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Part V

Environmental Protection Agency

Toxic Substances Control: Initial and Revised Inventories; Premanufacturing Notification Requirements and Review Procedures

ENVIRONMENTAL PROTECTION AGENCY

Office of Toxic Substances

Availability of TSCA Initial Inventory; Beginning of 210-Day Reporting Period for Revised Inventory

AGENCY: Environmental Protection Agency (EPA or the Agency).

ACTION: Notice of Availability of TSCA Initial Inventory; beginning of 210-day reporting period for Revised Inventory.

SUMMARY: This notice announces that the Initial Inventory of Chemical Substances, compiled under the authority of section 8(a) and (b) of the Toxic Substances Control Act (TSCA), will be published on June 1, 1979. EPA will distribute copies of the Initial Inventory throughout the month of May, in advance of this official publication date. The 210-day reporting period for processors and users of chemical substances and importers of chemical substances as part of mixtures or articles to add substances to the Initial Inventory will begin on June 1, 1979. On July 1, 1979 the premanufacture notification provisions of section 5 of TSCA will take effect for manufacturers and bulk importers of chemical substances for commercial purposes.

This notice explains how to obtain a copy of the Initial Inventory in printed form, microfiche, or computer-readable tape, and presents the Agency's policy for disclosing information from Inventory reports. In addition, this notice addresses reporting for the Revised Inventory, and responds to the significant comments received by EPA on the October 24, 1978 **Federal Register** notice which discussed EPA's policy for the Revised Inventory reporting period and proposed a draft report form. The last section of this notice, entitled "Industry Assistance," provides information on the kinds of materials and services provided by EPA's Industry Assistance Office.

FOR FURTHER INFORMATION CONTACT: Director, Industry Assistance Office, Office of Toxic Substances (TS-799), Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460. Or call the toll-free number 800-424-9065. In Washington, D.C. please call 554-1404.

SUPPLEMENTAL INFORMATION: The inventory reporting regulations (40 CFR Part 710) were promulgated under the authority of section 8(a) of the Toxic Substances Control Act (90 Stat. 2003; 15 U.S.C. 2601 et seq.). These regulations were published in the *Federal Register* on December 23, 1977 (42 FR 64572), and were supplemented on March 6, 1978 (43 FR 9254) and April 17, 1978 (43 FR 16178). These regulations implemented section 8(b) of TSCA, which requires EPA to compile, keep current, and publish a list of chemical substances manufactured, imported, or processed in the United States for a commercial purpose. This notice announces that the TSCA section 8(b) Inventory will be first published on June 1, 1979.

Section 710.6 of the inventory reporting regulations establishes a two-phase reporting schedule designed to prevent duplicative reporting. During the initial reporting period, manufacturers and certain importers reported to EPA concerning chemical substances they manufactured or imported for a commercial purpose since January 1, 1975. Manufacturers and importers reported most chemical substances for the Inventory by the May 1, 1978 reporting deadline. Since that date they have been reporting substances first manufactured or imported for a commercial purpose. Based on these reports, EPA has compiled an Initial Inventory. Manufacturers and importers may continue to report new chemical substances eligible for the Initial Inventory until July 1, 1979.

A second Inventory reporting period lasting 210 days will begin on the official publication date of the Initial Inventory. During this period, a person who processes or uses a chemical substance for a commercial purpose or imports a chemical substance as part of a mixture or article may report a chemical substance that was not included on the published Initial Inventory if the substance was manufactured, imported, or processed for a commercial purpose since January 1, 1975. Substances that are manufactured or imported (in bulk) for a commercial purpose for the first time after July 1, 1979 may not be reported for the Revised Inventory. As of that date, (thirty days after the June 1, 1979 official publication date of the Initial Inventory) the manufacturer or bulk importer of such a substance is subject to the premanufacture notification requirements of section 5(a)(1)(A) of TSCA. These requirements will apply to all persons who intend to manufacture or import (in bulk form) for a commercial purpose, a chemical substance not included on the Inventory. Rules governing premanufacture notification were proposed in the **Federal Register** on January 10, 1979 (44 FR 2242). The Agency has developed an interim policy to govern the submission and review of premanufacture notices until final rules are promulgated.

The premanufacture notification and Revised Inventory reporting requirements apply to any eligible chemical substance which is not included on the Inventory. The published list is not the complete Inventory. The published list alone can never be complete since substances are continually being added to the Inventory. Some substances were reported to late to be included on the published list. In addition, some reported substances were inadequately identified for the Initial Inventory, and publication of these substances has been delayed pending resolution of identity problems. These substances were reported in accordance with the Agency's inventory reporting regulations and are included in the Master Inventory File, which is maintained by EPA. The Initial Inventory includes all substances which are on the published list and other substances reported to EPA before July 1, 1979 in accordance with the inventory reporting regulations. As is discussed in greater detail below, this later category includes substances reported too late to be included on the printed Inventory, substances reported by Colour Index names about which there is some ambiguity, substances reported as products of reactions involving trade name materials, and some substances reported with ambiguous confidentiality claims. The Revised Inventory and premanufacture notification requirements do not apply to these substances.

Anyone who reported a chemical substance that is not on the published Inventory may contact EPA to verify that the substance is included in the Master Inventory File. In addition, persons who may be subject to premanufacture notification requirements may request a determination that a particular chemical substance is or is not on the Inventory. Requests should be directed to the Industry Assistance Office. Persons making such requests must provide complete, descriptive information about the substance. The Agency has provided guidance for identifying chemical substances in the instruction booklet "Reporting for the Chemical Substance Inventory", which may be obtained through the Industry Assistance Office. In response to a request, EPA will determine whether a particular chemical substance is included in the Master Inventory File. In those few cases where the chemical substance identity was ambiguous, EPA has requested the necessary additional information from

the manufacturer of the substance to resolve the identity. Persons who are unable to locate on the published Inventory a substance they process, or import as part of a mixture or article, should report the substance during the 210-day reporting period for the Revised Inventory.

Resolving chemical identity problems has been the major effort in compiling the Initial Inventory. Defining and naming chemical substances often involves a highly specialized vocabulary, detailed knowledge of the origin of substances, and the application of complex nomenclature rules. EPA has worked very closely with the Chemical Abstracts Service (CAS), numerous trade and technical associations, and individual reporting companies to assure that chemical substances are identified as accurately and unambiguously as possible on the Initial Inventory.

There are two classes of identity problems which merit separate discussion. First, some chemical substances were reported by Colour Index names. In processing these reports, EPA found that in many cases, although such names provided useful information about the substances, they did not sufficiently identify them. Information necessary to resolve ambiguities with respect to these substance identities has been requested from the reporting companies, and these substance identities will be published subsequently. Those Colour Index names which were reported for the Initial Inventory and about which there is some ambiguity are listed separately and will be distributed with the printed Initial Inventory as an addendum. These names do not appear on the microfiche or computer-readable versions of the Inventory; however, copies of the printed addendum will be included with these media versions. Persons who may report for the Revised Inventory should not be concerned about reporting substances that appear on this list. However, a person who intends to manufacture or import for the first time a substance which may be described by one of the listed Colour Index names should ask EPA to determine whether the particular substance he intends to manufacture or import is included in the Master Inventory File.

The second class of substances that merit separate discussion are those which were reported as products of reactions involving trade name substances (or mixtures). Where the reporting company was unable to give more than a general discription of the trade name material, and was therefore unable to identify sufficiently the substance it manufactures, EPA must request the precise identity of the trade name material from its manufacturer in order to resolve ambiguities about the identity of the substance. The identities of substances manufactured using these trade name materials will be published when their identities are resolved. EPA will take all necessary steps to protect the confidentiality of the data submitted by the manufacturer of the trade name product. EPA expects that in some cases these substances have already been reported for inclusion on the Inventory by persons who knew the complete identities of the substances.

Finally, some report forms were submitted with ambiguous confidentiality claims. To avoid inadvertent disclosure of confidential information, EPA has decided not to publish the substances identified on these forms on the Inventory until these claims are resolved.

Chemical substances whose identities are confidential for purposes of the Inventory are included on the Initial Inventory under the category "chemical substances with confidential identities." In accordance with the inventory reporting regulations, EPA has published generic names for most of these substances in an appendix to the Initial Inventory. However, generic names for some substances have not yet been approved. The Agency is continuing to review these names, and has been in contact with the affected companies. Since EPA knows the precise identities of these substances, the Agency will have no difficulty in responding to inquiries concerning whether a particular chemical substance is "new" or is already on the Inventory. EPA will only respond to such inquiries after a person establishes a *bona fide* intent to manufacture a chemical substance for a commerical purpose, in accordance with section 710.7 of the inventory reporting regulations. If the particular substance is included on the Inventory, premanufacture notification will not be required of the person proposing to manufacture the substance.

In the next few months, EPA will publish a supplement to the Initial Inventory. This supplement is expected to include substances that were reported for the Initial Inventory but do not appear on the published list for the reasons stated above. It will also include substances that have completed premanufacture review and have begun to be manufactured or imported for commercial purposes.

EPA expects to publish the Revised Inventory sometime in 1980. After publication of the Revised Inventory, it will become unlawful for any person to process or use for a commercial purpose a chemical substance that was manufactured or processed in violation of section 5 of TSCA. Thirty days after publication of the Revised Inventory, the premanufacture notification requirements of section 5 of TSCA will be applied to importers of new chemical substances as part of mixtures.

