomas,

Administrator.

PART 720—[AMENDED]

Therefore, 40 CFR Part 720 is amended as follows:

1. The authority citation for Part 720 is revised to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2613.

2. In § 720.3, paragraphs (s) and (y) are revised to read as follows:

§ 720.3 Definitions.

* * * * *

(s) "Manufacture solely for export" means to manufacture or import for commercial purposes a chemical substance solely for export from the United States under the following restrictions on activities in the United States:

(1) Distribution in commerce is limited to purposes of export or processing solely for export as defined in § 721.3 of this chapter.

(2) The manufacturer or importer, and any person to whom the substance is distributed for purposes of export or processing solely for export (as defined in § 721.3 of this chapter), may not use the substance except in small quantities solely for research and development in accordance with § 720.36.

* * * * *

(y) "Possession or control" means in possession or control of the submitter, or of any subsidiary, partnership in which the submitter is a general partner, parent company, or any company or partnership which the parent company owns or controls, if the subsidiary, parent company, or other company or partnership is associated with the submitter in the research, development, test marketing, or commercial marketing of the chemical substance in question. (A parent company owns or controls another company if the parent owns or controls 50 percent or more of the other company's voting stock. A parent company owns or controls any partnership in which it is a general partner). Information is included within this definition if it is:

(1) In files maintained by submitter's employees who are:

(i) Associated with research, development, test marketing, or commercial marketing of the chemical substance in question.

(ii) Reasonably likely to have such data.

(2) Maintained in the files of other agents of the submitter who are associated with research, development, test marketing, or commercial marketing of the chemical substance in question in the course of their employment as such agents.

* * * * *

3. In § 720.30, paragraph (e) is revised and paragraph (i) is added to read as follows:

§ 720.30 Chemicals not subject to notification requirements.

* * * * *

(e) Any new chemical substance manufactured solely for export if, when the substance is distributed in commerce:

(1) The substance is labeled in accordance with section 12(a)(1)(B) of the Act.

(2) The manufacturer knows that the person to whom the substance is being distributed intends to export it or process it solely for export as defined in § 721.3 of this chapter.

* * * * *

(i) Any chemical substance which is manufactured solely for non-commercial research and development purposes. Non-commercial research and development purposes include scientific experimentation, research, or analysis conducted by academic, government, or independent not-for-profit research organizations (e.g., universities, colleges, teaching hospitals, and research institutes), unless the activity is for eventual commercial purposes.

* * * * *

4. Section 720.36 is revised to read as follows:

§ 720.36 Exemption for research and development.

(a) This Part does not apply to a chemical substance if the following conditions are met:

(1) The chemical substance is manufactured or imported only in small quantities solely for research and development.

(2) The manufacturer or importer notifies all persons in its employ or to whom it directly distributes the chemical substance, who are engaged in experimentation, research, or analysis on the chemical substance, including the manufacture, processing, use, transport, storage, and disposal of the substance associated with research and development activities, of any risk to health, identified under paragraph (b) of this section, which may be associated with the substance. The notification must be made in accordance with paragraph (c) of this section.

(3) The chemical substance is used by, or directly under the supervision of, a technically qualified individual.

(b)(1) To determine whether notification under paragraph (a)(2) of this section is required, the manufacturer or importer must review and evaluate the following information to determine whether there is reason to believe there is any potential risk to health which may be associated with the chemical substance:

(i) Information in its possession or control concerning any significant adverse reaction by persons exposed to the chemical substance which may reasonably be associated with such exposure.

(ii) Information provided to the manufacturer or importer by a supplier or any other person concerning a health risk believed to be associated with the substance.

(iii) Health and environmental effects data in its possession or control concerning the substance.

(iv) Information on health effects which accompanies any EPA rule or order issued under sections 4, 5, or 6 of the Act that applies to the substance and of which the manufacturer or importer has knowledge.

(2) When the research and development activity is conducted solely in a laboratory and exposure to the chemical substance is controlled through the implementation of prudent laboratory practices for handling chemical substances of unknown toxicity, and any distribution, except for purposes of disposal, is to other such laboratories for further research and development activity, the information specified in paragraph (b)(1) of this section need not be reviewed and evaluated. (For purposes of this paragraph, a laboratory is a contained research facility where relatively small quantities of chemical substances are used on a non-production basis, and where activities involve the use of containers for reactions, transfers, and other handling of substances designed to be easily manipulated by a single individual.)

(c)(1) The manufacturer or importer must notify the persons identified in paragraph (a)(2) of this section by means of a container labeling system, conspicuous placement of notices in areas where exposure may occur, written notification to each person potentially exposed, or any other method of notification which adequately informs persons of health risks which the manufacturer or importer has reason to believe may be associated with the substance, as determined under paragraph (b)(1) of this section.

(2) If the manufacturer or importer distributes a chemical substance manufactured or imported under this section to persons not in its employ, the manufacturer or importer must in written form:

(i) Notify those persons that the substance is to be used only for research and development purposes.

(ii) Provide the notice of health risks specified in paragraph (c)(1) of this section.

(3) The adequacy of any notification under this section is the responsibility of the manufacturer or importer.

(d) A chemical substance is not exempt from reporting under this Part if any amount of the substance, including as part of a mixture, is processed, distributed in commerce, or used, for any commercial purpose other than research and development, except where the chemical substance is processed, distributed in commerce, or used only as an impurity or as part of an article.

(e) Quantities of the chemical substance, or of mixtures or articles containing the chemical substance, remaining after completion of research and development activities may be:

(1) Disposed of as a waste in accordance with applicable Federal, state, and local regulations, or

(2) Used for the following commercial purposes:

(i) Burning it as a fuel.

(ii) Reacting or otherwise processing it to form other chemical substances for commercial purposes, including extracting component chemical substances.

(f) Quantities of research and development substances existing solely as impurities in a product or incorporated into an article, in accordance with paragraph (d) of this section, and quantities of research and development substances used solely for commercial purposes listed in paragraph (e) of this section, are not subject to the requirements of paragraphs (a), (b), and (c) of this section, once research and development activities have been completed.

(g) A person who manufactures or imports a chemical substance in small quantities solely for research and development is not required to comply with the requirements of this section if the person's exclusive intention is to perform research and development activities solely for the purpose of determining whether the substance can be used as a pesticide.

5. Section 720.50 is amended by removing and reserving paragraph (c) to read as follows:

§ 720.50 Submission of test data and other data concerning the health and environmental effects of a substance.

* * * * *

(c) [Reserved]

* * * * *

6. In § 720.78, paragraph (b) is revised to read as follows:

§ 720.78 Recordkeeping.

* * * * *

(b)(1) Persons who manufacture or import a chemical substance under § 720.36 must retain the following records:

(i) Copies of, or citations to, information reviewed and evaluated under § 720.36(b)(1) to determine the need to make any notification of risk.

(ii) Documentation of the nature and method of notification under § 720.36(c)(1) including copies of any labels or written notices used.

(iii) Documentation of prudent laboratory practices used instead of notification and evaluation under § 720.36(b)(2).

(iv) The names and addresses of any persons other than the manfacturer or importer to whom the substance is distributed, the identity of the substance to the extent known, the amount distributed, and copies of the notifications required under § 720.36(c)(2). These records are not required when substances are distributed as impurities or incorporated into an article, in accordance with paragraph (d) of this section.

(2) A person who manufactures or imports a chemical substance under § 720.36 and who manufactures or imports the substance in quantities greater than 100 kilograms per year must retain records of the identity of the substance to the extent known, the production volume of the substance, and the person's disposition of the substance. The person is not required to maintain records of the disposition of products containing the substance as an impurity or of articles incorporating the substances.

(3) Records under this paragraph must be retained for 5 years after they are developed.

* * * * *

7. In § 720.102, paragraph (a) is revised to read as follows:

§ 720.102 Notice of commencement of manufacture or import.

(a) *Applicability.* Any person who commences the manufacture or import of a new chemical substance for a nonexempt commercial purpose for which that person previously submitted a section 5(a) notice under this Part must submit a notice of commencement of manufacture or import.

