ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 704, 720 and 721

[OPPTS–50593B; FRL–4921–8]

RIN 2070–AC14

Premanufacture Notification; Revisions of Premanufacture Notification Regulations; Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: Pursuant to section 5 of the Toxic Substances Control Act (TSCA), EPA is promulgating procedural amendments to the premanufacture notification (PMN) rule to incorporate a number of regulatory initiatives designed to streamline and reduce the administrative costs and burdens of the section 5 new chemicals program. These actions will allow EPA to concentrate its limited resources on identifying and controlling those new chemical substances most likely to present an unreasonable risk of injury to human health and the environment.

DATES: This rule will become effective May 30, 1995. In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1:00 p.m. eastern savings time on April 12, 1995.

FOR FURTHER INFORMATION CONTACT: James B. Willis, Acting Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554–1404, TDD: (202) 554–0551.

SUPPLEMENTARY INFORMATION: EPA published its final PMN rule (40 CFR part 720) on May 13, 1983 (48 FR 21722) and subsequently amended certain parts of the rule on September 13, 1983 (48 FR 41132) and April 22, 1986 (51 FR 15096). On February 8, 1993, EPA proposed additional amendments to the PMN rule (58 FR 7661). Please consult those documents for further information on the PMN rule and the proposed amendments. The docket control number for this action is OPPTS–50593B.

I. Background

A. Statutory Authority

Section 5(a)(1) of TSCA requires that persons notify EPA at least 90 days before they manufacture or import a new chemical substance for commercial purposes. For the purposes of TSCA, a new chemical substance is one that is not listed in the Master File of the TSCA Chemical Substance Inventory (''the Inventory'') compiled under TSCA section 8(b), which consists of substances originally reported under the Inventory reporting regulations (40 CFR part 710) and substances added via notices of commencement of manufacture or import (NOCs)(40 CFR 720.102) from submitters of PMNs.

B. History

Since 1979, EPA has reviewed over 25,000 section 5 notices for new chemical substances. During the intervening years, EPA has implemented a number of initiatives which have enabled the Agency to review a growing number of new chemical substances more efficiently. As discussed in the February 8, 1993 proposed rule (58 FR 7661), EPA is amending the PMN rule at 40 CFR part 720 to further reduce the costs of administering the Agency's new chemicals program and to implement other efficiencies for EPA and submitters. Please consult the proposed rule for a more detailed discussion of the objectives and rationale for these amendments.

II. Discussion of Final Amendments and Response to Comments

The final rule adopts the proposed amendments with minor revisions. The Agency reviewed and considered all comments received on the proposed amendments. A complete copy of all comments received is available in the public docket for this rulemaking, along with EPA's response to comments not addressed in this document. A discussion of the final amendments including a summary of significant comments and the Agency's response follows:

A. Correct Chemical Identity

EPA is amending §720.45(a) of the PMN rule to require that submitters of section 5 notices provide the currently correct Chemical Abstracts (CA) Index Name or CA Preferred Name for each chemical substance included in the notice (''reported substance'') that is consistent with TSCA Inventory listings for similar substances. Persons who request a search of the confidential Inventory by demonstrating a *bona fide* intent to manufacture or import a chemical substance for commercial purposes (''*bona fide*'') will also be required to provide CA nomenclature and chemical identity information in accordance with amended §720.25, as discussed later in this document. The rule also requires that a currently valid Chemical Abstracts Service (CAS) Registry Number (CASRN) consistent with the CA name be reported for the substance if a CASRN already exists for that substance. Until now, the PMN rule has indicated that CA nomenclature is the preferred, but not required chemical nomenclature system for PMN reporting. Therefore, submitters were able in the past to identify the PMN substance using alternative nomenclature. Having the currently correct CA identification for a substance is important to EPA because the reporting of incorrect, inconsistent, ambiguous, or obsolete chemical names, molecular formulae, or chemical structure information, or names that are not CA Index or CA Preferred Names, causes extra resources to be spent by EPA in establishing the best descriptions for substances under TSCA for searching the Inventory.

Although a CASRN has not been routinely required for a reported substance if a CASRN is not already available and the amendment only requires that CASRNs be reported for substances that already have them, EPA strongly recommends that submitters provide CASRNs for all reported substances, especially when the chemical identity is not being claimed as confidential business information (CBI). The fact that a CASRN exists does not prohibit a submitter from claiming this information as confidential. Having more substances reported with CASRNs will save EPA resources involved with chemical review and Inventory searching.