Initial Inventory

I. Content

The Initial Inventory lists over 44,000 chemical substances, identified by a preferred name and a unique Chemical Abstracts Service (CAS) Registry number. Each preferred name (and, for some substances, an associated definition) identifies a chemical substance or category of chemical substances reported to EPA by manufacturers and importers during the Initial Inventory reporting period. The accompanying indices, in three volumes, are intended to aid in the use of the Initial Inventory by providing different access routes to the published list.

The Initial Inventory is part of a four volume set. The Inventory itself is contained in Volume I, and includes two appendices. Appendix A: Chemical Substance Definitions, further identifies chemical substances whose preferred names alone on the Inventory do not permit their unambiguous identification. Appendix B: Confidential Chemical Substance Identities, lists generic names for substances whose specific chemical identities were claimed as confidential by all persons who reported them for the Inventory. The other three volumes, entitled *User Guide and Indices to the Initial Inventory*, were published for use in conjunction with, but not as a substitute for, the Initial Inventory. The three indices, the Substance Name Index (contained in Volume II and III) and the Molecular Formula and UVCB [1] Indices (contained in Volume IV) provide alternate means for finding substances which are listed on the Inventory.

In addition to these four volumes, EPA has published a two volume *Trademark and Product Name List*, which was compiled from Voluntary Product Trademark Report Form D's submitted to EPA during the Initial Inventory reporting period. This list was compiled solely to assist processors in determining whether to report for the Revised Inventory. Manufacturers who reported their products for inclusion on this list were required to certify that all the reportable chemical substances

[1] Chemical Substances of Unknown of Variable Composition, Complex Reaction Products, and Biological Materials

comprising the product have been reported for the initial inventory. If the person reporting the trademark only processed certain components of the product he had to certify that any component not included on the initial inventory would be reported by him for the Revised Inventory. (Refer to 43 FR 9254, March 8, 1978.) Therefore, if a processor finds the name of a product he processes on this list, he does not need to report the components for the Revised Inventory.

II. Availability

Due to the high cost of printing and distribution, EPA will provide only one free copy of the Initial Inventory (including the three indices and the Trademark and Product Name List), in printed form to each company, corporation (or subsidiary, division or major department of a large corporation if they are located in different geographical areas), or interested organization while supplies last. EPA encourages persons to request microfiche copies wherever equipment permits, since these copies are less expensive to print and distribute. Companies that have already reserved copies of the Initial Inventory can expect to receive them automatically—there is no need to reorder. Others may order copies by calling the Industry Assistance Office toll-free number listed above. Allow three weeks for delivery.

EPA will place reference copies of the Initial Inventory, in printed form or microfiche (as equipment permits), in the libraries of all large cities, GPO regional depository libraries, State environmental offices, and EPA Regional Offices. The Industry Assistance Office can direct persons to the nearest location. Persons requiring minimal access to the Inventory are encouraged to make use of reference copies, rather than ordering a complete copy of the Inventory from EPA.

Additional copies of the Initial Inventory in printed form may be purchased from:

Superintendent of Documents, Government Printing Office (GPO), Washington, D.C. 20402, Order Desk: 202/783-3238.

Requests for copies of the Initial Inventory and the three indices should specify the document number: GPO No. 055-007-00004-7 and be accompanied by a check or money order in the amount of $34.50 per four volume set. Requests for the two volume Trademark and Product Name List should specify the document number: GPO No. 005-007-00003-9 and be accompanied by a check or money order for $19.50. Requests for the complete, six volume set should specify both document numbers and be accompanied by a check or money order for $54.00. Persons who purchased printed copies of the Inventory from GPO are encouraged to inform EPA's Industry Assistance Office so that EPA can inform such persons of the availability of supplements to the Inventory.

Additional microfiche sets of the Initial Inventory, the three indices, and the Trademark and Product Name List may be obtained through the Industry Assistance Office while supplies last.

The Initial Inventory is also available on computer tape. The tape consists of two sections. The first section of the Inventory lists each substance by CAS Registry Number, preferred name, and, where appropriate, molecular formula. The second section is an alphabetic listing of chemical synonyms appearing in the Inventory. Only synonyms that were reported to EPA for the Inventory are included in this section, unlike the printed version which contans additional synonyms derived from CAS files. The tape does *not* include generic names for confidential substance identities nor the definitions prepared for certain substances, all of which appear in the appendices to the printed Inventory.

The computer readable version of the Inventory may be obtained by written request from:

National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22161, Sales Desk: 703/557-4650.

Requests should specify the document number EPA/DF-79/005 and be accompanied by check or money order in the amount of $125.00 per tape. Anyone who has a deposit account with NTIS on an American Express card may call the NTIS Sales Desk (703) 557-4620 and place the order by phone. A copy of the documentation for the computer tape may be obtained by calling the Industry Assistance Office.

Information Disclosure From Inventory Reports

The published Inventory only identifies the reported substances. There is no reference on the Inventory either to the company that reported the substance or to the additional data about each substance which was required by the inventory reporting regulations.

The elements of the set of data that exists in EPA's report records (both computerized and hardcopy) about each chemical substance (with the exception of substances reported by persons who were not required to provide every item of information) are: the chemical name and CAS Registry Number of the substance; plant site(s) [1] at which it was manufactured; for each plant site, how much of the substance was manufactured or imported in 1977 (reported by ranges); whether its manufacture was site limited; and whether it was manufactured or imported (activity). In addition, where a plan site was owned by a parent company, the name of the parent company (corporation) was usually reported. To the extent that items of information were claimed by the reporting companies to be confidential business information, EPA will initially honor these claims in answering requests by members of the public for information from Inventory records. Any initial denials for information will be made in accordance with EPA's Public Information procedures, which appear at 40 CFR Part 2 (as amended, 43 FR 39997, September 8, 1978; 44 FR 17673, March 23, 1979).

EPA is planning to create a data base that contains nonconfidential information from the Inventory records. If it is merited by the number of requests for information received, this data base will be set up as an independent operation for answering requests and will be made available on magnetic tape for purchase through the National Technical Information Service.

The confidentiality claims were made on the Inventory report forms in such a fashion that some elements could be individually claimed confidential and links between other elements could be claimed confidential. For instance, the production range, the fact that a substance was manufactured or imported (activity), and the fact that the substance was or was not site limited could be claimed confidential individually. The *link* between plant site or parent company and a particular chemical substance (and its CAS Registry Number) could also be claimed confidential.

In its initial answers to requests for information by members of the public, EPA will disclose only individual record elements or links which have not been claimed confidential. Suppose that in some hypothetical record the links between plant site, parent company, and chemical substance name (including CAS Registry Number) have been

[1] The space provided on the report form for plant site information was also used to report headquarters addresses for importers, small manufacturers, trade associations, or persons who reported optionally. Therefore, the data set for a particular substance does not necessarily include plant site information per se.

claimed confidential and no other elements have been so claimed. In answering an information request for all records about the particular chemical substance, EPA would disclose all nonconfidential elements (production range, site limited, manufacture or import) from the hypothetical record but would reveal no information identifying the plant site or parent company. If, on the other hand, only production range has been claimed confidential, EPA would disclose the plant site and parent company, and whether the substance was manufactured or imported, or site limited, but would not disclose the production.

In addition to the method of disclosure described above, EPA will apply certain other operational disclosure rules. These other operational rules have been formulated after studying possible Inventory confidentality problems, and are as follows:

1. The first operational rule is set forth in the September 8, 1978 amendment to EPA's Public Information procedures (43 FR 39999, section 2.113(d)). In instances where merely stating that a record exists will comprise confidential information, neither the existence nor the nonexistence of the record will be revealed. Instead, the initial answer to a requestor will be that the request is denied because either the record does not exist or it is exempt from disclosure. For example, suppose someone asked for all information on production of ethanol by XYZ Company, and suppose that XYZ Company had reported that it made ethanol but claimed the link between itself and ethanol as confidential. If EPA disclosed that a record existed which was covered by the request, it would be revealing the confidential link between XYZ Company and ethanol. Therefore, in this example EPA would apply its operational rule and answer the request by stating that the request is denied because either the record does not exist or it is exempt from disclosure.

This rule has a corollary. The same answer will be given to the requester *whether or not any record exists* in response to questions where the rule would apply. If it were revealed that a record does not exist when indeed none does, and the special answer were given only where a record exists but revealing its existence would compromise confidentiality, then the operational rule and the special answer it provides would not serve their intended purpose.

2. If either the fact that a substance was manufactured or the fact that it was imported has been claimed confidential in a record, EPA will not disclose whether the substance was manufactured *or* imported. For example, if a substance was manufactured and this fact was claimed confidential, EPA will not reveal either the fact that it was manufactured or the fact that it was *not imported*. Revealing that one or the other statement is not true would indirectly disclose the confidential information.

3. The inventory reporting regulations required persons to indicate whether a reported substance was site limited, and permitted persons to claim the fact that a chemical substance was site limited to be confidential. In processing the Inventory reports, EPA discovered that many companies claimed the fact that a substance was *not* site limited as confidential. EPA will honor both types of site limited claims. Therefore, if either the fact that a substance was site limited or the fact that it was not site limited was claimed as confidential, EPA will answer a request for this information by stating that the fact that a particular chemical substance either was or was not site limited is confidential. If no claim of confidentiality was asserted for this information, EPA will disclose whether or not the substance was reported as site limited.

