federal register

Friday
November 7, 1980

Part VI

Environmental Protection Agency

Toxic Substances Premanufacture Notification Requirements and Review Procedures; Statement of Revised Interim Policy

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 720

[OPTS-50019; TSH-FRL 1653-5]

Toxic Substances Premanufacture Notification Rquirements and Review Procedures; Statement of Revised Interim Policy

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed-Rule-Related Notice.

SUMMARY: On January 10, 1979, EPA proposed rules and notice forms for permanufacture notification for new chemical substances under section 5 of the Toxic Substances Control Act, 15 U.S.C. 2604 (44 FR 2242). On that date, EPA also established an interim policy for the submission of premanufacture notices. This policy was to apply for 90 days after the effective date of the premanufacture notification requirement. On May 15, 1979, EPA published a statement of Interim Policy to clarify its earlier proposal (44 FR 28564). The latter statement extended the Interim Policy's coverage to all notices filed before the effective date of the final premanufacture rules and notice forms. The May 15 statement also outlined procedures that the Agency intended to follow concerning premanufacture notices filed under the Interim Policy.

This Revised Interim Policy Statement, is intended to clarify further the original interim policy. Provisions of the May 15 notice which are not addressed in this statement will remain in effect as published on May 15, until the final rules are promulgated.

ADDRESS: All materials regarding the premanufacture notification rulemaking are available for public inspection from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays at: Document Control Officer (TS-793). Office of Toxic Substances, Environmental Protection Agency, Rm. E-447, 401 M St. SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: John B. Ritch, Jr., Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-429, 401 M St., SW., Washington, DC 20460, Toll Free: 800-424-9065; in Washington, D.C., 202-554-1404.

SUPPLEMENTARY INFORMATION:

I. Background

On January 10, 1979, EPA proposed regulations governing the submission of premanufacture notices under section 5 of the Toxic Substances Control Act (TSCA or the Act) (44 FR 2242). Section 5 provides that any person who intends to manufacture (or import) a new chemical substance for a commercial purpose must submit a notice to EPA at least 90 days before he commences manufacture (or import). A "new chemical substance" is defined in section 3(a) of the Act as any chemical substance which is not included on the list of existing substances which EPA keeps under section 8(b). Premanufacture notices are required for all new chemical substances manufactured or imported 30 or more days after publication of the section 8(b) list. The notification requirement for any chemical substance manufactured, or imported in bulk became effective July 1, 1979, 30 days after publication of the Revised Inventory. The notification requirement for new chemical substances imported as part of a mixture was effective August 30, 1980, 30 days after publication of the Revised Inventory.

The preamble to the January 10, 1979 proposed regulations contained an interim policy for the submission of notices for new chemical substances to be manufactured or imported within 90 days after the section 5 requirement took effect (44 FR 2245). That policy covered notices submitted prior to publication of the Inventory, for chemicals believed to be "new" and which submitters intended to initially manufacture or import within 120 days after publication of the Inventory.

On May 15, 1979, EPA published another Statement of Interim Policy to clarify the terms of the initial interim policy statement. The May 15 statement replaced the interim policy published in January and applied to all notices received prior to the effective date of the premanufacture notification rules. Reporting under this policy began on July 1, 1979, 30 days after publication of the Inventory.

The purpose of this notice is to clarify the Interim Policy based on the comments received and on the Agency's experience with notices since July 1, 1979. As stated in the May 15 Interim Policy Statement, EPA cannot require compliance with the proposed regulations before completion of the rulemaking. However, pending final rulemaking, EPA will continue to act on a case-by-case basis when a notice fails to meet the statutory requirements. The provisions of the May 15 notice which are not addressed in this statement will remain in effect as published on May 15, until the final rules are promulgated.

The Agency currently is working on various aspects of section 5 rulemaking. EPA is reviewing comments received on the proposals of January 10, 1979 and October 16, 1979 (44 FR 59764). In addition, the Agency will propose the economic analysis and Draft Regulatory Analysis for public comment. In the Federal Register of August 15, 1980, the Agency proposed a rule extending reporting requirements to processors (45 FR 54642). This may be incorporated into the final section 5 rules. After a review of the economic analysis and the comments received on all these issues, the Agency will promulgate the final section 5 rules.