* * * * *

[FR Doc. 86-8626 Filed 4-21-86; 8:45 am]
BILLING CODE 6560-50-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[OPTS-50527; FRL-2928-8]

Toxic Substances; Significant New Use Rules; Proposed Amendments to General Provisions and Individual Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing amendments to 40 CFR Part 721 and to four significant new use rules (SNURs) currently codified in Subpart B of Part 721, under section 5(a)(2) of the Toxic Substances Control Act (TSCA, 15 U.S.C. 2604(a)(2)). The Agency is proposing these amendments in order to clarify specific existing provisions, and to incorporate new sections developed in response to public comments.

DATE: Written comments should be submitted by June 23, 1986.

ADDRESS: Since some comments may contain confidential business information, all comments should be sent in triplicate to: Document Control Officer (TS-793), Office of Toxic Substances, Environmental Protection Agency, Rm. E-409, 401 M St., SW., Washington, DC 20460.

Comments should include the docket control number OPTS-50527. Nonconfidential comments and sanitized versions of confidential comments received on this proposal will be available for reviewing and copying from 8 a.m to 4 p.m., Monday through Friday, excluding legal holidays, in Rm. E-107 at the address given above.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, DC 20460. Toll free: (800-424-9065). In Washington, DC: (554-1404). Outside the USA: (Operator 202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Authority

Section 5(a)(2) of TSCA authorizes EPA to determine that a use of a chemical substance is a significant new use. EPA must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Once a use is determined to be a significant new use, persons must, under section 5(a)(1)(B), submit a notice to EPA at least 90 days before they manufacture, import, or process the substance for that use.

II. Background

On September 5, 1984 (49 FR 35011), the Agency promulgated 40 CFR Part 721, Subpart A—General Provisions. Subpart A contains general reporting provisions that apply to all SNURs. In addition, the Agency has promulgated SNURs in the current Subpart B to Part 721, covering a number of specific chemical substances.

The Agency has received public comments on the general provisions in Subpart A and on certain SNURs in Subpart B (listed in Unit III of this preamble). EPA also has received comments proposing adoption in certain SNURs of the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200). This rule is being proposed in response to all of these comments.

III. Summary of This Proposed Rule

The Agency is proposing the following amendments to 40 CFR Part 721: (1) Substantive revisions of §§ 721.5 and 721.10; (2) the addition of a new § 721.12 that would establish a mechanism whereby persons subject to SNURs in which worker exposure controls or environmental release controls are identified may seek an equivalency determination for alternative worker exposure and/or environmental release controls; (3) the redesignation of § 721.19 as § 721.18 and addition of a new paragraph that would establish procedures for advance compliance with SNURs; (4) the addition of a new § 721.19 that would establish risk evaluation, notification, and recordkeeping requirements applicable to the section 5(h)(3) research and development exemption for SNURs; (5) the addition of four sections that set forth hazard communication requirements for certain significant new uses, to be codified as a new Subpart B to be designated as Generic Requirements for Certain Significant New Uses; and (6) the redesignation of the existing Subpart B as Subpart C, and revisions of the following SNURs in that Subpart:

P-83-394 (§ 721.180, 49 FR 43653);
P-83-255 (§ 721.290, 49 FR 43064);
P-83-23, P-83-24, P-83-49, P-83-75, and P-83-272 (§ 721.615, 49 FR 50396);
P-82-684 (§ 721.975, 49 FR 42932).

IV. Agency Rationale

A. Persons Who Must Report

Section 721.5 describes those persons who must submit a significant new use notice. Paragraph (a)(2) requires each person who intends to manufacture, import, or process a SNUR substance for commercial purposes and who intends to distribute the substance in commerce to submit a significant new use notice. However, persons subject to paragraph (a)(2) currently are exempt from SNUR reporting requirements if they satisfy two requirements: (1) The person must not have a reasonable belief at the time of commercial distribution that customers intend to engage in a significant new use without submitting a notice to EPA, and (2) the person must be able to document that customers were notified in writing of the SNUR.

Subsequent to the promulgation of Subpart A, the Agency received comments requesting clarification of the responsibility of manufacturers, importers, and processors to submit significant new use notices as specified under the provisions of section 5(a)(1)(B) of TSCA and § 721.5(a)(2). Specifically questioned were the provisions of paragraph (a)(2). Concern was expressed that, as currently phrased, paragraph (a)(2) "might infer" an affirmative obligation upon manufacturers, importers, and processors to monitor or familiarize themselves with the activities of their customers. The Agency's intent, under this paragraph, was not the creation of an affirmative obligation for manufacturers, importers, and processors of SNUR substances to monitor or familiarize themselves with their customers' activities, when they would not do so as a normal course of business. The Agency simply intended to require a manufacturer, importer, or processor of a SNUR substance to submit a significant new use notice when that person has a reasonable belief that a customer intends to engage in a significant new use without submitting a notice to EPA.

Although the Agency believes this paragraph clearly exempts a manufacturer of a SNUR substance who has a reasonable belief that a customer does not intend to engage in a significant new use, there may be some ambiguity as to the circumstances when EPA will deem a manufacturer to have formed this "reasonable belief." To clarify its intent, the Agency is proposing to delete the phrase "reasonable belief" from § 721.5 and amend paragraph (a)(2) to specify that the Agency allows optional methods for SNUR compliance. Thus, a manufacturer, importer, or processor of a SNUR substance need not submit a significant new use notice if they do not intend to engage in the significant new use themselves, *and* they can document

(1) that they have provided all recipients of the substance with notice of the SNUR, (2) all recipients of the substance know of the SNUR, or (3) it is technically or otherwise infeasible for recipients of the substance to engage in the significant new use.

Under the revised § 721.5, then, the manufacturer, importer, or processor of a SNUR substance would have the flexibility of choice either to submit a significant new use notice, as required by TSCA (because recipients of the substance may engage in the significant new use) or to adopt EPA's optional method of compliance (by notifying recipients or by documenting that recipients otherwise know about the SNUR or cannot engage in the significant new use). The revised § 721.5 does not require customer notification, but instead offers an alternative means of compliance.

To provide consistency, the Agency is proposing to amend paragraphs (b), (c), (c)(1), and (2) of § 721.5 to reflect the changes in paragraph (a)(2). It is proposed that the phrase "reasonable belief" be deleted and replaced with the word "knowledge," and the word "customer" be deleted and replaced with the word "recipient."

B. Notice Requirements and Procedures

Section 721.10(d) provides that "any person submitting a significant new use notice in response to the requirements of this Part 721 shall not commence manufacture, import, or processing. . . ." Because a notice could be submitted under § 721.5 after manufacture, import, or processing has begun, the Agency intended that such manufacture, import, or processing not go on during the notice review period. Deleting the word "commence" clarifies this intention. The Agency is, therefore, proposing a technical amendment to § 721.10(d) to delete the word "commence" to clarify the meaning of this section.

C. Equivalency Determination

The Agency's approach to SNURs in which worker exposure or environmental release controls are identified for specific chemical substances is to ensure that: (1) Adequate measures are utilized to limit worker exposure and environmental release to reduce risk, or (2) EPA will receive notice of those circumstances when these controls may not be provided, and will have an opportunity to review the data in the notice before the significant new use occurs. These two Agency goals are attained when controls are employed which the Agency has previously reviewed and identified in a SNUR or when a SNUR notice is submitted and EPA has reviewed and acted upon the notice.

Comments to proposed SNURs which would require reporting for the failure to employ specific worker exposure controls or environmental release controls indicated a desire for EPA to create a means by which persons who manufacture, import, or process substances identified in SNURs could select alternative methods of controlling worker exposure or environmental releases (other than the methods identified in the SNUR). It was suggested that if alternative exposure or release control measures provided an "equivalent level of protection," such exposure or release controls might be allowed to begin without waiting 90 days for review of a SNUR notice.

There may be instances when alternative exposure or release controls that EPA has not considered are available to a manufacturer, importer, or processor. These exposure or release controls may provide protection from exposure or release that is substantially equivalent to or better than the controls identified in the SNUR. In those instances, the Agency is willing to evaluate those methodologies in an abbreviated fashion and possibly allow the substantially equivalent approach if it believes it reasonable to do so.

The Agency is proposing to amend certain SNURs and to add a new § 721.12 to the General Provisions for SNURs which would establish a mechanism by which manufacturers, importers, or processors of substances subject to SNURs may propose alternative exposure or release controls. Under this proposal, alternative controls which EPA determines provide substantally the same degree of protection against exposure or release would not constitute a significant new use because increased releases or exposure will not occur. The Agency would determine in each instance whether the alternative exposure or release controls provide protection substantially equivalent to those controls identified in the specific SNUR.