4. Certain elements of the report records will be treated similarly for purposes of answering requests for information. The reports contained names and addresses for technical contacts at the plant sites. This technical contact information will be treated the same as the plant site name and addresses for disclosure purposes because both pieces of information identify the plant site. In addition, because of an unintended ambiguity in the reporting instructions, claiming the fact of either manufacture or import of a substance as confidential served also to claim corporation (parent company) as confidential. The instructions said that "by checking the box under 'Manufacture' ['Import'] for a particular chemical substance, you assert that the fact that *you* manufacture [import] the chemical substance at the plant site * * * is confidential" (emphasis added). The use of the word "you" made it possible for a reader to assume that not only the fact of manufacture or import but also the connection of the parent company could be claimed confidential at the same time.

5. EPA is not required to create records in response to a Freedom of Information Act request, and EPA will not create records by aggregating data from the Inventory records upon request. The term "aggregation" means, in this context, creating totals or other arithmetic or descriptive statistics which include elements of separate records. EPA is developing aggregation rules, and will propose these rules in the **Federal Register** for public comment in the near future. Each aggregation from Inventory records will be designed to avoid revealing any confidential information. Aggregations must also be designed so that they do not overlap.

Reporting for Revised Inventory

I. Who May Report

In accordance with § 710.3(b) of the inventory reporting regulations, the following persons may report a chemical substance that is not listed on the published Inventory for inclusion on the Revised Inventory:

1. a person who has processed or used a chemical substance (including use in the manufacture of a mixture or article containing that chemical substance) for a commerical purpose since January 1, 1975, or

2. a person who has imported a chemical substance as part of a mixture or article for a commercial purpose since January 1, 1975.

Any person who is permitted to report substances for the Revised Inventory may either report individually or authorize a trade association or other agent to report on his behalf (see § 710.5(f)).

II. When To Report

The reporting period for the Revised Inventory will begin on June 1, 1979 and will end on December 31, 1979. Persons who begin processing a chemical substance or importing a chemical substance a part of a mixture or article FOR THE FIRST TIME after December 31, 1979 may report such substance to EPA at the time processing or importation begins, up to thirty days after publication of the Revised Inventory.

III. How to Determine Whether To Report

The following suggested procedures are provided to assist persons in determining whether to report a substance for the Revised Inventory. There is no obligation to follow these procedures, and persons may use any suitable method to determine whether to report. (Refer to the response to Comment 1 below, under the heading "Significant Comments and Responses.") In general, if a processor has received written certification from his supplier that all the component

chemical substances in the product(s) he processes have been reported for the Inventory, the processor should not be concerned about reporting.

If a person knows the chemical composition of the product he processes or imports, he should consult the Initial Inventory to determine whether all the reportable chemical substances comprising the product are included. EPA encourages persons to read carefully the introductory material in Volume I of the Inventory. Of particular importance is the section entitled "*Eligibility Criteria* for Inclusion of Chemical Substances on the Inventory," which provides a detailed explanation of what is meant by the term "chemical substance" under TSCA, and the section entitled "Use of the Inventory." If the person determines that one or more component substances are not included on the published Initial Inventory, he should report them for inclusion on the Revised Inventory.

If a person does *not* know the chemical composition of the product he processes, he should consult the Trademark and Product Name List. If the product is listed, the processor can, in good faith, assume that the components are included on the Inventory, and he should not be concerned about reporting. (Refer to the response to Comment 2 below.) If the product is not listed, the processor should ask his supplier to do one of the following: (1) provide him with a letter certifying that all reportable chemical substances comprising the product have been reported for the Inventory, (2) reveal to the processor the identities of the component substances so that the processor may determine whether or not the substances are reportable, and, if they are, report them for the Revised Inventory, or (3) assist the processor in reporting by following the procedure outlined in the instruction booklet, "Reporting for the Chemical Substance Inventory" (May 1979). This procedure is described briefly in the response to Comment 1 below. If the supplier refuses to do any of the above, the processor is encouraged to write a letter to EPA, providing the name and address of the supplier and the name of the trademarked product, and indicating that his supplier has refused to provide him the information necessary to determine whether he should report for the Revised Inventory. EPA will then attempt to obtain the necessary information directly from the supplier. Letters should be addressed to: Document Control Officer, Attn: IMS, Office of Toxic Substances (TS-793), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460.

An importer of a chemical substance as part of a mixture or article may not know the specific identity of the chemical substance because the foreign supplier may choose to keep it confidential. In this situation, the importer may be assisted in reporting by the foreign supplier by following the procedure outlined in the instruction booklet for the Revised Inventory.

IV. Report Form E

All reports for the Revised Inventory must be submitted on an official Inventory Report Form E. One chemical substance may be reported on each form. EPA has published a revised edition of the original instruction booklet, "Reporting for the Chemical Substance Inventory" to assist persons in completing the form. Persons should determine how many substances they intend to report and order an instruction booklet and the appropriate number of report forms from EPA's Industry Assistance Office.

Persons who choose to report for the Revised Inventory must provide the following information on the form: (1) The name and address of the reporting company (or corporation, trade association or other agent); (2) the specific identity of the chemical substance (including its CAS Registry Number, if known); and (3) the activity the reporting company is engaged in with respect to the chemical substance (i.e., "process" or "import"). Persons should also provide the name, address, and phone number of a technical contact whom EPA may contact to clarify any information submitted on the form. It is extremely important that all information regarding the technical contact be complete and accurate, since a report may require clarification before the substance can be added to the Inventory.

In accordance with § 710.7 of the Inventory reporting regulations, persons who report for the Inventory may claim certain reported information to be confidential. The procedure for asserting confidentiality claims on Form E is discussed in detail in the chapter entitled "Confidentiality" in the instruction booklet.

V. Significant Comments and Responses

EPA received several comments in response to the October 24, 1978 Federal Register notice (43 FR 49688) which announced the Agency's policy for the Revised Inventory reporting period and proposed a draft report form. The following summarizes and responds to the significant issues raised in these comments. Comments that concern problems specific to one particular company are not included, as they were referred to EPA's Industry Assistance Office for direct reply.

Comment 1: EPA should not advise processors to ask their suppliers for written certification that the components of trademarked products are on the Inventory, as such requests will serve no other purpose than to create unnecessary paperwork. EPA should not interfere with the business relationship between a processor and his supplier.

Response: EPA *suggested* the procedure outlined in the section headed "Reporting Trademarks" (43 FR 49689) to assist processors in determining whether to report substances that may not be included on the Initial Inventory for inclusion on the Revised Inventory. Processors are not *required* to follow this procedure, and may use any means at their disposal to determine whether to report. EPA does not wish to create burdensome paperwork or interfere in industry business relationships; rather, EPA is concerned that persons take the necessary steps to ensure that they are in compliance with TSCA after the Revised Inventory is published.

In recognition of the difficulties that processors may have in identifying chemical substances, the Agency has revised its report form to encourage suppliers to assist their customers in reporting for the Inventory while at the same time permitting them to withhold from their customers the identities of confidential component substances. Under this procedure, a processor would complete blocks I through III of the report form(s) naming his supplier as the technical contact in block II, and send the form(s) to his supplier. The supplier would then enter the specific chemical identity of the substance(s) on the form(s) and submit the completed form(s) to EPA. Instructions for reporting in this manner are contained in the instruction booklet, "Reporting for the Chemical Substance Inventory" (May 1979). Refer to the section of this notice entitled "How to Determine Whether to Report" under the heading "Reporting for Revised Inventory."

Comment 2: EPA told processors that if a trademark appears on the Trademark and Product Name List, the component chemical substances "should not be reported for the Revised Inventory by anyone other than the person who reported the trademark." A processor or user may report any substance eligible for the Initial Inventory for inclusion on the Revised

Inventory. If a processor must rely on the owner of the trademark to report, he will have no assurance that the substance has been reported for the Inventory.

Response: In the March 6, 1978 supplement to the inventory reporting regulations (44 FR 9254) EPA allowed persons who only processed certain components of a trademarked product to report the trademark for the Trademark and Product Name List if the person amended the Voluntary Product Trademark Report Form D certification statement to certify that any component of the product that was not reported for the Initial Inventory would be reported by him for the Revised Inventory. EPA told processors that the component substances of the trademarked products should not be reported for the Revised Inventory by anyone other than the person who reported the trademark in order to prevent duplicative reporting. If processors reported the components of all products that appear on the Trademark and Product Name List, EPA would be inundated by unnecessary reports. Therefore, EPA discourages persons from reporting chemical substances that are components of products that appear on this list. The person who reported the product name and signed the Form D certification statement is responsible for reporting the components for the Inventory. However, if a processor has reason to believe that a particular component will not be reported for the Revised Inventory he may report the substance himself. EPA recognizes that it is in the processor's best interest to ensure that all the substances he processes are on the Inventory.

Comment 3: EPA should update the Trademark and Product Name List periodically, just as the Inventory will continue to be updated.

Response: The Agency does not intend to update the Trademark and Product Name List. EPA compiled and published the list solely to assist processors in determining whether to report for the Revised Inventory. After the Revised Inventory is published the Agency expects companies to have established an independent network to inform one another of the status of their compliance with TSCA. Since the components of certain products on the list may change over time, it would become increasingly difficult for EPA to be certain that the components of these products were actually included on the Inventory.