II. Notice Contents

Section 5(d) of TSCA requires that notices contain certain categories of information that are listed in section 8(a)(2) of the Act and reprinted in the May 15 Interim Policy. Persons who do not submit any data relevant to one of those categories or who submit little data should indicate in their notice that the missing information is "not known or reasonably ascertainable." This is preferable to simply failing to provide information without any explanation. However, in some cases EPA will presume that certain information is known to or reasonably ascertainable by the submitter. This may be true for some types of chemicals or processes in question, or for some kinds of information, such as production volume and use. EPA particularly will question responses by submitters that molecular structure is not known or reasonably ascertainable.

To date, EPA has received several submissions which initially did not meet these statutory requirements. The policy has been to notify the submitter as soon as possible of the inadequacy of the submission and what action must be taken to fulfill the statutory requirements. The notice period does not begin until the required information is provided by the submitter. To avoid similar problems, which cause both the submitter and the Agency unwanted delays, EPA is providing the following examples of responses which did not meet the statutory requirements.

One submission did not include the molecular structure of the new chemical substance. Section 8(a)(2)(A) requires this information to the extent that it is known to or reasonably ascertainable by the submitter. In providing identity information, submitters should follow the instructions for reporting for the Inventory. Substances with no known Chemical Abstract Service (CAS) number should be identified in accordance with Appendix 5 of

"Reporting for the Chemical Substance Inventory" which describes the development of chemical structure diagrams. If submitters cannot provide exact structural diagrams because of the nature of the substances, representative structures are satisfactory. For the notice in question, EPA scientists determined that representative molecular structures for the new chemical substance were in fact known to or reasonably ascertainable by the submitter because a knowledgeable chemist should have been able to derive the structure from available process information. Therefore, the notice review period did not begin until this information was provided to EPA.

Section 8(a)(2)(B) requires the submitter to include in the premanufacture notice the categories or proposed categories of use for the chemical substance described in the notice. The category of use should be specific enough to enable EPA to estimate potential consumer exposure as part of the risk assessment of the subject chemical. The Agency received several submissions that were incomplete since, without use information, it was unable to make reasonable assessments of consumer exposure. In one case, the submitter described the new substance only as a "captive intermediate" without specifying the substance's end use. Clearly EPA could not estimate consumer exposure from such a use description. Therefore, the 90-day review period did not start until the submitter supplied more specific use information.

Section 8(a)(2)(C) requires that a notice include "reasonable estimates of the total amount of the new substance to be manufactured or processed." In one case, the notice submitter only provided minimum production volume estimates. EPA does not believe that an estimate with only a lower limit is a "reasonable" estimate of the "total amount." Submitters should provide a range for production estimates, or at least provide an estimated maximum production volume.

Sections 8(a)(2) (D), (F) and (G) require submitters to describe the byproducts, the number of individuals exposed in their places of employment and the duration of that exposure, and the method of disposal of the new chemical, respectively. Such information should be provided for the total lifecycle of the new substance to the extent it is known or reasonably ascertainable. The submitter, knowing proposed uses of the new chemical, should be able to provide information on worker exposure, byproducts, and disposal beyond those processess such as manufacturing or processing over which the submitter has control. If such information is not known to or reasonably ascertainable by the submitter, EPA will make its own best estimates of worker exposure, byproducts and disposal for the lifecycle of the chemicals.

Regarding workplace exposure, one submitter only stated that exposures would be in accord with OSHA requirements. Such a statement is not sufficient to meet the statutory requirements of section 8(a)(2)(F) since EPA under TSCA may reach workplace exposures OSHA cannot. Section 8(a)(2)(F) requires estimates for workplace exposure, at least in the aggregate, and preferably divided among the stages of manufacture, processing, distribution in commerce, use, and disposal to the extent that they are known or reasonably ascertainable. The notice review period did not begin until the Agency had received this information.