The Agency's new § 721.12 contains procedures for a manufacturer, importer, or processor to seek an EPA determination that the person's alternative exposure or release controls provide substantially the same degree of protection against exposure or release as the identified exposure or release controls in a specific SNUR—an "equivalency determination." The person would provide EPA information on the proposed exposure or release controls, and EPA would make a determination within 45 days. If EPA determined that the proposed alternative exposure or release controls provided substantially the same degree of protection as the specific controls in the SNUR, EPA would notify the person in writing, and the person could begin the activities using the alternative exposure or release controls. The person would not be in violation of the SNUR as long as the person continued to use those approved alternative exposure or release control measures.

A person asking EPA to determine whether alternative exposure or release controls provide substantially the same degree of protection as those in the SNUR would also be required to submit any test data in their possession or control or other data known to or reasonably ascertainable by them as they would in an SNUR notice (see § 750.50 (a) and (b) of the PMN rule). The person would not be required to submit any data which had already been submitted to the Office of Toxic Substances, for example, in a previous Premanufacture Notice (PMN) or SNUR notice or in a notice under section 8(e). EPA would not use this particular information to make the equivalency determination under the proposed § 721.12. Rather, the data would enable EPA to review whether the specific SNUR requires modification or whether other regulatory action might be necessary with respect to the specific chemical substance.

In addition, EPA is proposing that each provision of the affected SNURs which provides for specific controls to prevent worker exposure or environmental release be amended to include additional language which takes into account the new equivalency provision, § 721.12. These individual SNURs would identify the significant new use as the failure to use either the specified controls in the original SNURs or other exposure or release controls which EPA has determined provide substantially the same degree of protection against exposure or release as the original controls.

D. Research and Development Exemption

Section 5(h)(3) of TSCA exempts the manufacturer, importer, or processor of a chemical substance for a significant new use from the SNUR notification requirements if the substance is manufactured, imported, or processed only in small quantities solely for research and development (R&D), provided the manufacturer, importer, or processor notifies persons engaged in the R&D of any health risks that the company or EPA has reason to believe

may be associated with the chemical substance.

On May 13, 1983, EPA promulgated its general PMN rule (48 FR 21722) including § 720.3(cc) which defines "small quantities solely for research and development," § 721.0(ee) which defines "technically qualified individual," § 720.36 which set out the requirements to evaluate health risks and to notify persons engaged in the R&D activities of the risks, and § 720.78(b) which set out the associated recordkeeping requirements. After receiving comments from the public, EPA stayed §§ 720.36 and 720.78(b) pending further rulemaking. EPA proposed revisions of §§ 720.36 and 720.78(b) on December 27, 1984 (49 FR 50201), and is publishing these two provisions in a final rule elsewhere in this issue of the **Federal Register**.

Since §§ 720.36 and 720.78(b) were stayed at the time the general SNUR provisions were published in September 1984, EPA did not include specific requirements for SNUR-related R&D activities, pending the outcome of the PMN rulemaking activity. Now that the PMN rulemaking has been completed, EPA is proposing to redesignate § 721.19 as § 712.18, to modify § 721.18(b), and to add a new § 721.19 to specify the requirements that manufacturers, importers, and processors of a SNUR substance for a significant new use must meet to qualify for the section 5(h)(3) R&D exemption.

The proposed new § 721.19 is worded very closely to §§ 720.78 and 721.36. It applies only to persons who manufacture, import, or process a substance identified in a specific SNUR for a designated significant new use in small quantities solely for R&D. Proposed paragraphs (a), (b), and (c) relating to evaluation of risks and notification of persons conducting R&D activities and paragraph (e) containing recordkeeping requirements are virtually the same as §§ 721.36 (a), (b), and (c) and 721.78(b), respectively. A discussion of §§ 720.36 (a), (b), and (c) and 720.78 can be found in the final PMN rule preamble in this **Federal Register**.

No provision comparable to § 720.36(d) would be included in the new § 721.19 because the use of the substance would already be restricted by the other provisions of § 721.20 and the underlying SNUR.

Proposed § 721.19(d) would be comparable to § 720.36(e) but modified to allow quantities of the chemical substance, or of mixtures or articles containing the substance, to be disposed of, or used for commercial purposes other than R&D provided the disposal activity or use would not itself constitute a significant new use. If the disposal activity or the use would be a significant new use, a notice would be required.

No provision comparable to § 720.36(g) has been included. It is not necessary in a SNUR context because pesticide-related R&D activities would not constitute a significant new use.

The close correspondence between §§ 720.36 and 720.78(b) and the proposed new § 721.19 would ensure that persons engaging in R&D activities related to new chemical substances and to substances identified in SNURs would be able to conduct their risk evaluation, notification, and recordkeeping activities in the same manner, regardless of the type of substance, simplifying compliance.

E. Applicability of Proposed Rules to Uses Occurring Before Promulgation of Final Rules

In the preambles to previously proposed SNURs, the Agency described its finding that section 5(a)(1)(B) of TSCA is best served by determining whether a use is a significant new use as of the date of proposal. The Agency continues to maintain that this interpretation of section 5 reflects the intent of Congress with regard to SNURs; if uses begun during the proposal period of the SNUR were not considered to be significant new uses, it would be difficult for the Agency to establish SNUR notice requirements, because any person could defeat the SNUR by initiating a proposed significant new use before the rule became final.

Persons who engage in a proposed significant new use prior to promulgation of a final SNUR would be required to cease production and submit a SNUR notice as of the effective date of the final rule. However, it is not the intent of the Agency to unnecessarily disrupt the commercial activities of these persons. EPA therefore is proposing that such persons be allowed to comply with a SNUR before the rule is promulgated. If a company were to meet all of the conditions of advance compliance, as specified in the proposed new § 721.19(h) in Subpart A, the company would be exempt from the requirements of the final SNUR for those activities. It should be emphasized that EPA intends to use its full TSCA authority to control the company's activities should the Agency determine that such activities will present an unreasonable risk to human health or the environment.

The first requirement for advance compliance with a SNUR would be to submit a complete significant new use notice to EPA. Any person that submits an advance SNUR notice for a subject chemical substance would be required to follow the general notification requirements of § 721.10, except that the company would not have to submit the notice to the Agency at least 90 days before it begins manufacturing, importing, or processing. However, should the final SNUR be promulgated prior to completion of the Agency's review, the company would be required to cease manufacturing, importing, or processing for the remaining portion of the 90-day period. The notice would have to contain all requisite SNUR data, with limitations described in the applicable proposed SNUR.

EPA's procedures for the receipt, handling, and evaluation of advance significant new use notices under this rule generally would be the same as for any other significant new use notices. The Agency would publish a notice of receipt in the **Federal Register**, as required by section 5(d)(2) of TSCA. Nonconfidential data from the advance notice would be added to EPA's public file for SNUR notices. The Agency then would conduct an evaluation of all data from the advance SNUR notice, together with any other relevant data in EPA's possession. The Agency would determine whether the intended significant new use would adequately control exposure to and/or release of the substance (thus, preventing a potential unreasonable risk to health or the environment), and whether further regulatory action would be required.

There are four possible situations which may occur after EPA completes its review of an advance significant new use notice.

1. If there is sufficient information for EPA to conclude that the activities described in the notice would represent no unreasonable risk to human health or the environment under any reasonably foreseeable circumstances, the Agency would take no further regulatory action with regard to the proposed activities of the company. Under this option, EPA would notify the manufacturer, importer, or processor of its intent not to take further action. The company would be allowed to undertake the significant new use after the final SNUR became effective, without delay or the need to comply further with the rule for the activities described in the notice.

2. If there is not sufficient information for EPA to reasonabley determine whether the activities described in the notice would present an unreasonable risk under any reasonably foreseeable circumstances, but the Agency believes that the intended activities would not

pose such a risk if certain procedures or restrictions are followed (until additional data demonstrated them to be unnecessary), the Agency would attempt to negotiate a section 5(e) consent order with the company. The consent order would specify that the manufacturer, importer, or processor must follow the restrictions or procedures while undertaking the activities. If a consent order is signed, it would go into effect on the effective date of the final rule. The company would not be able to deviate from the terms of the consent order after the effective date without being in violation of TSCA.