Comment 4: EPA should recognize that the terms "processor" and "user" are not synonymous. If the definition of "user" is restricted to one who "processes" a chemical substance for commercial purposes, a person who uses a chemical substance to lubricate or clean machinery, for example, would be prevented from adding the substance to the Inventory, and would risk having his supply of the substance interrupted.

Response: EPA recognizes that there is a distinction between processors and users of chemical substances. This distinction, however, is irrelevant for purposes of Inventory reporting. Under section 8(b) of TSCA, the Inventory is to include substances which have been manufactured (including imported) or processed for commerical purposes in the United States since January 1, 1975. The inventory reporting regulations permit users of chemical substances to report substances that have been manufactured or processed for commercial purposes since 1975, regardless of whether the user of the substance also manufactures or processes the substance. An eligible substance that is used to lubricate or clean equipment may be reported for the Inventory by a user if it has been manufactured or processed since 1975.

Comment 5: If a substance reported by a processor during the 210-day period cannot be manufactured until it is included on the Inventory, the processor risks an interruption in his supply of the substance until the Revised Inventory is published in 1980.

Response: EPA does not wish to impose economic hardships on processors by contributing to the interruption of supplies of chemical substances. Therefore, once a processor reports a substance and receives the postcard from EPA acknowledging receipt of the report form, his supplier may continue to manufacture the substance. However, EPA intends to survey reports from processors to determine whether the supplier is a manufacturer who should have reported the substance for the Initial Inventory. EPA will bring enforcement action, as appropriate, against suppliers who failed to report for the Inventory.

Although manufacture of the substance may continue once the acknowledgement postcard is received, this does not mean that the substance is included on the Inventory at that time. EPA must first determine whether the substance was reported in accordance with the inventory reporting regulations, i.e., the substance is eligible for inclusion on the Inventory. If there are any problems with the report, EPA will notify the submitter, who will be given an opportunity to make necessary corrections to the report. If the submitter does not make the appropriate amendments to the report, EPA cannot process the form and the substance will not be added to the Inventory unless it is reported by someone else. Thereafter, manufacture of the substance for a use subject to premanufacture notification requirements would be illegal.

Comment 6: The Thirty-day period following publication of the Initial Inventory is not long enough for persons to make corrections to the Inventory or to add substances that manufacturers or importers inadvertently omitted.

Response: The thirty-day period between publication of the Initial Inventory and the beginning of premanufacture notification is required by TSCA and is intended to ensure that persons have the Inventory in hand before premanufacture notification takes effect. There is no requirement that EPA give the industry an opportunity to review and correct the Inventory before the premanufacture notification requirements are activated. If a manufacturer discovers that he inadvertently failed to report a substance for the Inventory he should either report it himself during the thirty-day period or check with a processor or user of the substance to see if he has reported it. If a substance is not on the Initial Inventory, the manufacturer of the substance would be subject to premanufacture notification requirements. EPA's Office of Enforcement will investigate the reason why a substance was not reported for the Initial Inventory by its manufacturer. In deciding upon the appropriate enforcement action, EPA will determine whether there was good cause for the omission. If a reported substance is not included on the Inventory by an oversight on EPA's part, the reporting party should notify EPA of the omission as soon as possible. Notification of such an error may be made after the thirty-day period following publication of the Inventory, but should be brought to the Agency's attention as soon as it is detected.

Comment 7: EPA should provide companies that reported for the Initial Inventory a list of the CAS Registry Numbers and preferred names assigned to the reported substances to facilitate locating them on the Inventory.

Response: EPA does not plan to provide reporting companies with such lists. If a company is unable to locate a substance on the Initial Inventory because it does not know the CAS Registry Number by which the substance is ordered on the Inventory, the company should consult the indices to the Inventory. It should first search

for the substance name in the Substance Name Index. In most cases the name reported by the company will appear in this index as a synonym, even though EPA may have chosen a different or "preferred" name for inclusion on the Inventory. Companies can also search for a substnce on the inventory by using the other indices. (Refer to the Introduction to the Initial Inventory which appears in Volume I, and the User Guide to the three indices to the Initial Inventory.)

In the event that a company cannot locate the reported substance on the Initial Inventory using the indices, it may request verification from EPA that the substance is included in the Master Inventory File. Such requests should be directed to the Industry Assistance Office. EPA will require the inquiring company to provide information necessary to permit the Agency to comply with such a request. The kind of information necessary will be determined on a case-by-case basis, depending, in part, on what information, if any, was claimed confidential on the form.

Industry Assistance

EPA's Industry Assistance Office was established to provide industry with technical, policy, and procedural assistance in complying with TSCA, in accordance with section 26(d) of the Act. This office is prepared to provide the materials and services necessary for Inventory use and reporting. The following is a list of relevant materials which may be obtained through the Industy Assistance Office.

(1) The inventory reporting regulations (42 FR 64572, December 23, 1977)

(2) Supplements to the regulations (43 FR 9254, March 8, 1978; 43 FR 16178, April 17, 1978)

(3) Policy for Revised Inventory Reporting (43 FR 49688, October 24, 1978)

(4) Initial Inventory of Chemical Substances (May 1979); available in printed form or microfiche

(5) User Guide and Indices to the Initial Inventory—three volumes (May 1979); available in printed form or microfiche

(6) Trademark and Product Name List (May 1979)—two volumes; available in printed form or microfiche

(7) Inventory Report Form E (specify quantity)

(8) "Reporting for the Chemical Substance Inventory" (May 1979) instructions for reporting for the Revised Inventory

(9) Documentation for computer-readable version of the Initial Inventory

(10) Guidelines for Creating Proposed Generic Names for Confidential Chemical Substance Identities for the TSCA Inventory.

In addition to the materials listed above, the Industry Assistance Office provides the following services:

(1) Provides assistance in interpreting the inventory reporting regulations.

(2) Responds to inquiries concerning the contents and use of the Inventory.

(3) Handles requests for verification that a reported substance which does not appear on the printed Inventory is included on the most current Inventory maintained by the Chemical Information Division of EPA's Office of Toxic Substances. Requests for verification will be accepted over the telephone; however, all determinations will be transmitted in writing.

(4) Provides assistance in completing the report form.

The Industry Assistance Office may be contacted by calling the toll-free number 800-424-9065. In Washington, D.C. please call 554-1404.

In addition to the Industry Assistance Office, each EPA Regional Office is staffed by persons who can respond to inquiries concerning the inventory reporting regulations, the contents and use of the Inventory, and completion of the report form. The person to contact in each Regional Office is identified below.

Region I

Mr. Robert Dangel, John F. Kennedy Federal Building, Boston, Massachusetts 02203, 617-223-0585.

Region II

Mr. Michael P. Bonchonsky, Raritan Depot, Building 209, Edison, New Jersey 08817, 201-321-6673.

Region III

Mr. Edward Cohen, Curtis Building, 6th & Walnut Streets, Philadelphia, Pennsylvania 19106, 215-597-7668.

Region IV

Mr. Ralph W. Jennings, 345 Courtland Street, N.E., Rm 345, Atlanta, Georgia 30308, 404-881-3864.

Region V

Mr. Karl E. Bremer, 230 South Dearborn Street, Chicago, Illinois 60604, 312-353-2291.

Region VI

Dr. Larry Thomas, First Internation Building, 1201 Elm Street, Dallas, Texas 75270, 214-767-2734.

Region VII

Mr. William Brinck, 324 East 11th Street, 15th Floor, Kansas City, Missouri 64106, 816-374-3038.

Region VIII

Mr. Ralph Larsen, 1860 Lincoln Street, Denver, Colorado 80295, 303-837-3926.

Region IX

Mr. Jerry Gavin, 215 Freemont Street, San Francisco, California 94105, 415-556-3362.

Region X

Dr. James Everts, 1200 6th Avenue, Seattle, Washington 98101, 206-442-1090.

Dated: May 8, 1979.

Steven D. Jellinek,
Assistant Administrator for Toxic Substances.

[FRL 1236-6]
[FR Doc. 79-15133 Filed 5-14-79; 8:45 am]
BILLING CODE 6560-01-M

Toxic Substances Control; Premanufacturing Notification Requirements and Review Procedures; Statement of Interim Policy

AGENCY: Environmental Protection Agency (EPA).

ACTION: Statement of Interim Policy.

SUMMARY: On January 10, 1979, EPA proposed rules and notice forms for premanufacture notification for new chemical substances under § 5 of the Toxic Substances Control Act, 15 U.S.C. § 2604. (44 FR 2242) EPA also established an interim policy for the submittal of premanufacture notices. This interim policy applied to notices for substances intended to be first manufactured or imported for a commercial purpose between the effective date of the premanufacture notification requirement (30 days after publication of the Inventory under § 8(b)) and 90 days thereafter (i.e. 120 days after publication of the Inventory). This notice clarifies certain aspects of that interim policy, modifies it to a limited degree, and extends the interim policy to cover all notices filed prior to the effective date of the premanufacture rules and notice forms. In addition, it details the procedures the Agency intends to follow for premanufacture notices filed under the interim policy. Finally, this notice discusses EPA's policy on contacts with the public concerning premanufacture notification issues, prior to the promulgation of the § 5 rules.