In another case, a submitter only provided statements that exposures would be "minimal or nonexistent" or "no hazard". Such qualitative statements do not meet the requirements of section 8(a)(2)(F) for estimates of the number of individuals who will be exposed in their places of employment and the duration of that exposure. In this case, the notice review period did not begin until the Agency received quantitative exposure estimates.

Finally, section 5(d)(1)(B) requires the submission of any test data on the health or environmental effects of the new substance in the possession or control of the person submitting the notice. In some cases the Agency has received only conclusions based on the health or environmental effects data. A submitter should provide actual test data (including protocols or methods), results, and conclusions of tests for health or environmental effects of the new substance in the notice.

III. Use of the Notice Form

EPA proposed a notice form in January 1979 and proposed a revised form in October 1979. While use of a form is not mandatory until the Agency has completed its rulemaking, EPA strongly encourages submitters to use the revised form. Using the form will (1) provide the Agency with a consistent format, (2) speed the review process, and (3) provide the Agency with experience for additional, future clarification of the form when finally promulgated. Use of the form also benefits the submitters by allowing standard organization of data, thus reducing completion time.

The following is a brief explanation of the parts of the form which have most often raised questions.

Byproducts and impurities: Some submitters have been unsure where to list byproducts, impurities and other related substances. Impurities should be listed in Subsection 4 of Part I, Section B, Chemical Identity. Information on other related chemical substances, such as byproducts that are produced during manufacture of the new substance, should be included in the Block Diagram, Part II, Section A, Subsection 2. For industrial sites controlled by the submitter, Part II, Section A, Subsection 3.5, requests a listing of related chemicals to which workers may be exposed. For sites controlled by others, information on related chemicals such as byproducts or feedstocks should be provided in Part II, Section B, Subsection 2 as part of the process description and in Subsection 4.3 for those related materials that contain the new chemical substance and will be disposed of as solid or liquid waste. In addition, byproducts which are formed as a result of consumer and commercial categories of use should be reported in Part II, Section C, Subsection 4.

Manufacture, processing, use and disposal: Some submitters indicated that it is difficult to distinguish between manufacture, processing, use and disposal and as a result they were uncertain for which industrial sites they must submit information. Submitters must provide worker exposure and environmental release and disposal data for all industrial sites where activity with the new chemical substance occurs. The following examples will clarify where this information should appear on the form.

If submitter A produces a new solvent X to be used in paints, data on human exposure and environmental release during manufacture should be provided in Part II, Section A, Industrial Sites Controlled By the Submitter. If another party manufactures the substance under contract, this information should be provided in Section B, Industrial Sites Controlled By Others. If the solvent X is used in paint formulation, processing may be conducted by manufacturer A or it may be conducted by paint manufacturer B to whom manufacturer A has supplied solvent X. If A produces the paint at his own site, he should provide worker exposure and environmental release information in Part II, Section A. However, if manufacturer A supplies solvent X to manufacturer B, then manufacturer A should supply the worker exposure and

environmental release information in Section B.

Site-specific exposure and environmental release data are required only for use of the new substance at an industrial site. The paint containing solvent X in the previous example may be used to paint automobiles at an automotive manufacturing site not controlled by manufacturer A. In this case, A should provide information concerning worker and environmental release in Part II, Section B of the form. If, however, the paint containing the solvent X is distributed for general consumer use and no further use occurs at an industrial site, A should complete Part II, Section C, Consumer and Commercial User Exposure.

Site disposal information must be provided for any site where liquid or solid wastes are generated during manufacture, processing, or industrial use of the new chemical substance. For example, if disposal occurs at the manufacturing site, manufacturer A should complete Part II, Section A, Subsections 3 and 4. If disposal occurs at commercial or municipal disposal sites, manufacturer A should complete Section B. If solvent X is used by manufacturer B to produce auto paint, manufacturer A should report disposal by manufacturer B in Section B, no matter where disposal occurs. If solvent X is used as a degreasing agent at an automotive manufacturing site, manufacturer A should also report disposal of the waste solvent in Section B.