Submitters must provide a CA Index Name or CA Preferred Name that is consistent with the application of the Ninth Collective Index (9CI) of CA nomenclature rules and conventions. (This definitive guide to CA nomenclature has been used since 1972.) Whether to report a CA Index Name or Preferred Name for a substance depends on whether the chemical identity of the substance is well-defined or poorly defined.

For well-defined substances appropriately named using CA Index nomenclature, the specific chemical name chosen as most accurately describing the substance should be based on all information that the submitter can reasonably ascertain about its chemical structure, including, where applicable, the degree of structural specificity of the substance (e.g., whether specific isomers are intended to be manufactured in the reaction that produces the substance). For poorly defined substances properly named using CA Preferred nomenclature, the specific name of choice should be based on the

submitter's knowledge of the identities of the chemical precursors used, the sources of the reactants (synthetic, isolated by processing from certain naturally occurring materials, etc.), the nature of the reaction, and the types of chemical substances constituting the product combination, etc. For naming any kind of substance, the submitter's knowledge of impurities or byproducts is also a consideration.

When more than one substance results from a reaction, one should determine whether the product combination can be viewed for TSCA purposes as a mixture of separately reportable substances. For example, when the intended product combination is known to always be completely composed of a specific number of identified substances that do not react with one another, the combination can be represented as a mixture of individual components. If this is not the case, a single chemical name must be used to collectively describe the product combination as one substance. Where the chemical components can be represented as a mixture, they may be reported in a single PMN as long as the components are not intended to be separated. Otherwise, multiple PMNs or a consolidated PMN (requiring pre-approval by EPA) must be submitted.

The PMN rule retains all of the other chemical identity information required at §720.45(a), including molecular formula and chemical structure information. However, for substances not able to be characterized by a single chemical structure, the amendments require the submitted representative or partial structural diagram to be as complete as known to or reasonably ascertainable by the submitter. Failure to fully comply with the chemical identification elements of this requirement will result in the notice being declared incomplete by EPA pursuant to §720.65(c)(1). Such incomplete notices will not be processed or reviewed by the Agency until the chemical identification requirement is satisfied.

Concerning the degree of chemical structure information that can be reasonably ascertained for a given substance, submitters should understand that, for TSCA Inventory purposes, all substances are categorized by EPA into two groups according to the degree of certainty about the chemical structure of a substance: Class 1 and Class 2. Class 1 substances are those of precisely known chemical composition for which a single, complete structural diagram can be drawn. Class 2 substances are those having chemical compositions not completely definite or known; therefore, they cannot be characterized by definite, complete chemical structure diagrams. This rule amendment requires complete structural diagrams to be provided for Class 1 substances; for Class 2 substances, partial structure diagrams are required that are as complete as can be reasonably ascertained from the Class 2 chemical identity.

All of the chemical identification requirements described above should be satisfied if the submitter uses the CAS Registry Services Inventory Expert Service, which is a special extension of CAS for identifying substances to be submitted under TSCA. Submitters may also choose to use the services of another chemical information service or consultant that the submitter considers capable of generating correct CA names, chemical structure diagrams or molecular formulae where appropriate, and obtaining existing CASRNs. Alternatively, the submitter can search publicly available databases to retrieve this information, if available, or attempt to generate a name without assistance from another person or organization, if the submitter has sufficient knowledge about the Ninth Collective (9CI) Index of CA nomenclature rules and conventions and about how similar substances are named for the Inventory.

Information describing CA nomenclature rules and conventions can be obtained from CAS. In addition, the Agency is preparing a series of Inventory nomenclature papers that are intended to generate better understanding of how various classes of substances or types of complex product combinations are identified for TSCA purposes. The Inventory papers provide informal technical guidance that is intended solely to illustrate how various types of substances are represented on the TSCA Inventory based on the information provided by the submitters. The papers are not intended to be used for identifying substances for reporting purposes or for determining the need to report. Generally, EPA has attempted to maintain a consistent Inventory by closely following the guidance contained in the papers. However, EPA cannot guarantee that the guidance discussed in these papers has been applied to all substances listed on the Inventory. The initial Inventory reporting utilized four types of reporting forms with very different format and data requirements, making it difficult to ensure complete consistency. The Inventory papers will be available from the TSCA Assistance Information Service at (202) 554–1404; TTD (202) 554–0551; on line service modem (202) 554–5603.

An information sheet on the CAS Registry Services is also available from the TSCA Assistance Information Service. Printed copies of the non-confidential Inventory can be purchased from the Government Printing Office; computer tapes, CD ROM, and PC diskettes, (up-dated semi-annually) containing this Inventory information can be purchased from the National Technical Information Service (NTIS).