DATES: As announced today elsewhere in this Federal Register, EPA will publish the Initial Inventory on June 1, 1979. The premanufacture notification requirement applies to any new chemical substance manufactured or imported for commercial purposes more than 30 days thereafter, or July 1, 1979. Interested persons may comment on this interim policy on or before June 14, 1979.

ADDRESS: Written comments on this interim policy should bear the document control number OTS-050002C and should be submitted in triplicate to the Document Control Officer (TS-793), Office of Toxic Substances, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460. EPA has established a public record for the premanufacture notification rulemaking. The public record is available for inspection in the Office of Toxic Substances Reading Room from 9:00 a.m. to 5:00 p.m. on working days (Room 709E, 401 M St., S.W., Washington, D.C. 20460).

FOR FURTHER INFORMATION CONTACT: Mr. John B. Ritch, Director, Office of Industry Assistance, Office of Toxic Substances (TS-799), U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; 800-424-9065 toll free; in Washington, D.C. call 554-1404.

SUPPLEMENTARY INFORMATION On January 10, 1979, EPA proposed regulations to govern submittal of premanufacture notices under § 5 of the Toxic Substances Control Act (TSCA). (44 FR 2242.) Section 5 requires any person who intends to manufacture (or import) a new chemical substance for a commercial purpose to submit a notice to EPA at least 90 days before he commences manufacture. Section 3(a) of the Act defines a "new chemical substance" as any chemical substance which is not included on the "list," or Inventory, of existing substances maintained by EPA under § 8(b). The notification requirement applies to all new chemical substances manufactured or imported on or after the 30th day after EPA first publishes the Inventory. As explained in the notice announcing publication of the Inventory which appears elsewhere in today's Federal Register, this effective date for the premanufacture requirement will be July 1, 1979.

In the preamble to the January 10, 1979, proposed regulations, EPA announced an interim policy for the submittal of notices for new chemical substances to be manufactured or imported within the first 90 days after the § 5 requirement becomes effective. (44 FR 2245.) This policy provided for submittal of notices before publication of the Inventory, and applied to a chemical substance believed by a person to be "new," and for which first manufacture or import for commercial purposes was intended between the effective date for premanufacture notification (30 days after publication of the Inventory under § 8(b)), and 90 days thereafter (i.e. 120 days after publication of the Inventory). EPA has received a number of inquiries and comments with regard to the interim policy, including questions concerning the Agency's policy for notices filed after publication of the Inventory.

The purpose of this notice is to clarify the terms of the interim policy, including limited modifications EPA has made in response to a petition from the Manufacturing Chemists Association, and to extend the policy and procedures discussed below to apply to all notices received before the effective date of the premanufacture notification rules.

EPA requests comment on this interim policy. If on the basis of these comments EPA believes that the policy should be modified or further clarified, the Agency will publish another notice in the Federal Register.

Overall Policy

Any person who intends to manufacture or import (in bulk) for a commercial purpose a new chemical substance on or after July 1, 1979, must submit to EPA a notice at least 90 days before the start of manufacture or import. The notice must satisfy the requirements of TSCA. EPA's § 5 rulemaking is intended to provide the Agency's detailed interpretation of the requirements of the Act. Pending completion of this rulemaking, EPA obviously can't provide comprehensive guidance. The interim policy therefore provides only limited guidance on submittal of notices prior to the effective date of the premanufacture rules and forms. Persons seeking further clarification concerning the statutory requirements should contact EPA.

In the January 10 interim policy statement, EPA stated that a notice should be filed on the proposed forms and in accordance with the proposed regulations. Some persons interpreted this statement to mean that EPA intended to make effective its proposed § 5 regulations before persons could comment and the Agency could consider the comments and promulgate final rules. Some persons also construed the term "should," used in explaining the interim policy, to mean that persons were required to comply with the terms of the proposal. EPA did not intend this meaning.

The Agency is taking this approach because it would be inappropriate to make these regulations effective pending completion of the rulemaking procedures. EPA has received a large volume of comments on the proposed premanufacture rules and notice forms, and is in the process of reviewing them. The provisions of this interim policy should not be considered an indication of the Agency's final resolution of the issues raised in the rulemaking proposal.

Submitters are free to follow EPA's proposed regulations. EPA will not take any action because a notice does not comply with the proposal. However, the Agency will take appropriate actions on a case-by-case basis in situations where a notice does not meet the statutory requirements.

Persons who manufacture, import or process substances which are included on the Inventory are not required to submit notices prior to manufacturing or processing the substances for new uses. At the present time, only the § 5(a)(1)(A) requirement for notice for a new chemical substance is in effect. A chemical included on the Inventory is not a new chemical substance. Section 5(a)(1)(B) of the Act requires persons to submit notices prior to manufacturing or processing a substance for a use which EPA has determined is a significant new use. In accordance with § 5(a)(2), the Agency must make this determination by rule promulgated after consideration of various factors. At this time, EPA has neither proposed nor promulgated any significant new use rules (SNURs). The Agency intends to utilize SNURs for selected existing chemical substances, and as a tool for followup of certain new chemical substances for which premanufacture notices are submitted under § 5. EPA intends to commence general rulemaking on SNURs during late 1979.

Timing of Premanufacture Review Period

The premanufacture review period will commence upon receipt of a notice which meets the statutory criteria. As soon as EPA receives the notice, the Agency will date stamp it and will transmit a notice of receipt to the submitter which indicates the official date when the notice period commences. The period will run for 90 days, unless the Agency for "good cause" extends the notice review period for up to an additional 90 days, under § 5(c) of the Act.

This position represents a change from the policy announced in the January 10, 1979, Federal Register notice. On February 2, 1979, the Manufacturing Chemists Association (MCA) submitted to EPA a petition requesting, among other things, that the Agency modify its policy on the timing of the review period. EPA has included the MCA petition and the Agency's response (dated March 2, 1979) in the public record of the premanufacture

rulemaking, and they are avialable for public inspection in the Office of Toxic Substances Reading Room.

Persons and Substances Subject to Section 5 Requirements

IN general, § 5(a) requires any person who intends to manufacture (including import) a new chemical substance for a commercial purpose to submit a premanufacture notice at least 90 days before he commences manufacture.

The Act contains a lengthy definition of the term "chemical substance" in § 3(a). Substances not falling within this definition are not subject to the premanufacture notification requirement. In addition to this statutory provision, § 710.4 of the inventory reporting requirements ("inventory rules") (42 FR 64572, December 23, 1977) excludes certain chemical substances from the requirement to report for the Inventory of chemical substances under § 8(b). Substances excluded under the inventory reporting rules will be excluded from the premanufacture notification requirements under this interim policy. Persons considering whether to submit a notice should consult TSCA and § 710.4 of the inventory rules to determine whether the premanufacture notification requirement applies.

The premanufacture notification requirement is applicable to both *manufacturers* and *importers* of new substances. Under § 720.10(a)(1) of the proposed rules, EPA stated that the requirement for manufacturers to submit a premanufacture notice included persons who intended to manufacture a substance solely for export from the U.S. EPA has received extensive comment on this requirement, and has not had the time to fully evaluate it. Therefore, in the interim, the premanufacture notification requirement will not apply to manufacture of a substance solely for export. However, EPA expects to include this provision in the final rules if the Administrator determines that such reporting is necessary to accomplish the purpose of TSCA.

In § 710.3 of the inventory rules EPA provides that, until publication of the Revised Inventory, only importers of new substances in "bulk form" will be subject to the premanufacture notification requirement. The inventory rules define "bulk form" to include imports in cans, bottles, drums, barrels, packages, tanks, bags and other containers, but not to include chemical substances imported as part of mixtures or articles. EPA's interim policy will implement the statute in a manner consistent with this limitation on importers' reporting responsibilities.

Information Submittal Requirements

Section § 5(d) of the Act requires that each notice include the following information:

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable:

(1) The common or trade name, the chemical identity, and the molecular structure of each chemical substance for which such a notice is submitted.

(2) The categories or proposed categories of use of each such substance.

(3) The total amount of each such substance manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.

(4) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance.

(5) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance in their places of employment and the duration of such exposure.

(6) The manner of method of disposal of the substance. (B) any test data in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and (C) a description of any other data concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

In providing the identity of the new chemical substance, the submitter should follow § 710.5 of the inventory rules, and the instructions EPA has prepared for inventory reporting ("Reporting for the Chemical Substances Inventory," U.S.E.P.A. December 1977, or "Instruction for Reporting for the Revised Inventory.") In particular, substances which have no known CAS number should be identified in accordance with Appendix 5 of the inventory instruction book, or chapter 3 of the instruction book for the Revised Inventory.

Persons who do not submit any data relevant to one of the categories discussed above, or who submit only a small amount of data, are encouraged to indicate in their notice that the missing information is not "known or reasonably ascertainable" or "not in possession or control", as appropriate. This will be preferable to simply failing to provide information for a category, without any explanation.

Procedures for Submittal of Notices

For expeditious handling, and for safe processing of confidential material, persons should submit notices to the following address:

Document Control Officer, Office of Toxic Substances (TS-793 PN), U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460.

Hand-delivered notices should be directed to: Document Control Officer, Office of Toxic Substances, Rm. 711, East Tower, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460.