If the submitter controls an industrial site, Part II, Section A should be completed. If other persons control the site, Part II, Section B should be completed.

Category of use: Some submitters have asked what information should be provided on the categories of use that are the basis for the production volume estimates for Category of Use, Part I, Section D, Subsection 2. The category of use list should include all phases of industrial, commercial and consumer applications. For example, if the submitter intends to manufacture a new solvent to be used in house paint the following categories of use would be reported: solvent: paint manufacture, industrial; solvent: house paint, consumer, commercial.

Detailed data concerning human exposures and environmental release associated with these categories are required in Part II of the notice. Information concerning the processing of the new solvent in the manufacture of paint would be reported in Part II, Section A, if the submitter controlled the site, or Section B, if other persons controlled the site. Similarly, information concerning consumer use and exposure for the "house paint" category of use would be provided in Part II, Section C, Consumer and Commercial User Exposure. If the submitter believes that completion of these parts of the form does not explain the exact nature of each category of use, he may attach a narrative description of the operation and conditions that are expected for each category of use.

Human exposure and environmental release data: Some submitters have asked what kind of exposure data should be provided and how detailed it should be. Part II of the proposed form requires human exposure and environmental release and disposal data to be submitted for all industrial, commercial and consumer uses of the new chemical substance. In most places where quantitative estimates are requested, ranges have been provided. If ranges are not provided, submitters may use their own ranges. If submitters have information more detailed than that requested by the form, they may voluntarily provide such information.

Plant hours of operation: Some submitters were confused about reporting the hours of operation of the industrial plant that manufacturers, processes, or uses the new chemical substance. Estimates should be based on the operations that involve the new chemical substance only and not total hours of operation for each site.

Federal Register *notice:* The October 16 reproposal also included a page for information to be published in the **Federal Register** in accordance with section 5(d)(2) of the Act. This information comes from various parts of the form. The submitter is given the opportunity to provide generic substitutes for any of the information which would appear in the **Federal Register** but has been claimed confidential on the form. If the submitter does not complete this part of the proposed form, EPA will compile nonconfidential information from other parts of the form and publish it in the **Federal Register**.

IV. Confidentiality

Pending the promulgation of section 5 regulations, the assertion and review of confidentiality claims and the disclosure of information will be governed by EPA's general rules for confidentiality of business information submitted under TSCA (40 CFR 2.306.)

Until the section 5 rules are effective, the policy discussed below will apply to all information submitted to EPA under the premanufacture notification program. After the rules are effective, all such information in the possession of the Agency will be subject to the rules. EPA will give submitters ample opportunity to update past confidentiality claims to conform to the new rules.

A. Asserting Claims

As stated in the May 15 Interim Policy, if a person wishes to assert a business confidentiality claim for all or part of the information submitted to EPA, he must assert this claim with the notice. If the person does not assert a claim at the time he submits the information, EPA will make the information available to the public without further notice to the submitter.

If the submitter uses the proposed notice form, he may assert his claims of confidentiality in accordance with the instructions published as an appendix to the October 16 reproposal.

The form as proposed in October provided a system for asserting claims of confidentiality. The Agency, recognizing the relationship between various pieces of information, allowed submitters, by checking one box, to claim several pieces of related information confidential for the same reason. For example, if submitters want to claim confidential all the information in questions 1, 2, 3 under Manufacturer Identification (Part I) on page 2 of the proposed form, they only have to check the box at the top of Section A. There is no need to individually check the boxes next to items 1, 2, and 3 to assert the same claim of confidentiality.