3. If there is not sufficient information for EPA to reasonably determine whether the activities described in the notice would present an unreasonable risk under any reasonably foreseeable circumstances, and EPA and the company are not able to negotiate acceptable terms of a section 5(e) consent order, the manufacturer, importer, or processor would not qualify for an advance compliance exemption under the SNUR. The company therefore would be subject to the requirements of the final SNUR as though it had not submitted an advance significant new use notice, including ceasing the activities until it complies with the notice requirements.

4. If there is sufficient information for EPA to reasonably conclude that the activities described in the notice will present an unreasonable risk to human health and the environment, the manufacturer, importer, or processor would not have met all of the conditions of the advance compliance exemption. The Agency would not pursue a section 5(e) consent order in this case. Instead, the company would be required to cease the significant new use (if not already done) on the effective date of the final SNUR, submit a significant new use notice, and wait until completion of the statutory review period before resuming the activities. If the Agency believes that the risk requires immediate control, EPA could take action under TSCA section 6(a) (made immediately effective under section 5(f)) or section 7 to control the risk.

The Agency believes that its approach to advance SNUR compliance is an acceptable means of accomplishing its risk assessment and risk management objectives regarding possible significant new uses, without causing members of the regulated community to suffer unnecessary delays in their business activities. The advance compliance exemption in this rule would not waive EPA's enforcement authority with regard to any SNUR notice submitter.

F. Hazard Communication Requirements

The Agency is proposing amendments intended to establish certain generic hazard communication requirements that can be incorporated subsequently, by cross-reference, into individual SNUR notice requirements. In particular, certain SNURs could require the submission of significant new use notices for the failure to implement a communication program that includes, among other things, the labeling of packages containing certain substances, the creation and maintenance of material safety data sheets (MSDSs) for substances, and employee information and training programs.

This proposal is in response to comments received on certain SNURs which contained hazard communication requirements. Commenters suggested that EPA adopt the OSHA Hazard Communication Standard rather than promulgate communication requirements unique to each rule. Because these comments were not submitted in a timely fashion, and the Agency believed it to be in the public interest not to delay promulgation of potentially affected SNURs, these SNURs were promulgated without the suggested changes. However, at this time the Agency is proposing to amend these and other SNURs to make specific aspects consistent, to the extent appropriate under TSCA, with the relevant provisions of the recently promulgated OSHA standard.

These proposed amendments of individual SNURs would, in effect, substitute uniform hazard communication requirements for those similar elements now contained in the individual SNUR reporting triggers. For example, the segments of the SNUR covering the substance P–83–394 (§ 721.180, 49 FR 43653), which pertain to informing workers of the reasons for the specified worker protection equipment, would be altered under the proposed amendments. The rule would require the submission of a significant new use notice by manufacturers (excluding importers) and processors of the substance if they fail to provide workers with the requisite information in accordance with the proposed § 721.27 of Subpart B.

OSHA's Hazard Communication Standard places the burden of identifying hazards and the appropriate protective measures on the employer; however, under these SNUR amendments EPA would specify which potential hazards must be communicated and what protective measures must be employed.

For the purposes of SNURs incorporating the proposed hazard communication requirements, manufacturers, importers, and processors subject to such a SNUR would have the option to either comply with these requirements or submit a significant new use notice prior to manufacturing, importing, or processing. EPA's hazard communication requirements would apply regardless of whether the manufacturer, importer, or processor is subject to the OSHA Hazard Communication Standard.

G. Recordkeeping

The Agency has two goals for recordkeeping provisions contained in SNURs. They are: (1) To encourage conscientious compliance with these rules, and (2) to provide written records for compliance monitoring activities.

Comments have indicated that certain sectors of the chemical industry would prefer a more flexible approach to recordkeeping than that contained in certain SNURs. The comments have stated that requiring the maintenance of records which would "demonstrate compliance" would allow that flexibility. In particular, persons would have the option of incorporating recordkeeping for substances subject to SNURs into their present recordkeeping systems, rather than having to implement a completely different method of recordkeeping to comply with specific requirements of the Agency's present SNURs.

The Agency agrees, in part, with these comments and has investigated alternative recordkeeping strategies. The Agency has not, however, arrived at a final position with regard to this issue. In lieu of proposing recordkeeping amendments at this time, the Agency is choosing instead to solicit additional public comment. The Agency encourages persons to provide comments regarding recordkeeping, and is particularly interested in receiving comments that address recordkeeping strategies for previously published significant new uses, i.e., waste disposal, employee training, use of protective equipment, etc.

H. Conforming Changes

EPA is proposing minor changes to §§ 721.1, 721.5, 721.6, 721.7, and 721.10 to conform to the other elements of this proposal.

Economic Analysis

Promulgation of these amendments will result in costs to both EPA and

industry. However, as will be addressed below, the costs are not expected to be more than without the proposed amendments, and in some cases may be less. Where quantification is possible, the costs associated with each proposed amendment are discussed. In come cases, only a qualitative discussion is possible. The costs of the relevant sections of previously proposed SNURs (in the absence of the proposed amendments) are also discussed.

1. *Section 721.5 Persons who must report.* Companies involved in the manufacture, import, or processing of a SNUR substance would incur costs of compliance with this section. The costs could range from those costs associated with a letter notifying the customer of the existence of the SNUR, up to the costs of filing a SNUR notice. The Agency has estimated the costs of filing a SNUR notice to be $1,400 to $8,000. Additional costs of filing a SNUR notice could be incurred up to a 3.2 percent reduction in profits due to delays in manufacturing or processing and the costs of regulatory follow-up, if any.

The actual costs of notifying customers of the existence of a SNUR are expected to be minimal, e.g., the cost of a letter to the customer. The Agency believes that most companies will choose to document that customers know of the rule via a notification letter as it is the least costly alternative.

This proposed amendment will not result in any additional cost to future proposed SNURs; rather it clarifies an existing section in Subpart A.

2. *Section 721.12 Equivalency determination.* Based on comments to proposed SNURs which would require reporting for failure to employ specific worker exposure or environmental release controls, the Agency believes that most companies seeking an equivalency determination would either already have or will have access to the alternative controls for which they are seeking an equivalency, such companies would either have to submit a SNUR notice ($1,400 to $8,000 plus up to a 3.2 percent reduction in profits) and/or incur the cost of instituting the control as specified in the SNUR.

The cost to companies of this proposed amendment would be the costs associated with the development of the data submitted to the Agency, i.e., justification that the alternative exposure or release controls provide at least the same degree of protection. The Agency cannot estimate the exact costs at this time. Other costs associated with equivalency determination involve filing the request for equivalency determination, and delay costs during Agency review. The Agency expects the costs of filing the equivalency notice to be equal to or less than the costs of filing a SNUR notice, since the data required in a request for an equivalency determination are less than that required in a SNUR notice. In addition, any potential loss in profits due to delays associated with Agency review would be less. Delay costs are estimated to be a 3.2 percent reduction in profits due to delays in manufacturing and processing during the 90-day Agency review of SNUR notices. Delay costs associated with an equivalency determination would be half of delay cost for a SNUR notice, or a 1.6 percent reduction in profits due to delays during the 45-day Agency review.

Therefore, while the Agency cannot quantify the exact costs, the total costs are expected to be less for an equivalency determination than for submitting a SNUR notice.

3. *Section 721.19 Advance compliance.* The procedures for advance compliance are generally the same as for any SNUR notice. The manufacturer, importer, or processor must submit a complete SNUR notice. This notice would not, however, need to be submitted 90 days prior to commencing manufacture, import, or processing but could be submitted anytime between proposal and promulgation of the SNUR. The costs to the company for filing a SNUR notice are estimated to be between $1,400 and $8,000.

The major difference is that if the Agency negotiates with the company to control or limit the significant new use, or does not ban, the company can continue production of the chemical without interruption when the SNUR is promulgated, thereby avoiding any loss in profits usually attributed to delays in manufacturing or processing during Agency review.

If the Agency takes action or is unable to negotiate a control or limit, or would ban the chemical, the effect of the request for advance compliance is little more than advance notice to the company or the Agency's intention should the company pursue the significant new use after promulgation.