A notice must be complete, including all referenced attachments and enclosures. It must be in English, or must be accompanied by an English translation certified to be accurate.

Each notice must include a certification, signed by an authorized representative of the submitting company, stating that the manufacturer or importer has complied with the statutory requirements of § 5. The following is an example of acceptable certification language:

I hereby certify that, to the best of my knowledge and belief: (1) I intend to manufacture (or import) for a commercial purpose (other than only in small quantities solely for purposes of research and development) the chemical substance for which this notice is submitted;

(2) all information contained in this notice is complete and truthful as of the date of submittal. Finally, the Agency expects each notice to include a complete identification of the submitter. The following information would constitute a sufficient identification:

(1) *Person Filing Notice*

Name of Authorized Office _____
Title _____
Organization _____
Mailing Address _____
Telephone Number _____

(2) *Incorporation Information*

Legal Title of Organization _____
Place of Incorporation _____
Street _____
City _____
State _____

(3) *Principal Place of Business*

Street _____
City _____
State _____

(4) *Technical Contact*

Name and Title _____
Street _____
State _____
Telephone Number _____

(5) *Parent Company* (Any company that owns or controls 50% or more of the submitter's voting stock).

Name _____
Street _____
City _____
State _____

Notice in the "Federal Register"

Section 5(d)(2) requires EPA to publish in the **Federal Register** a notice of receipt of each premanufacture notice within five days of receipt of the premanufacture notice. Subject to § 14, this notice must include an identification of the new substance, a list of uses or intended uses, and a description of certain test data. As a matter of policy, EPA will publish the notice in the manner described in § 720.32 of the proposed regulations. In addition, the Agency will publish the name of the submitting company, unless this information is claimed confidential. Persons should review the interim confidentiality procedures, below, with regard to EPA's policy on publication of information which a person considers to be confidential.

Notice of Commencement of Manufacture or Import

Any person who submits a notice under this interim policy, and who begins to manufacture or import the new substance for commercial purposes, must submit a notice of this fact to EPA on or about the date when manufacture or import commences so that the Agency can add the substance to the Inventory. At a minimum this notice must include the identity of the substance; the premanufacture document number which the Agency previously assigned to the substance in the § 5(d)(2) Federal Register notice; and the date upon which manufacture or import commences. There is no requirement that the notice be submitted in any particular form. It should be addressed to the Document Control Officer, Office of Toxic Substances, at the address indicated above.

This reporting requirement is imposed under § 8(b) of TSCA. That provision states "In the case of a chemical substance for which a notice is submitted under Section 5, such chemical substance shall be included in such list [the Inventory] as of the earliest date (as determined by the Administrator) on which such substances was manufactured or processed in the United States." EPA believes that a submittal of a notice of commencement is a reasonable method to implement this statutory provision.

Confidentiality

Pending the promulgation of § 5 regulations, the assertion and review of confidentiality claims, and the substantive determination of whether information should be disclosed, will be governed by EPA's general rules for confidentiality of business information submitted under TSCA, 40 CFR § 2.308. Section 2.308 incorporates by reference the bulk of the general provisions of 40 CFR Part 2, the Agency's rules for the handling of confidential business information. EPA amended 40 CFR Part 2 on September 8, 1978 (43 FR 39997) and on March 23, 1979 (44 FR 17673). The remainder of this section addresses what EPA believes those provisions require, and how the Agency will implement them. Except as stated to the contrary, EPA will follow the confidentiality procedures of 40 CFR Part 2. The Agency will resolve individual issues not covered by this discussion on a case-by-case basis, in accordance with 40 CFR § 2.308 and relevant provisions of TSCA.

Until the § 5 rules are final and 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 those rules. To the extent that EPA imposes new or different requirements in the rules, EPA will give submitters ample opportunity to update or modify confidentiality claims prior to becoming subject to any new requirements.

General Procedures for Asserting Confidentiality

A person may assert a business confidentiality claim for any information required to be submitted to EPA under TSCA, including any information submitted in the premanufacture notice or the notice of commencement of manufacture or import.

In accordance with 40 CFR § 2.203, 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 when he submits the information. He must assert this claim in the manner described in § 2.203(b) (See below.) The Agency will disclose information covered by such a claim only to the extent, and following the procedures, set forth in 40 CFR Part 2, Subpart B. If the person does not assert a claim of confidentiality at the time he submits the information, EPA will make the information available to the public without further notice to the submitter.

Section 2.203(b) of EPA's business confidentiality regulations prescribes the methods for asserting confidentiality claims. Among other things, confidential portions of otherwise non-confidential documents should be clearly identified. EPA strongly urges the submitter 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. Failure to submit two copies will not affect EPA's determination of whether confidential treatment is appropriate. Section 5(d)(1) of TSCA requires the Agency to make non-confidential information in premanufacture notices available to the public. Therefore if a submitter does not file a non-confidential copy, EPA will prepare an excised copy for inclusion in 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 will inadvertently disclose information which a submitter claims as confidential.

Substantiation of Claims for Certain Types of Information

If a person asserts a confidentiality claim with respect to the specific chemical identity of a new substance, or for health and safety data submitted with the notice, EPA will review the confidentiality claim and may immediately make an initial determination of whether the information is entitled to confidential treatment. EPA will take this action under § 2.204 even prior to the receipt of a request for release of the information, because the Agency has determined that EPA probably will be requested to disclose the information under the Freedom of Information Act (FOIA). Initiation of the procedures of § 2.204

early in the notification period will enable EPA to make all information not entitled to confidential treatment available to the public, and to more effectively meet FOIA response deadlines.

To speed up the process of making this initial determination of confidentiality, EPA strongly urges persons to substantiate their claims with respect to health and safety data and the specific chemical identity of the new chemical substance at the time the information is submitted. If a person wishes to subtantiate his claim for either type of information, his submittal must address the confidentiality questions developed by EPA. Separate questions are included below for use in substantiating claims for health and safety data and for specific chemical identity.

The substantiation must be signed by a responsible company official who has direct knowledge of the information. EPA will regard as confidential any information which the submitter furnishes in response to any of the substantiation questions set forth in this notice, provided the submittal is marked CONFIDENTIAL at the top of each page containing confidential information and provided that, if the information has previously been submitted otherwise, provided that, it is entitled to confidential treatment. If these conditions are met, EPA will not disclose this information without the consent of the submitter unless disclosure is ordered by a federal court.

If a person does not submit appropriate substantiation with his notice EPA automatically will give notice to the submitter under § 2.204(e) that the Agency is making a confidentiality determination. In its notice, EPA will afford the company the opportunity to substantiate its claim by submitting timely comments with respect to the questions which the Agency has developed. Under § 2.204(e) EPA will require the company to furnish substantiation within 15 business days of the company's receipt of the written notice. Persons who submit the appropriate substantiation with the § 5 notice will avoid the difficulties of preparing a thorough substantiation for the Agency in such a short time period. Section 2.205(d) provides that if a company fails to provide substantiation in a timely fashion, EPA shall determine that the company has waived its claim. In this event, the Agency will make such information available to the public without further notice to the submitter.

If the person submits substantiation as discussed above and EPA denies the claim under § 2.306(e), the Agency will transmit a notice of denial to the submitter. This notice will state that EPA intends to make the information available to the public on the 31st day after the notice is received by the submitter.

This discussion is only a brief introduction to the Part 2 procedures which will apply to submitters of confidential information and EPA during the interim period. Persons will be governed by the specific terms of Part 2, and should become aware of those requirements.

Health and Safety Data

If a person asserts a claim of confidentiality for health and safety data submitted with his premanufacture notice, and if the person intends to substantiate his claim, his substantiation must address the following questions:

1. Will disclosure of the information claimed as confidential in your health and safety study disclose a process used in manufacturing or processing a chemical substance or mixture? If so, describe how the information will disclose the process.

2. Will disclosure of the information claimed as confidential in your health and safety study disclose the portions of a mixture comprised by any of the chemical sustances in the mixture? If so, describe how the information will disclose the portions.

3. Will disclosure of the data claimed as confidential in your health and safety study disclose information which is not related in any way to the effects of the substance on health or the environment? If so, describe how the data will disclose this information.

4. Has any of the information claimed as confidential been disclosed in a patent? If so, why should it treated as confidential?

5. Is this information available to the public or your competitors without restriction? If so, why should it be treated as confidential?

6. How do you protect this information from undesired disclosure?

7. Has this information been disclosed to others? If so, what precautions have you taken in regard to these disclosures? Has the information been disclosed to the public or to competitors?

8. In the case of information concerning portions of a mixture comprised by one or more chemical substances, does the mixture leave the control of your company and move in commerce? If so, can the mixture be analyzed to determine the portions of the chemical substances in it?

9. Has EPA, another federal agency, or any federal court made any pertinent confidentiality determinations regarding this information? If so, please attach copies of such determinations.

10. For what period of time should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

11. What harmful effects to your competitive position, if any, do you think would result from disclosure of the process? The portions? Information not related in any way to the effects of a substance on the health or the environment? How would a competitor use this information? How substantial would the harmful effects of disclosure be? What is the causal relationship between disclosure and the harmful effects?

Uses of the New Chemical Substances

Under § 5(d)(1)(A) of the Act and § 8(a)(2)(B), a submitter must include in his premanufacture notice the "categories or proposed categories or use" of the new chemical substance. He may assert a claim of confidentiality for the information. Until the § 5 rules become final and effective, EPA urges that if the person claims such information to the confidential, he also submit both a generic description of the use and a non-confidential description of the type of exposures which may occur from the use.