If the submitter does not use the proposed form, section 2.203(b) of EPA's business confidentiality regulations prescribes the methods for claiming confidentiality. For example, confidential portions of otherwise non-confidential documents should be identified clearly. EPA strongly urges submitters to be as specific as possible in identifying confidential information. Each page of a document should be marked appropriately. In some cases, if non-confidential and confidential material are mixed on a single page, item-by-item markings would be appropriate. Section 2.203(b) also states that where a portion of an otherwise non-confidential document is asserted to be confidential, the person may submit separate confidential and non-confidential documents to facilitate identification and handling by EPA. The Agency strongly encourages persons to submit two copies of premanufacture notices if some of the information is claimed confidential. Section 5(d)(1) of TSCA requires the Agency to make public any non-confidential information in premanufacture notices. Therefore, if

a submitter does not file a non-confidential copy, EPA will prepare an excised copy for the public file, based upon the submitter's confidentiality claims. Submitter preparation of the public copy will ease the administrative burden on EPA, and will reduce the remote possibility that EPA inadvertently will disclose information which a submitter claims as confidential.

Another question raised about confidentiality concerns the treatment of generic names submitted to the Agency when the specific chemical identity of a new chemical substance is claimed confidential. The proposed form requests the submitter to provide three generic names. Because disclosure of more than one generic name could reveal the confidential chemical identity of a substance, EPA treats as confidential business information the two generic names not included in the section 5(d)(2) notice published in the Federal Register.

B. Substantiation of Claims

The Agency encourages submitters of notices containing claims of confidential business information to substantiate those claims when the notice is submitted. The October 16 reproposed form and accompanying instructions provide a method for substantiating the claims. If the claim is not substantiated, the Agency, early in the notification period, will send the notice submitter a detailed letter requesting substantiation of all information claimed confidential. EPA must do this to meet short Freedom of Information Act deadlines in view of the large number of requests received and anticipated. Therefore, the Agency encourages persons to substantiate their confidentiality claims at the time the notice is submitted and thus avoid the duplication and delay which is caused by separate substantiation.

Any information which the submitter furnishes in response to substantiation questions, can be claimed as confidential by marking Confidential at the top of each page containing such information. EPA will not disclose such information to the public unless ordered by a court.

C. Disclosure of Chemical Identity during the Interim Period

Pending completion of section 5 rulemaking, EPA will not disclose a specific chemical identity included in a health and safety study submitted with a premanufacture notice, if such disclosure would reveal confidential business information. This policy will apply both before and after a person has commenced manufacture or import of the substance. However, all information submitted to the Agency during the interim period will be subject to the section 5 rules when they become final.

V. Test Marketing Exemptions

Section 5(h)(1) of TSCA authorizes EPA, upon application, to exempt persons from any requirements of section 5(a) or section 5(b) of the Act, and to permit applicants to manufacture or process new chemical substances for test marketing purposes. To grant an exemption, the Agency must find that the test marketing activities will not present any unreasonable risk of injury to health or the environment. Section 5(h)(6) provides that EPA must either approve or deny the application within 45 days of its receipt and must publish a notice of its decision in the Federal Register. If EPA grants a test marketing exemption, it may impose restrictions on the test marketing activities.

Based on the exemption applications received to date, the Agency is concerned about the failure of test marketing applicants to provide sufficient data for EPA to make the required finding that the test marketing will not present any unreasonable risk of injury to health or the environment. For example, some manufacturers have not provided any toxicity data in their applications. In some cases, EPA may not be able to obtain sufficient information to determine that the substance will not present any unreasonable risk during test marketing and thus could not approve the application. To approve an exemption application, the Agency must make an affirmative finding that there will not be any unreasonable risk presented by the test marketing activities. It is not sufficient for EPA to find only that there is no basis to conclude that there may be an unreasonable risk. Moreover, EPA has only 45 days to determine if there is an adequate basis for making the statutory finding for approval of an exemption. This limits the extent to which EPA can search beyond the manufacturer's application for information indicating a lack of unreasonable risk.

If the manufacturer does not include adequate information to assess the risks presented by a proposed exemption and if data otherwise are not readily available to EPA during the 45-day review period for the applications, EPA will not be able to make the finding of no unreasonable risk and will deny the request for an exemption. Taken alone, the absence of data in the application will not be the basis for a denial. However, if at the end of the 45-day review period there is significant uncertainty concerning the risk presented because of a lack of data on the toxicity of, or exposure to, the chemical substance during test marketing, the Agency will not approve the application.