4. *Subpart B: Hazard communication requirements.* Manufacturers, importers, and processors subject to a SNUR incorporating the proposed hazard communication requirements have the option of complying with these requirements or submitting a SNUR notice. The costs of complying with these requirements would not differ from the costs previously assumed in each proposed SNUR; these costs are summarized below. It is important to note that EPA would specify which potential hazards must be communicated and what protective measures must be employed, unlike OSHA's Hazard Communication Standard which places the burden of identifying the hazards and the appropriate protective measures on the employer.

The proposed amendment contains requirements for employee information, labeling containers, and MSDSs. As in previously proposed SNURs, the Agency has not separated the cost of informing employees of the potential hazards associated with the use of one chemical from the employee training program assumed to be already in place. The initial labeling costs are estimated to be between $135 and $500, which is the development cost of the label. Other labeling costs are expected to be minimal. An MSDS has been estimated to cost $20 (this cost is for preparation of the form only).

To the extent the proposed amendments would allow employers to merge the SNUR requirements with the employers system to comply with the OSHA Hazard Communication Standard, the overall costs of compliance with the SNURs may be reduced.

VI. Confidential Business Information

Any person who submits comments which the person claims as confidential business information (CBI) must mark the comments as "confidential," "trade secret," or other appropriate designation. Any comments not claimed as confidential at the time of submission will be placed in the public file. Any comments marked as confidential will be treated in accordance with the procedures in 40 CFR Part 2. EPA requests that any party submitting confidential comments prepare and submit a sanitized version of the comments which EPA can place in the public file.

VII. Rulemaking Record

EPA has established a record for this proposal (docket control number OPTS-50527). A public version of this record from which CBI has been deleted is available to the public from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in the OTS Reading Room, Rm. E-107, 401 M St. SW., Washington, DC.

The record includes basic information considered by the Agency in developing this proposed rule. The record now includes the following:

1. The public comments which have prompted this action.

2. This proposal.

3. The economic analysis in support of this proposed rule.

VIII. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore requires a Regulatory Impact Analysis. EPA has determined that these proposed amendments are not "Major Rules" because they will not have an effect on the economy of $100 million or more and will not have a significant effect on competition, costs, or prices. While there is no precise way to calculate the potential annual cost of this proposal, for the reasons explained in this preamble, EPA believes that the cost will be low. In addition, because of the nature of the proposed amendments and the substances subject to them, EPA believes that there will be few significant new use notices and requests for equivalency determinations submitted.

These amendments were submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 605(b), EPA certifies that these amendments will not have a significant economic impact on a substantial number of small businesses. The Agency cannot determine whether parties affected by these amendments are likely to be small businesses. However, EPA believes that the number of small businesses affected by this proposed rule would not be substantial even if all the potential new uses were developed by small companies. EPA expects to receive few SNUR notices for the substances subject to the amendments.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in the proposed rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq. and has assigned OMB control number 2070–0012. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB, marked Attention: Desk Officer for EPA. The final rule package will respond to any OMB or public comments on the information collection requirements.

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Recordkeeping and reporting requirements, Significant new uses.

Dated: April 10, 1986.

J. A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

PART 721—[AMENDED]

Therefore, it is proposed that 40 CFR Part 721 be amended as follows:

1. The authority citation for Part 721 would continue to read as follows:

Authority: 15 U.S.C. 2604 and 2607.

2. In § 721.1 by revising paragraphs (a) and (b) to read as follows:

§ 721.1 Scope and applicability.

(a) This Part identifies uses of chemical substances which EPA has determined are significant new uses under the authority of section 5(a)(2) of the Toxic Substances Control Act. In addition, it specifies procedures for manufacturers, importers, and processors to report on those significant new uses. This Subpart A contains general provisions applicable to this Part. Subpart B of this Part identifies generic requirements for certain significant new uses cross referenced in specific provisions of Subpart C of this Part. Subpart C of this Part identifies chemical substances and their significant new uses.

(b) This Subpart A contains provisions governing submission and review of notices for the chemical substances and significant new uses identified in Subpart C of this Part. The provisions of this Subpart A apply to the chemical substances and significant new uses identified in Subpart C of this Part except to the extent they are specifically modified or supplanted by specific requirements in Subpart C of this Part. In the event of a conflict between the provisions of this Subpart A and the provisions of Subpart C of this Part, the provisions of Subpart C of this Part shall govern.

* * * * *

3. In § 721.5 by revising the entire section to read as follows:

§ 721.5 Persons who must report.

(a) The following persons must submit a significant new use notice as specified under the provisions of section 5(a)(1)(B) of the Act, Part 720 of this chapter, and § 721.10.

(1) A person who intends to manufacture, import, or process for commercial purposes a chemical substance identified in a specific section in Subpart C of this Part, and intends to engage in a significant new use of the substance identified in that section.

(2) A person who intends to manufacture, import, or process for commercial purposes a chemical substance identified in a specific section in Subpart C of this Part, and intends to distribute the substance in commerce. A person described in this paragraph is not required to submit a significant new use notice if that person can document one of the following:

(i) That the person has notified all recipients of the substance, in writing, of the specific section in Subpart C of this Part which identifies the substance and its designated significant new uses.

(ii) That the recipients have knowledge of the specific section in Subpart C of this Part which identifies the substance and its designated significant new uses.

(iii) That the recipients cannot undertake any significant new use described in the specific section in Subpart C of this Part.

(b) A person described in paragraph (a)(2) of this section must submit a significant new use notice if that person has knowledge at the time of commercial distribution of the substance identified in the specific section in Subpart C of this Part that a recipient intends to engage in a designated significant new use of that substance without submitting a notice under this Part.

(c) A person who processes a chemical substance identified in a specific section in Subpart C of this Part for a significant new use of that substance is not required to submit a significant new use notice if that person can document the following:

(1) That the person does not know the specific chemical identity of the chemical substance being processed, and

(2) That the person is processing the chemical substance without knowledge that the substance is identified in Subpart C of this Part.

(d) If at any time after commencing distribution in commerce of a chemical substance identified in a specific section in Subpart C of this Part a person described in paragraph (a)(2) of this section has knowledge that a recipient of the substance is engaging in a significant new use of that substance designated in that section without submitting a notice under this Part, the person is required to cease supplying the chemical substance to that recipient and to submit a significant new use notice for that chemical substance and significant new use, unless the person is able to document the following:

(1) That the person has ceased supplying the chemical substance to the

recipient when the person had knowledge that the recipient is engaging in a significant new use or processing the substance for a significant new use without submitting a notice under this Part.

(2) That the person has promptly notified EPA enforcement authorities that the recipient is engaging in a significant new use or processing the substance for a significant new use without submitting a notice under this Part.

(3) That the person has not resumed supplying the chemical substance to the recipient until all notices required under this Part have been submitted to EPA and the notice review periods have ended without regulatory action by EPA.

(e) Any significant new use notice relating to import of a substance must be submitted by the principal importer.

4. In § 721.6 by revising paragraphs (a) and (e) to read as follows:

§ 721.6 Applicability determination when the specific chemical identity is confidential.

(a) A person who intends to manufacture, import, or process a chemical substance which is described by a generic chemical name in Subpart C of this Part may ask EPA whether the substance is subject to the requirements of this Part. EPA will answer such an inquiry only if EPA determines that the person has a bone fide intent to manufacture, import, or process the chemical substance for commercial purposes.

* * * * *

(e) If the manufacturer, importer, or processor has shown a bond fide intent to manufacture, import, or process the substance and has provided sufficient unambiguous chemical identity information to enable EPA to make a conclusive determination as to the identity of the substance, EPA will inform the manufacturer, importer, or processor whether the chemical substance is subject to this Part and, if so, which section in Subpart C of this Part applies.

* * * * *

5. In § 721.7 by revising the entire section to read as follows:

§ 721.7 Exports and imports.

Persons who intend to export a substance identified in Subpart C of this Part, or in any proposed rule which would amend Subpart C of this Part, are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR Part 707. Persons who import a substance identified in a specific section in Subpart C of this Part are subject to the TSCA section 13 import certification requirements, which are codified at 19 CFR 12.118 through 12.127 and 127.28. The EPA policy in support of the import certification rquirements appears at 40 CFR Part 7076.

6. In § 721.10 by revising paragraphs (a), (b), and (d) to read as follows:

§ 721.10 Notice requirements and procedures.

(a) 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 manufacture, import, or processing of a chemical substance identified in Subpart C of this Part for a significant new use. The submitter must comply with any applicable requirement of section 5(b) of the Act, and the notice must include the information and test data specified in section 5(d)(1) of the Act. The notice must be submitted on the notice form in Appendix A to Part 720 of this chapter and must comply with the requirements of Part 720, except to the extent that they are inconsistent with this Part 721.