Regardless of how submitters determine correct CA chemical nomenclature, submitters should provide the party generating the CA nomenclature with the same chemical identity information that the submitter would have to send to EPA if reporting the substance in a PMN: the same types of information, levels of detail, degrees of specificity, byproduct and impurity information, etc. The party assigning a chemical identity should ensure that the name choice reflects the current CA nomenclature rules and conventions, as well as how similar substances are named for the Inventory, or the chemical name will be incorrect and the notice may be declared incomplete by the Agency.

The final rule at §720.45(a)(3)(i) and (ii) sets forth the required mechanism for obtaining CA nomenclature directly from CAS or alternative sources, as follows:

Method 1. A submitter using this method obtains the correct chemical identification directly from the CAS Registry Services Inventory Expert Service prior to submitting a notice to EPA. CAS will provide such services pursuant to arrangements between CAS and persons informing CAS that their substances will be reported to EPA in a notice. Submitters should call or write to the CAS Registry Services for information. Submitters must provide EPA with a copy of the chemical identification report obtained from CAS along with the completed notice, to verify that they obtained the information directly from CAS.

EPA believes that most submitters will find it advantageous to utilize the services of CAS to meet this requirement. As discussed in the proposed rule, due to CAS' authoritative position in the field of chemical identification and its familiarity with TSCA Inventory and nomenclature policies, EPA believes that chemical names and other chemical identity information assigned by CAS according to this method should be acceptable to the Agency. For these reasons, EPA strongly recommends that submitters use the services of CAS to satisfy the amended provisions.

Submitters should note, however, that if EPA disagrees with the identification assigned by CAS to a given substance, the Agency reserves the final authority to designate how a reported substance should be named and represented for the Inventory. This will not delay processing of the PMN by EPA. In the event EPA does not agree with a chemical name, CASRN, chemical structure or molecular formula provided to a submitter by CAS for TSCA purposes according to Method 1, EPA will work with CAS to either modify the submitted chemical identity when necessary or confirm that CAS' identification is most appropriate, to ensure that a correct TSCA description is assigned. Using Method 1, there will be no delay in EPA review or additional cost to the submitter resulting from an identification error by CAS or an identity verification request by EPA provided that the submitter has given complete chemical information to CAS that is identical to the chemical identity information contained in the section 5 notice to EPA. EPA will assume responsibility for resolving chemical identity problems occurring when Method 1 is used. However, if EPA determines that the chemical identity information submitted to EPA is not identical to that provided CAS, the notice may be deemed incomplete in accordance with §720.65(c)(1).

Method 2. Using this method, a submitter may obtain the required chemical identity information from any chemical information service or consultant, or can retrieve or develop the proper CA identifications without assistance. EPA emphasizes that with this method submitters will need to provide for each substance a correct CA Index or Preferred Name and other chemical identity information, as required under §720.45(a)(1) and (2), that is consistent with Inventory listings for similar substances. It will be the submitter's responsibility under Method 2 to seek the required information from a source the submitter believes to be sufficiently knowledgeable about CA nomenclature conventions and TSCA Inventory listings.

In contrast to Method 1, if a submitter uses Method 2 and reports any chemical identity information that is considered incorrect by EPA, the submitter, not the Agency, will be considered responsible for correcting the chemical identification. EPA will declare such a notice incomplete under §720.65(c)(1) and will not further process or review it until the submitter provides the fully correct chemical identity information specified in this amendment.

Concerning the task of generating correct CA nomenclature, it should be noted that there are many chemical names on the CAS Registry File, particularly CA names for indefinitely described substances, that are not appropriate for uniquely identifying substances on the Inventory. Thus, the application of just the CA nomenclature rules to name a new substance may not necessarily guarantee an acceptable chemical name for TSCA purposes. One must also be familiar with the ways in which similar substances are listed in the Inventory. As stated above, EPA is developing papers on specific Inventory nomenclature issues for public distribution.

Whether a submitter uses CAS or another method to obtain CA nomenclature, EPA will assume that upon sending a notice to the Agency, the submitter agrees with the chemical identity information provided by the source. Regardless of which method is chosen by a submitter for properly identifying a reported substance, EPA remains the final authority for naming new substances for the TSCA Inventory.

For submitters to have ample time to become familiar with the process of obtaining chemical identity information from CAS, another chemical information service, or a consulting party for obtaining chemical identifications, submitters should contact their chosen source at least 1 or 2 months before the intended submission date of a notice. This is especially important the first time one would have to report under this amendment.