To facilitate review of applications and to enable EPA to meet the statutory burden for granting test marketing exemptions, applicants are encouraged to include, at minimum: all existing data regarding health and environmental effects of the substance, including physical and chemical properties and in the absence of such data, a discussion of toxicity based on Structure-Activity Relationships (SAR) and relevant data on the selected analogues; the maximum quantity of the substance which the applicant will manufacture for test marketing purposes; the maximum number of persons that may be provided the substance for test marketing purposes; the maximum number of persons who may be exposed to the substance as a result of test marketing, including information regarding duration, concentration, and route of such exposures; and a description of the test marketing operation, including its length, and how it can be distinguished from full-scale commercial production.

VI. Public Inquiries

Since the effective date of the premanufacture notification program, the Agency has received inquiries concerning various aspects of the program. This Revised Interim Policy Statement will outline the Agency's policy on how these inquiries will be handled.

EPA has received three types of inquiries related to the premanufacture notification program.

1. General inquiries concerning the status of the program.

2. Inquiries from persons preparing a notice or considering the submission of one, who have specific questions about their responsibilities.

3. Inquiries concerning notices that have been submitted to EPA.

Guidance for those who may wish to consult with the Agency in any of these areas is discussed below.

General inquiries: The Office of Toxic Substances (OTS) created an Industry Assistance Office to respond to general inquiries concerning the various programs operating under TSCA. General inquiries concerning the premanufacture notification program, not related to a specific chemical or notice, should be directed to the Industry Assistance Office. That office is open from 8:00 a.m. to 5:00 p.m., Monday through Friday (except holidays). Persons may contact that

office by telephone toll-free at 800–424–9065 or, in Washington, 554–1404. Written inquiries may be sent to: John B. Ritch, Jr., Director, Industry Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, Rm. E–429, 401 M St., SW., Washington, D.C. 20460.

Prenotice communications: The Notice Review Branch (NRB) of the Chemical Control Division (CCD), the office primarily responsible for implementation of the premanufacture notification program, employs a Prenotice Communications Coordinator to assist persons preparing a notice of considering the submission of one. Although a wide range of topics is covered under this category, the NRB Prenotice Communications Coordinator should be the initial Agency contact. The Coordinator will either respond directly to the question or refer the inquirer to the OTS staff person who can best answer the specific question. The NRB Prenotice Communications Coordinator can be reached by telephone at 202–426–3980 or by writing to the: Prenotice Communications Coordinator, Chemical Control Division (TS–794), Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

EPA staff may respond to telephone inquiries but the Agency will consider the response only informal advice by staff that may not necessarily represent the official Agency view. The Agency will treat prenotice communications with high priority and will respond as quickly as possible.

Inquiries about notices submitted to EPA: Once a notice has been submitted, a notice manager in the Chemical Control Division is assigned to that notice. The notice manager is responsible for coordinating the review of that notice and is the Agency spokeperson for all matters concerning the notice. During the review, as a general rule, no information about a specific notice, othe than that available in the Public File, will be discussed with anyone other than an authorized representative of the company and preferably only with those listed as company contacts on the notice. Persons wishing to speak with the notice manager for a particular notice can contact the NRB Prenotice Communications Coordinator for the notice manager's name and phone number. That information also is listed in the section 5(d)(2) Federal Register notice.

In addition, the Agency is establishing an Advisory Circular System to inform the regulated industry and the general public of EPA decisions or interpretations which may affect the implementation of section 5. The Advisory Circular System will provide information on the Agency's procedures under the Interim Policy and under the rules when promulgated. Subscriptions to the series can be obtained free of charge by writing to: John B. Ritch, Jr., Director, Industry Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, Rm. E–429, 401 M St., SW., Washington, D.C. 20460.

Dated: October 23, 1980.

Steven D. Jellinek,

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 80–34723 Filed 11–6–80; 8:45 am]

BILLING CODE 6560–01–M