(b) If two or more persons are required to submit a significant new use notice for the same chemical substance and significant new use identified in Subpart C of this Part, they may submit a joint notice to EPA. Persons submitting a joint notice must individually complete the certification section of Part I of the required notification form. Persons who are required to submit individually, but elect to submit jointly, remain individually liable for the failure to submit required information which is known to or reasonably ascertainable by them and test data in their possession or control.

* * * * *

(d) Any person submitting a significant new use notice in response to the requirements of this Part 721 shall not manufacture, import, or process a chemical substance identified in Subpart C of this Part for a significant new use until the notice review period, including all extensions and suspensions, has expired.

7. By adding a new § 721.12 to read as follows:

§ 721.12 EPA approval of alternative control measures.

(a) In certain sections in Subpart C of this Part, significant new uses for the identified substances are described as the failure to establish and implement programs providing for the use of either: specific measures to control worker exposure to or environmental release of substances which are identified in such sections, or alternative measures to control worker exposure or environmental release, which EPA has determined provide substantially the same degree of protection as the specified control measures. Persons who manufacture, import, or process a chemical substance identified in such sections and who intend to employ alternative measures to control worker exposure or environmental release must submit a request to EPA for a determination of equivalency before commencing manufacture, import, or processing involving the alternative control measures.

(b) A request for a determination of equivalency must be submitted in writing and must contain:

(1) The name of the submitter.

(2) The specific chemical identity of the substance.

(3) The citation for the specific section in Subpart C of this Part which pertains to the substance for which the request is being submitted.

(4) A detailed description of the activities involved.

(5) The specifications of the alternative worker exposure control measures or environmental release control measures.

(6) An analysis justifying why such alternative control measures provide substantially the same degree of protection as the specific control measures identified in the specific section in Subpart C of this Part which pertains to the substance for which the request is being submitted.

(7) The data and information described in § 720.50 (a) and (b) of this chapter unless such data and information have already been submitted to the Office of Toxic Substances, EPA.

(c) Requests for determinations of equivalency will be reviewed by EPA within 45 days. Notice of the results of such determinations will be mailed to the submitter.

(d) If EPA notifies the submitter under paragraph (c) of this section that the Agency has determined that the alternative control measures provide substantially the same degree of protection as the specific control measures identified in the specific section of Subpart C of this Part which pertains to the substance for which the request is being submitted, then the submitter may commence manufacture, import, or processing in accordance with the specifications for alternative worker exposure control measures or environmental release control measures identified in the submitter's request, and

may alter any corresponding notification to workers to reflect such alternative controls. Deviations from the activities described in the EPA notification constitute a significant new use and are subject to the requirements of this Part.

8. By redesignating § 721.19 as § 721.18, by revising the introductory text and paragraphs (a) and (b), and by adding a new paragraph (h), to read as follows:

§ 721.18 Exemptions.

The persons identified in § 721.5 are not subject to the notification requirements of § 721.10 for a chemical substance identified in Subpart C of this Part if:

(a) The person has applied for and has been granted an exemption for test marketing the substance for a significant new use identified in Subpart C of this Part in accordance with section 5(h)(1) of the Act and § 720.38 of this chapter.

(b) The person manufactures, imports, or processes the substance for a significant new use identified in Subpart C of this Part in small quantities solely for research and development in accordance with § 721.19.

* * * * *

(h) The person submits a significant new use notice for the substance prior to the promulgation date of the section in Subpart C of this Part which identifies the substance, and the person receives written notification of compliance from EPA prior to the effective dates of such section. The notice submitter must comply with any applicable requirement of section 5(b) of the Act. The notice must include the information and test data specified in section 5(d)(1) of the Act and must be submitted on the notice form in Appendix A to Part 720 of this chapter. For purposes of this exemption, the specific section in Subpart C of this Part which identifies the substance and §§ 721.1, 721.3, 721.6, 721.13, and 721.17 apply; after the effective date of the section in Subpart C of this Part which identifies the substance, §§ 721.5 and 721.7 also apply. EPA will provide the notice submitter with written notification of compliance only if one of the following occurs:

(1) EPA is unable to make the finding that the activities described in the significant new use notice will or may present an unreasonable risk of injury to health or the environment under reasonably foreseeable circmustances.

(2) EPA and the person negotiate a consent order under section 5(e) of the Act, such order to take effect on the effective date of the section in Subpart C of this Part which identifies the substances.

9. By adding a new § 721.19 to read as follows:

§ 721.19 Conditions for research and development exemption.

(a) A person who manufactures, imports, or processes a chemical substance identified in Subpart C of this Part for a significant new use identified in Subpart C of this Part is not subject to the notification requirements of § 721.10 if the following conditions are met:

(1) The person manufactures, imports, or processes the substance for the significant new use in small quantities solely for research and development.

(2) The manufacture, importer, or processor notifies all persons in its employ or to whom it directly distributes the chemical substance, who are engaged in experimentation, research, or analysis on the chemical substance, including the manufacture, processing, use, transport, storage, and disposal of the substance associated with research and development activities, of any risk to health, identified under paragraph (b) of this section, which may be associated with the substance. The notification must be made in accordance with paragraph (c) of this section.

(3) The chemical substance is used by, or directly under the supervision of, a technically qualified individual.

(b)(1) To determine whether notification under paragraph (a)(2) of this section is required, the manufacturer, importer, or processor must review and evaluate the following information to determine whether there is reason to believe there is any risk to health which may be associated with the chemical substance:

(i) Information in its possession or control concerning any significant adverse reaction by persons exposed to the chemical substance which may reasonably be associated with such exposure.

(ii) Information provided to the manufacturer, importer, or processor by a supplier or any other person concerning a health risk believed to be associated with the substance.

(iii) Health and environmental effects data in its possession or control concerning the substance.

(iv) Information on health effects which accompanies any EPA rule or order issued under sections 4, 5, or 6 of the Act that applies to the substance and of which the manufacturer, importer, processor has knowledge.

(2) When the research and development activity is conducted solely in a laboratory and exposure to the chemical substance is controlled through the implementation of prudent laboratory practices for handling chemical substances of unknown toxicity, and any distribution, except for purposes of disposal, is to other such laboratories for further research and development activity, the information specified in paragraph (b)(1) of this section need not be reviewed and evaluated. (For purposes of this paragraph (b)(2), a laboratory is a contained research facility where relatively small quantities of chemical substances are used on a non-production basis, and where activities involve the use of containers for reactions, transfers, and other handling of substances designed to be easily manipulated by a single individual.)

(c)(1) The manufacturer, importer, or processor must notify the persons identified in paragraph (a)(2) of this section by means of a container labeling system, conspicuous placement of notices in areas where exposure may occur, written notification to each person potentially exposed, or any other method of notification which adequately informs persons of health risks which the manufacturer, importer, or processor has reason to believe may be associated with the substance, as determined under paragraph (b)(1) of this section.

(2) If the manufacturer, importer, or processor distributes a chemical substance manufactured, imported, or processed under this section to persons not in its employ, the manufacturer, importer, or processor must in written form:

(i) Notify those persons that the substance is to be used only for research and development purposes.

(ii) Provide the notice of health risks specified in paragraph (c)(1) of this section.

(3) The adequacy of any notification under this section is the responsibility of the manufacturer, importer, or processor.

(d) Quantities of the chemical substance, or of mixtures or articles containing the chemical substance, remaining after completion of research and development activities may be:

(1) Disposed of as a waste in accordance with applicable Federal, State, and local regulations, to the extent the disposal activity is not identified as a significant new use in Subpart C, or

(2) Used for a commercial purpose, to the extent the use is not identified as a significant new use in Subpart C of this Part.

(e)(1) Persons who manufacture, import, or process a chemical substance under this section must retain the following records:

(i) Copies of or citations to information reviewed and evaluated under paragraph (b)(1) of this section to determine the need to make any notification of risk.

(ii) Documentation of the nature and method of notification under paragraph (c)(1) of this section including copies of any labels or written notices used.

(iii) Documentation or prudent laboratory practices used instead of notification and evaluation under paragraph (b)(2) of this section.

