Radio Technical Commission for Aeronautics (RTCA), RTCA Executive Committee; Notice of Meeting

Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. I) notice is hereby given of a meeting of RTCA Executive Committee to be held on May 16, 1986, in the RTCA Conference Room, One McPherson Square, 1425 K Street, NW., Suite 500, Washington, DC, commencing at 9:30 a.m.

The Agenda for this meeting is as follows: (1) Chairman's Introductory Remarks; (2) Approval of Minutes of Meeting Held March 25, 1986; (3) Executive Director's Report; (4) Special Committee Activities Report for March-April 1986; (5) Consideration of Proposals to Establish New Special Committees; (6) Consideration of Approval of Reports by Special Committees: a. SC–137 Proposed "Minimum Operational Performance Standards for Airborne Area Navigation Equipment Using Omega/VLF Inputs," b. SC–154 Proposed "Minmum Operational Performance Standards for Airborne Thunderstorm Detection Equipment"; (7) Other Business; (8) Date and place of next meeting.

Attendance is open to the interested public but limited to space available. With the approval of the Chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, One McPherson Square, 1425 K Street, NW., Suite 500, Washington, DC 20005; (202) 682–0266. Any member of the public may present at written statement to the committee at any time.

Issued in Washington, DC, on April 16, 1986.

S.B. Poritzky,

Designated Officer.

[FR Doc. 86–8693 Filed 4–21–86; 8:45 am]

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Sunshine Act Meetings

Federal Register
Vol. 51, No. 77
Tuesday, April 22, 1986

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]

BILLING CODE 8010–01–M

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.

* * * * *

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