If the submitter does not provide EPA any non-confidential use information for inclusion in the § 5(d)(2) Federal Register notice, the Agency will develop such a description and will provide the submitter with notice of its intent to release this information. As with information concerning chemical identity discussed below, the notice requirement may prevent inclusion of any use information in the initial § 5(d)(2) notice. If this happens, EPA wil publish an amended § 5(d)(2) Federal Register notice with the generic uses when the notification period under § 2.306(e) expires.

In any event, the Agency will not disclose use information if such disclosure would reveal confidential business information under the Agency's business confidentiality rules.

Specific Chemical Identity

Asserting a Confidentiality Claim for the Period Prior to Commencement of Manufacture or Import. A person who submits a premanufacture notice may claim that the specific chemical identity of a substance is confidential for the period prior to the commencement of manufacture or import of the substance

for a commercial purpose. In making this claim the submitter is asserting that the fact that *anyone* intends to manufacture or process the substance for a commercial purpose is confidential. However, a person should not assert a claim of confidentiality for the specific chemical identity if the only confidential fact is the link between the identity and the company. In such a case the submitter should restrict his claim of confidentiality to the link between a particular identity and the submitting company.

If the person intends to substantiate this claim of confidentiality his substantiation must address the following questions:

1. What harmful effects to your competitive position, if any, do you think would result if EPA discloses to the public the identity of the chemical substances which you reported in your premanufacture notice? How could a competitor use such information, given the fact that the link between your company and the chemical identity can be kept confidential? What is the causal relationship between the disclosure and the harmful effects?

2. For what period of time should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

3. Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential during the period prior to manufacture?

4. Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know that it will be manufactured or imported for a commercial purpose *by anyone*?

5. Has the fact that someone is planning to manufacture or import this chemical substance for commercial purposes been made available to the public? (E.g., in technical journals or other publications.)

6. What measures have you taken to prevent undesired disclosure of the fact that you will be manufacturing or importing this substance for a commercial purpose?

7. To what extent has the fact that you will be manufacturing or importing this chemical substance for a commercial purpose been disclosed to others? What precautions have you taken in regard to these disclosures? Has the information been disclosed to the public or to competitors?

8. Have samples of this substance left the premises of your company for any reason? If so, what measures have you taken to guard against discovery of its identity?

9. Has EPA, another federal agency, or any federal court made any pertinent confidentiality determinations regarding this chemical substance? If so, please attach copies of such determinations.

If the submitter claims the specific chemical identity confidential, EPA strongly encourages him to submit a proposed generic name (i.e., less specific), which is only as generic as necessary to protect the confidential identity of the substance, and which reveals to the maximum extent possible toxicologically significant aspects of the molecular structure. In choosing a generic name, the submitter is urged to consult the Agency's *Guidelines for Creating Proposed Generic Names*, included as Appendix II of the January 10, 1979 proposal (44 FR 2278–82). In addition, a person who intends to claim confidentiality for specific chemical identity may seek a determination by EPA of an appropriate generic name, prior to submittal of the premanufacture notice. If the submitter wishes such a determination, he should submit to the Agency the specific chemical identity of the substance, a proposed generic name (after consulting EPA's *Guidelines*), and an explanation of why any more specific name would reveal confidential business information.

Whether or not a proposed generic name is submitted with the premanufacture notice, EPA must develop such a name if the submitter claims the specific chemical identity confidential. The Act requires EPA to publish in the § 5(d)(2) Federal Register notice, among other things, information which "identifies the chemical substance for which notice or data has been received." This provision is subject to § 14, so that EPA must use a generic description if the specific chemical identity is claimed confidential. Therefore if EPA receives a notice which claims specific identity confidential but which does not include a proposed generic name, the Agency will choose a name which is only as generic as necessary to protect the confidential identity. Then, under § 14(c) of TSCA and 40 CFR § 2.306(e)(3), EPA will notify the submitter that it intends to disclose the proposed *generic* name in an amended § 5(d)(2) Federal Register notice.

EPA's rules require the Agency to provide notice to the submitter before disclosing information claimed to be confidential. Accordingly, if the submitter does not provide a generic name for the substance, the initial Federal Register notice will not include *any* identification of the substance for which the premanufacture notice had been submitted. In this case, EPA intends to publish an amended notice in the Federal Register with a generic name as soon as the notice period under 40 CFR § 2.306(e)(3) elapses.

If a person submits a generic name, that name will be published in the Federal Register. If this generic name is inadequate, EPA will publish an amended notice with a more specific chemical identity after following the procedures discussed above.

Asserting a Confidentiality Claim for the Period After Commencement of Manufacture or Import

A person who submits a premanufacture notice may assert that the specific chemical identity of a substance is confidential for the purposes of the inventory. In making this claim the submitter is asserting that the fact that *anyone* manufactures, imports, or processes the chemical substance for a commercial purpose is confidential. As discussed above, the person should not assert a claim of confidentiality for the specific chemical identity if the only confidential fact is the link between that identity and the company name. The submitter may make this claim when he submits his premanufacture notice if he intends to commence manufacture within one year from the date of the notice. He must assert the claim no later than the date of submittal of the notice of commencement of manufacture or import. Failure to submit the claim will result in the specific chemical identity being published on the Inventory.

If a person asserts this claim, he must substantiate the claim by submitting detailed answers to the following questions. These questions should be addressed separately from the questions applicable to a claim for the period prior to commencement of manufacture or import.

1. What harmful effects to your competitive position, if any, do you think would result if EPA publishes on the Inventory the identity of the chemical substance? How could a competitor use such information, given the fact that the identity of the substance otherwise would appear on the Inventory of chemical substances with no link between the substance and your company or industry? How substantial would the harmful effects of disclosure be? What is the causal

relationship between the disclosure and the harmful effects?

2. For what period of time should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

3. Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential for purposes of the Inventory?

4. Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know it is being manufactured or imported for a commercial purpose *by anyone?*

5. Is the fact that someone is manufacturing or importing this chemical substance for commercial purposes available to the public? E.g., in technical journals or other publications; in libraries, or state, local, or federal agency public files?

6. What measures have you taken to prevent undesired disclosure of the fact that you are manufacturing or importing this substance for a commercial purpose?

7. To what extent has the fact that you are manufacturing or importing this chemical substance for a commercial purpose been disclosed to others? What precautions have you taken in regard to these disclosures? Has this information been disclosed to the public or to competitors?

8. In what form does this particular chemical substance leave the site of manufacture? (E.g., As part of a product; in an effluent or emission stream.) If so, what measures have you taken to guard against discovery of its identity?

9. If the chemical substance leaves the site of manufacture in a product that is available to either the public or your competitors, can they identify the substance by analyzing the product?

10. For what purpose do you manufacture or import the substance?

11. Has EPA, another federal agency, or any federal court made any pertinent confidentiality determinations regarding this chemical substance? If so, please attach copies of such determinations.

If substantiation does not accompany the claim of confidentiality, EPA will initiate the procedures described above under "General Procedures for Asserting Confidentiality."

Generic Name

If the submitter claims the specific chemical identity of a substance to be confidential during the period prior to commencement of manufacture or import, a generic (i.e. less specific) name must be developed. If the submitter claims confidentiality for specific chemical identity for the Inventory, and if he believes that a narrower generic name than that developed for the period prior to commencement of manufacture would be adequate, the person should propose that name at the time he asserts the claim for the Inventory. Regardless of whether the submitter proposes a revised generic name, if the Agency determines that a narrower name is appropriate EPA will notify the submitter of this fact in the manner described above concerning claims of confidential identity for the period prior to commencement of manufacture.

Disclosure to Persons With Bona Fide Intent To Manufacture

All substances reported to EPA for inclusion on the Initial or Revised Inventories are subject to the inventory rules. In § 710.7(e)(2) of those rules EPA requires that a submitter who claims confidentiality for specific identity for the Initial or Revised Inventories must agree that EPA may disclose the fact that the substance is on the Inventory to another person with a *bona fide* intent to manufacture or import the substance for a commercial purpose. In addition, the inventory rules require the person reporting for the Inventory to have available, and to agree to furnish to EPA upon request, certain information which the Agency could use to resolve uncertainties of identity between the substance on the Inventory and a substance which another person intends to manufacture. Thus although a specific identity reported under the inventory rules is confidential, EPA will disclose to a *bona fide* manufacturer whether the substance is included on the Inventory.

The inventory rules do not apply to substances for which § 5 notices are submitted, and which are to be added to the Inventory upon receipt of a notice of commencement of manufacture or import. In its proposed rules for premanufacture notification, EPA included a procedure for disclosure of certain information to persons with a *bona fide* intent to manufacture which was identical in substance to the procedures established by § 710.7 of the inventory rules. However, these proposed rules are not in effect at this time.