(iv) The names and addresses of any persons other than the manufacturer, importer, or processor to whom the substance is distributed, the identity of the substance, the amount distributed, and copies of the notifications required under paragraph (C)(2) of this section.

(2) [Reserved]

10. By redesignating existing Subpart B as Subpart C, without any change in existing section numbers, and by adding a new Subpart B to read as follows:

Subpart B—Generic Requirements for Certain Significant New Uses

Sec.

721.20 Applicability.
721.27 Employee information.
721.30 Labeling for distribution in commerce.
721.32 Labeling for use in the workplace.
721.35 Material safety data sheets.

Subpart B—Generic Requirements for Certain Significant New Uses

§ 721.20 Applicability.

This Subpart B identifies generic requirements for certain significant new uses of specific chemical substances identified in Subpart C of this Part. The provisions of this Subpart apply only when referenced in specific sections of Subpart C of this Part.

§ 721.27 Employee information.

Whenever referenced in a specific section in Subpart C of this Part, the requirements for providing employees with information on the identified chemical substance are as follows:

(a) The manufacturer, importer, or processor shall ensure that employees are provided with information, either in writing or through training, on the substance identified in the specific section in Subpart C of this Part, at the time of their initial assignment to a work area where the substance is present, and whenever the substance is introduced into their work area.

(b) Information provided to employees shall include:

(1) The potential human health and/or environmental hazards, as specified in the specific section in Subpart C of this Part.

(2) The personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release identified in the specific section of Subpart C of this Part, or alternative control measures which EPA has determined under § 721.12 provide substantially the same degree of protection as the specified control measures.

(3) Identification of all operations in the employee's work areas where the substance is present.

(4) The location and availability of any material safety data sheets required for the substance by the specific section in Subpart C of this Part in accordance with § 721.35.

(5) Methods and observations that may be used to detect the presence or release of the substance in the employee's work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance, or odor).

§ 721.30 Labeling for distribution in commerce.

Whenever referenced in a specific section of Subpart C of this Part, the requirements for labeling containers of the chemical substance for distribution in commerce are as follows:

(a) The manufacturer, importer, or processor shall ensure that each container of the substance leaving the workplace is labeled in accordance with this section.

(b) The label shall contain the following information:

(1) The first word on the label shall be the word "WARNING."

(2) The name of the substance as identified in the specific section in Subpart C of this Part and the trade name or names by which may be commonly recognized.

(3) The potential human health and/or environmental hazards as identified in the specific section in Subpart C of this Part.

(4) The personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release identified in the specific section of Subpart C of this Part, or alternative control measures which EPA has determined under § 721.12 provide substantially the same degree of protection as the specified control measures.

(c) The first word on the label shall be capitalized, and the type size of the first word shall be no smaller than 6 point type for a label 5 square inches or less in area, 10 point type for a label above 5 but no greater than 10 square inches in area, 12 point type for a label above 10 but no greater than 15 square inches in area, 14 point type for a label above 15 but no greater than 30 square inches in area, or 18 point type for a label over 30 square inches in area, and the type size of the remainder of the warning statement shall be no smaller than 6 point type.

(d) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et seq.) and regulations issued under that Act by the Department of Transportation.

(e) If the label is to be applied to a mixture containing a substance identified in a specific section in Subpart C of this Part, in combination with another substance identified in a specific section in Subpart C of this Part and/or a substance defined as a "hazardous chemical" for the purposes of the Occupational Safety and Health Administration's Hazard Communication Standard (29 CFR 1900.1200), the manufacturer, importer, or processor may prescribe on the label the measures to control worker exposure or environmental release which the manufacturer, importer, or processor determines provide the greatest degree of protection. However, should these control measures differ from those identified in the specific sections in Subpart C of this Part, the manufacturer, importer, or processor must seek a determination of equivalency for such alternative control measures pursuant to § 721.12 before prescribing them on a label.

(f) The label shall be in English and shall be prominently displayed on the container. The label may be in languages other than English as long as the information is presented in English as well.

(g) The label shall be made available, upon request, to designated representatives of EPA.

§ 721.32 Labeling for use in the workplace.

Whenever referenced in a specific section in Subpart C of this Part, the requirements for labeling containers for the use of the chemical substance in the workplace are as follows:

(a) The manufacturer, importer, or processor shall ensure that each container of the substance which is in the workplace is labeled, tagged, or marked in accordance with this section.

(b) The label, tag, or other method of warning shall contain the following information:

(1) The first word shall be the word "WARNING."

(2) The name of the substance as identified in the specific section of Subpart C of this Part and the trade

name or names by which it may be commonly recognized.

(3) The potential human health and/or environmental hazards identified in the specific section in Subpart C of this Part.

(4) Any personal protective equipment, engineering controls, or other measures to control worker exposure and/or environmental release identified in the specific section in Subpart C of this Part, or alternative control measures which EPA has determined under § 721.12 provide substantially the same degree of protection as the specified control measures.

(c) If the label or alternative method of warning is to be applied to a mixture containing a substance identified in a specific section in Subpart C of this Part, in combination with another substance identified in a specific section in Subpart C of this Part and/or a substance defined as a "hazardous chemical" for the purposes of the Occupational Safety and Health Administration's Hazard Communication Standard (29 FR 1900.1200), the manufacturer, importer, or processor may prescribe on the label or alternative method of warning the measures to control worker exposure or environmental release which the manufacturer, importer, or processor determines provide the greatest degree of protection. However, should these control measures differ from those identified in the specific sections in Subpart C of this Part, the manufacturer, importer, or processor must seek a determination of equivalency for such alternative control measures pursuant to § 721.12 before prescribing them under this paragraph.

(d) Manufacturers, importers, and processors subject to this section may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the chosen method of warning identifies the containers to which it is applicable and conveys the information required by paragraph (b) (1) through (4) of this section. The written materials shall be readily accessible to the employees in their work area throughout each work shift.

(e) Manufacturers, importers, and processors subject to this section are not required to label portable containers into which substances identified in Subpart C of this Part are transferred from labeled containers, as long as the method chosen under paragraph (d) of this section identifies the containers to which it is applicable and conveys the information required by paragraph (b) (1) through (4) of this section.

(f) The manufacturer, importer, or processor subject to this section shall ensure that the label or other form of warning is legible, in English, and prominently displayed on the container, or readily available in the work area throughout each work shift. Employers with employees who speak languages other than English may provide the information in the employee's language, as long as the information is presented in English as well.

(g) The label or other form of warning shall be made available, upon request, to designated representatives of the EPA.

§ 721.35 Material safety data sheets.

Whenever referenced in a specific section in Subpart C of this Part, the requirements for obtaining or developing a material safety data sheet (MSDS) for the chemical substance are as follows:

(a) Each MSDS shall be in English and shall contain at least the following information:

(1) The name of the substance as identified in the specific section in Subpart C of this Part and the trade name or names by which it may be commonly recognized.

(2) The potential human health and/or environmental hazards as identified in the specific section in Subpart C of this Part.

(3) Any personal protective equipment, engineering controls, or other measures to control worker exposure and/or environmental release identified in the specific section in Subpart C of this Part, or alternative control measures which EPA has determined under § 721.12 provide substantially the same degree of protection as the specified control measures.

(4) Any time weighted average, threshold limit value, or other exposure limit identified in the specific section in Subpart C of this Part.

(b) If the MSDS is to be associated with a mixture that contains a substance identified in a specific section in Subpart C of this Part, in combination with another substance identified in a specific section in Subpart C of this Part and/or a substance defined as a "hazardous chemical" for the purposes of the Occupational Health and Safety Administration Hazard Communication Standard (29 CFR 1900.1200), the manufacturer, importer, or processor may prescribe in the MSDS the measures to control worker exposure or environmental release which the manufacturer, importer, or processor determines provide the greatest degree of protection. However, should these control measures differ from those identified in the specific sections in Subpart C of this Part, the manufacturer, importer, or processor must seek a determination of equivalency for such alternative control measures pursuant to § 721.12 before prescribing them under this paragraph.

(c) Manufacturers, importers, and processors subject to this section shall ensure that the information recorded in the MSDS accurately reflects the applicable terms and conditions provided in the specific section in Subpart C of this Part during the time that they manufacture, import, or process the substance identified in such section. Whenever the terms in the specific section of Subpart C of this Part are amended during the time that the manufacturer, importer, or processor is engaging in that activity, the manufacturer, importer, or processor shall revise the MSDS within 3 months of the effective date of such amendment.

(d) Manufacturers, importers, and processors subject to this section shall ensure that recipients of the substance identified in the specific section in Subpart C of this Part are provided an appropriate MSDS with their initial shipment and with the first shipment following the revision of an MSDS. The manufacturer, importer, or processor shall either provide the MSDS with the shipped containers or send the MSDS to the recipient prior to or at the time of shipment.

(e) The MSDS may be kept in any form, including operating procedures, and may be designated to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, the manufacturer, importer, or processor shall ensure that, in all cases, the required information is provided for each substance and is readily accessible during each work shift to employees when they are in their work areas.

(f) The MSDS shall be made available, upon request, to designated representatives of EPA.

10. In § 721.180 by revising the introductory text of paragraph (a)(2) (ii) and (ii) (A), and (B), and (C) to read as follows:

§ 721.180 Substituted polyglycidyl benzeneamine.

(a) * * *

(2) * * *

(ii) Manufacture (excluding import) or processing without:

(A) Requiring, during all stages of manufacture and processing of the

substance, and during response to emergencies or spills involving the substance, that any person employed by or under the control of the manufacturer or processor wear the following protective equipment, or employ other measures to control worker exposure which EPA has determined, in accordance with § 721.12, provide substantially the same degree of protection against exposure to the substance as the control measures described in this paragraph (a)(2)(ii)(A):

* * * * *

(B) Providing each employee described in paragraph (a)(2)(ii)(A) of this section with the following information in accordance with § 721.27: They should avoid all contact with this substance; structurally similar chemicals have been found to cause cancer and reproductive, kidney, and liver effects in laboratory animals, and allergic reactions in humans; this substance is a severe skin and eye irritant; and the use of impervious gloves, face shields, and other clothing to cover exposed areas of the arms, legs, and torso is required.

(C) Labeling containers for distribution of the chemical substance in commerce in accordance with § 721.30 to convey the information described in paragraph (a)(2)(ii)(B) of this section.

* * * * *

11. In § 721.290 by revising paragraph (a) (2)(ii) and (iii), to read as follows:

§ 721.290 Dicarboxylic acid monoester.

(a) * * *

(ii) Failure to require the use of gloves determined to be impervious to the substance, and/or failure to require the use of clothing to prevent dermal contact for any person involved in any processing or use operation where dermal contact may occur, or other measures to control worker exposure which EPA has determined, in accordance with § 721.12, provide substantially the same degree of protection against dermal exposure to the substance as the control measures described in this paragraph (a)(2)(ii). (Gloves may be determined to be impervious to the substance either by testing the gloves under the conditions of use or by relying on the manufacturer's specifications.)

(iii) Distribution in commerce without labeling containers in accordance with § 721.30 with the following information:

(A) The substance may be harmful if inhaled or absorbed through the skin.

(B) Persons must not breathe vapor, mist, spray, or dust containing the substance.

(C) Persons must not get any of the substance in the eyes, on skin, or on clothing.

(D) The substance is to be used only with adequate ventilation.

(E) Persons potentially exposed to the substance must wear impervious gloves and protective equipment to prevent contact or exposure and that contaminated non-impervious clothing must be promptly removed and washed before reuse.

(F) Contaminated leather shoes must be discarded.

(G) Persons exposed to the substance must wash thoroughly after handling the substance, and before eating, drinking, or smoking.

(H) All containers of the substance must be kept closed when not in use.

(I) The following first aid measures should be taken when necessary:

(*1*) In case of contact with eyes, immediately flush with water for at least 15 minutes.

(*2*) In case of contact with skin, promptly wash thoroughly with mild soap and water.

(*3*) In case of inhalation, remove the exposed person to fresh air. If breathing is difficult, give oxygen.

(*4*) In case of ingestion, and if conscious, give water and induce vomiting.

* * * * *

12. In § 721.615 by revising the entire section to read as follows:

§ 721.615 Substituted methylpyridine and substituted 2-phenoxypyridine.

(a) *Chemical substances and significant new uses subject to reporting.* (1) The following chemical substances referred to by generic chemical names and premanufacture notice numbers are subject to reporting under this section for the significant new uses listed in paragraph (a)(2) of this section: substituted methylpyridine (P–83–24, P–83–49, and P–83–272) and substituted 2-phenoxypyridine (P–83–23, and P–83–75).

(2) The significant new uses for P–83–49 and P–83–272 are manufacturing, importing, or processing without:

(i) Requiring use of the following personal protective equipment, or other measures to control worker exposure which EPA has determined, in accordance with § 721.12, provide substantially the same degree of protection against exposure to the substances as the control measures described in this paragraph (a)(2)(i), for persons involved in any operation where dermal contact and/or inhalation may occur, and where local exhaust ventilation is present at the site of the operation:

(A) Chemical cartridge respirator, approved by the National Institute for Occupational Safety and Health for protection from organic vapors, and used and fitted according to 29 CFR 1910.134 and 30 CFR Part 11.

(B) Chemical worker gloves and aprons or other equivalent personal protective clothing determined to be impervious to the particular substance in its conditions of use. (Equipment may be determined to be impervious either by testing under the conditions of use, including the duration of exposure, or by evaluating the specifications supplied by the supplier of the equipment.)

(ii) Requiring use of the following personal protective equipment, or other measures to control worker exposure which EPA has determined, in accordance with § 721.12, provide substantially the same degree of protection against exposure to the substances as the control measures described in this paragraph (a)(2)(ii), for persons involved in and in the immediate area of any operation where dermal contact and/or inhalation of the substances may occur, and where local exhaust ventilation is not present at the site of the operation:

(A) Full facepiece, positive pressure air-supplied respirator, approved by the Bureau of Mines, Department of Interior or by the National Institute for Occupational Safety and Health and fitted according to procedures established at 29 CFR 1910.134.

(B) Chemical worker gloves and aprons, or other equivalent personal protective clothing determined to be impervious to the particular substance in its conditions of use. (Equipment may be determined to be impervious either by testing under the conditions of use, including the duration of exposure, or by evaluating the specifications supplied by the supplier of the equipment.)

(iii) Providing each employee required to use the protective equipment described in paragraph (a)(2) (i) or (ii) of this section with the following information in accordance with § 721.27: Each of the substances may elicit liver, kidney, and nervous system toxicity; and the protective equipment described in this paragraph (a)(2) is required to be worn.

(3) The significant new uses for P–83–23, P–83–24, and P–83–75 are manufacturing, importing, or processing without:

(i) Requiring use of the following personal protective equipment, or other measures to control worker exposure which EPA has determined, in accordance with § 721.12, provide substantially the same degree of

protection against dermal exposure to the substance as the control measures described in this paragraph (a)(3)(i), for persons involved in any operation where dermal contact may occur.

(A) Chemical goggles.

(B) Chemical worker gloves and aprons, or other equivalent personal protective clothing determined to be impervious to the particular substance in its conditions of use. (Equipment may be determined to be impervious either by testing under the conditions of use, including the duration of exposure, or by the supplier of the equipment.)

(ii) Providing each employee required to use the protective equipment described in paragraph (a)(3)(i) of this section with the following information in accordance with § 721.27: Each of the substances may elicit liver, kidney, and nervous system effects in humans; P–83–23 and P–83–24 may cause skin and eye effects; P–83–23 and P–83–75 may cause reproductive effects; and the protective equipment described in paragraph (a)(3)(i) of this section must be worn.

* * * * *

13. In § 721.975 by revising the introductory text of paragraph (a)(2)(i), and paragraph (a)(2)(i)(B) to read as follows:

§ 721.975 Derivative of tetrachloroethylene.

(a) * * *

(2) The significant new uses are:

(i) Manufacturing, importing, or processing without requiring use of the following protective equipment, or other measures to control worker exposure which EPA has determined, in accordance with § 721.12, provide substantially the same degree of protection against exposure to the substance as the control measures described in this paragraph (a)(2)(i), for persons employed by or under the control of the manufacturer, importer, or processor who are in the immediate area of any operation where dermal contact and/or inhalation of the substance may occur:

* * * * *

(B) Labeled for use of the substance in the workplace in accordance with § 721.32 to convey the following information:

(*1*) The substance should be handled only while using a NIOSH approved respirator and impervious gloves.

(*2*) [Reserved]

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