Although there is no requirement under the interim policy that a person who has completed § 5 review and who claims confidentiality for the Inventory agree to EPA's disclosure to a *bona fide* manufacturer that the substance is on the Inventory, submitters are strongly encouraged to state this agreement. When persons do so, the Agency will follow § 710.7(g) of the inventory reporting rules. If a submitter does not agree to allow such disclosure, EPA will not disclosure to a person with a *bona fide* intent to manufacture the substance whether the substance is on the Inventory. Thus to ensure his compliance with § 5, a person with a *bona fide* intent to manufacture or import a chemical substance which has been added to the Inventory following § 5 may be required to submit a premanufacture notice although the substance has completed premanufacture review and is included on the Inventory. EPA developed the procedures for disclosure to persons with a *bona fide* intent to manufacture or import to address just this problem. In fact, representatives of the chemical industry suggested the need for this procedure.

Failure to disclosure identity to *bona fide* manufacturers may impose unnecessary burdens on the *bona fide* manufacturers. However, the chance and degree of inquiry to an original manufacturer who agrees to EPA's procedures is slight. To be informed whether a substance falling within one of the generic names is included on the Inventory, EPA's rules require a person to demonstrate that he has a *bona fide* intent to manufacture or import the substance. To show this, the rules require the person to submit a statement of present intent to manufacture or import, including a description of research and development activities to date and the purpose for which the substance will be manufactured or imported. In addition, EPA requires the inquiring manufacturer to submit an elemental analysis, either an X-ray diffraction pattern or a mass or alternative spectrum of the substance, and any additional information necessary to identify the substance. This approach discourages fishing expeditions by persons without a *bona fide* intent to manufacture or import and thereby protects trade secrets from disclosure to competitors. In addition, if EPA tells the *bona fide* manufacturer that the substance is on the Inventory, the Agency will inform the original manufacturer that someone has made this showing. This will give the original manufacturer similar information about the activities of a *bona fide* manufacturer as that person has with regard to the original manufacturer. The identities of the manufacturers involved will not be disclosed.

A person who submits a confidentiality claim for the identity of a substance on the Inventory should indicate clearly in his claim whether he agrees to disclosure to a person with a *bona fide* intent to manufacture in accordance with § 710.7(g) of the inventory rules. However, regardless of whether he agrees to such disclosure, unless EPA denies his confidentiality claim the Agency will publish the generic name in an appendix to the Inventory, and will not publish the specific identity on the Inventory. If a submitter does not agree that EPA may tell persons with a *bona fide* intent to manufacture whether their particular substances are on the Inventory, the Agency will deny any such request for the information. This interim policy only will be in effect until the premanufacture notification rules are final and effective. At that time, all substances added to the Inventory during the interim period will become subject to the new rules. EPA will provide persons who submitted notices of commencement of manufacture, but who failed to agree to disclosure to *bona fide* manufacturers, an opportunity to agree to the disclosure provisions included in the Agency's final § 5 rules. Failure to indicate such agreement in a timely manner will result in a waiver of the claim, and EPA will include the specific chemical identity on the Inventory.

Substantive Determination on Confidentiality of Specific Chemical Identity

One of the most significant issues in the proposed premanufacture rules is how EPA will handle claims of confidentiality for specific chemical identity, particularly when this information is part of a health and safety study submitted with the premanufacture notice. Until the § 5 rules become final, the only regulations EPA has promulgated pertaining to this area are the Agency's business confidentiality regulations, 40 CFR Part 2, Subpart B. However, in drafting those regulations, EPA did not focus on the particular confidentiality issues raised by the premanufacturing notification requirements.

Pending completion of the § 5 rulemaking, EPA will not disclose specific chemical identity as part of a health and safety study submitted with a premanufacture notice, if such disclosure would reveal confidential business information. This policy will apply both prior to 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 terms of the § 5 rules when they become final.

This interim policy should be distinguished from that contained in § 720.43 of EPA's proposed rules, with respect to confidentiality of specific chemical identity in the period following commencement of manufacture. In § 720.43, EPA proposed that during the period prior to commencement of manufacture the Agency would grant confidential treatment to the specific chemical identity in a health and safety study submitted under § 5 if public disclosure would reveal confidential business information. However, EPA also proposed that after commencement of manufacture, and addition of the chemical to the inventory, the specific chemical identity contained in a health and safety study would be entitled to confidential treatment only if the information would reveal either confidential processes used in the manufacturing or processing of a chemical substance or mixture, or the confidential portions of chemical substances in a mixture.

The proposed premanufacture rules represnt EPA's current view of the Agency's authority and responsibilities under TSCA. However, EPA recognizes that the Agency's resolution of this issue is one of the most important and controversial issues in the proposal. Industry representatives have maintained that EPA should apply its proposed policy for the period prior to commencement of manufacture or import to the period after commencement as well. On the other hand, representatives of public interest organizations and of organized labor have maintained that specific chemical identity should be disclosed both prior to and after manufacture begins, unless disclosure would reveal confidential processes or portions.

This interim policy will ensure that EPA takes no steps now that could be inconsistent with the Agency's resoulation of this issue in the final § 5 rules. If EPA discloses certain chemical identities prior to promulgation of the rules, and if the final rules do not otherwise mandate such disclosure, the interim disclosure could not be undone. On the other hand, if the Agency does not disclose the identities during the interim policy period and then promulgates a rule consistent with the proposed rules (or authorizing more disclosure), the interim policy will have resulted in a postponement of the release of the specific chemical identity. At most this would delay temporarily the ability of members of the public to examine this information, and to petition EPA to initiate regulatory action.

Compliance and Enforcement

EPA will bring enforcement actions against violators of § 5. In particular, persons who commence manufacture or import prior to notifying the Agency or before the termination period, and persons who fail to submit required data or who make false or misleading statements, will be the subject of enforcement actions. These may include actions for civil penalties, injunctive relief, and possible criminal prosecution. The Agency discussed its general approach to compliance and enforcement in greater detail in the preamble to the proposed premanufacture rules and notice forms (44 FR 2255, January 10, 1979)

Contracts After Close of the Comment Period

During the 75 day public comment period for the proposed rules and notice forms which ended March 26, 1979, interested persons had a variety of opportunities to review and comment upon the proposed rules and forms. EPA held nine public meetings and received written comments from more than 170 persons. In addition, prior to proposal the Agency distributed drafts of its rules and notice forms to interested persons, held a number of public and informal meetings, and received numerous written comments. EPA now is reviewing the transcripts and minutes of the public meetings, the written comments, and other written materials which comprise the public record; and the Agency will prepare its final regulations based on that record.

Until EPA promulgates the rules and forms, the Agency generally will discourage and not participate in discussions and meetings concerning the proposed rules and forms, in order to avoid the possibility of engaging in improper contracts. This includes telephone conversations and informal meetings or discussions. However, if such contacts do occur, EPA participants will make written records of the pertinent facts, including persons involved and the substance of the discussions. These materials will be included in the public record of the rulemaking.

This general policy does not apply to requests for EPA merely to summarize or describe the proposed rules and forms. Likewise it does not limit discussions concerning subjects not covered by the *proposed* regulations,

such as premanufacture testing guidelines and significant new use rules. The policy does not apply to comments or questions focused solely on the Agency's interim policy described elsewhere in this notice. Finally, this policy is not intended to restrict inquiries or comments pertaining to particular premanufacture notices. For example, certain manufacturers may find it helpful to consult with EPA before submitting their premanufacture notice. In addition, EPA expects to receive public comments in response to the § 5(d)(2) **Federal Register** notice of receipt of some premanufacture notices.

Although EPA generally will discourage discussions concerning the terms of the proposed rules and forms, the Agency from time to time nonetheless may determine that such discussions would be useful or necessary. When EPA decides to participate in such a discussion, Agency personnel will prepare an agenda for the meeting, place the agenda in the public record, and publicize the meeting to other interested persons. Any meeting of this type will be open to the public, although active participation may be limited to certain persons. EPA will include the minutes or transcription of the meeting in the public record.

EPA currently intends to hold additional meetings to focus on the development of a revised premanufacture notice form. The Agency has evaluated comments which it received concerning the form and various ways to respond to them. There are many aspects of this issue (e.g., scope of information requested, level of detail), and EPA would find it beneficial to discuss them and possible revisions of the form with interested persons. Thus the Agency will reopen the public comment period for a limited time concerning the forms, but *not* with regard to other rulemaking issues. EPA will announce this additional comment period in the **Federal Register**, including procedures to be followed in requesting meetings and submitting further written comments. The Agency will include in the public record all such comments, plus the transcripts and minutes of any meetings.

Consistent with EPA's approach on discussion of premanufacture notice issues, any person who wishes to meet with EPA personnel to discuss the proposed rules and forms should write a letter to the Agency setting forth an agenda and any materials or issues relevant to both the proposed topic and the need for a meeting. In particular, in light of EPA's general policy to discourage further meetings, the person should indicate why a meeting is needed, and why submittal of further written comment or reliance upon existing parts of the public record would be inadequate.

A person may find it to be necessary to submit additional comments if he develops new information or approaches based upon a reading of others' previously submitted comments, or upon new information or data. EPA will continue to supplement the public record with any such materials, and will consider them to the best of the Agency's ability, given time and resource limitations. Submitters should mark any such comments clearly as being comments for the rulemaking record and should *not* convey the comments as a personal letter or inquiry. The comments should bear the document control number OTS–050002 and should be submitted in triplicate to the Document Control Officer, (TS–793), Office of Toxic Substances, U.S. Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

Dated: May 8, 1979.

Steven D. Jellinek,

Assistant Administrator for Toxic Substances.

[FRL 1224–6; OTS–050002C]

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