EPA anticipates that many submitters would consider chemical identity information and/or submitter identity information given to CAS (by Method 1) or another third party (by Method 2) to be CBI. Until submitted to EPA under a provision of TSCA, CBI is not subject to EPA's procedural and security protections under TSCA. Therefore, provisions for handling any CBI first submitted to CAS or another outside party must be arranged directly with that party. Submitters should not assume that CAS or another outside party is required to adhere to EPA's TSCA-CBI procedures regarding the possession, handling, labelling, storage, tracking, auditing, or other processing of this information.

However, based on currently available information, it is EPA's understanding that any confidential, proprietary, or trade secret information that CAS would receive according to Method 1 of this rule amendment prior to the information being reported to EPA would be handled in accordance with the long-established security procedures and policies that CAS has implemented to safeguard any confidential information provided by its customers.

When submitting chemical substance identity information to CAS or any other information service, a submitter who indicates that the substance identity is CBI should be aware that a CASRN for that substance may already exist due to CAS's prior knowledge of the existence of that substance from another source. In such a case, the chemical identity would already have been assigned a CASRN and placed by CAS in its publicly accessible files.

Based on its knowledge of CAS's procedures, EPA believes that CAS currently does not place the substance identity into the publicly available CAS Registry File, if not already present there, when a submitter has requested confidential treatment of the information. However, EPA cannot ensure that CAS will continue this practice in the future, nor can EPA ensure how other services handle this type of information. As always, it is the submitter's responsibility to ensure that the information service it uses properly protects the confidentiality of its data. Submitters choosing to use either Method 1 or Method 2 should inquire how the information service, consultant, or party receiving their confidential information will handle, protect, and use such information.

The final rule at §720.45(a)(4) and (5) sets forth procedures for importers and manufacturers who do not possess the complete chemical identity information required to submit a notice to EPA about a substance they intend to import or manufacture because of proprietary claims by the U.S. or foreign supplier of the new chemical substance or a reactant used to manufacture the new chemical substance. Section 720.45(a)(4) requires that the importer of a proprietary new chemical substance have the foreign supplier follow the procedures for obtaining CAS nomenclature for the new chemical substance from CAS or alternative sources as specified in §720.45(a)(3). The foreign supplier would provide the chemical identity information on the new chemical substance specified in §§720.45 (a)(1) and (2) directly to EPA as part of a joint submission or letter of support clearly referencing the importer's notice and in the case of PMNs, the user fee identification number of the PMN submission established by the U.S. submitter (see 40 CFR 700.45(e)(3)).

Section 720.45(a)(5) contains provisions for manufacturers who cannot provide complete chemical

identity information because the new chemical substance is manufactured using a reactant whose identity is claimed confidential by its supplier. In this situation, however, due to logistical obstacles to generating correct CA nomenclature and other chemical identity information for a substance based on multiple submissions from different sources, each containing part of the overall chemical identity, EPA will not require the submitter to first develop or obtain a correct CA chemical identification for the given substance before submitting a section 5 notice. Instead, the final rule requires that the manufacturer provide all the information known by the manufacturer about the chemical identity of the reported substance and the proprietary reactant. This would typically include tradename, generic chemical name, or partial composition information about the confidential reactant such as that listed in a Material Safety Data Sheet (MSDS) or in other product literature and any other chemical identity information the submitter may know or reasonably ascertain about the confidential reactant or reported substance. In addition, the manufacturer must ensure that the supplier of the proprietary reactant sends a letter of support directly to EPA providing the specific chemical identity of the confidential reactant, including the CAS number, if available, and the appropriate PMN or exemption number, if applicable. This should be information known to or reasonably ascertainable by the supplier since that person is responsible for determining that the proprietary reactant is either on the Inventory or being manufactured under terms of an applicable section 5 exemption.

As indicated above, §§720.45(a)(4) and (5) require that persons providing information as part of a joint submission or letter of support clearly reference the importer or manufacturer's notice and user fee identification number (See 40 CFR 700.45(c)(3)), if appropriate so that EPA can be sure of properly linking the two submissions. In addition, any CBI claims must be clearly marked in the notice or letter of support along with a statement that this information must not be shared with the notice submitter. The statutory review period for a section 5 notice will not begin until EPA receives all parts of a joint notice, or all necessary supporting documents providing chemical identity information for a notice.

Comment. EPA should resolve nomenclature issues leading to inconsistency (1) within the TSCA Inventory, (2) between CAS and TSCA nomenclature and (3) between how a substance is named for TSCA purposes and how it is named by the chemical industry for marketing purposes.

Response. Basically, there is only one set of nomenclature rules used for the TSCA Inventory; the CA nomenclature system has always been utilized by EPA to represent and name substances for Inventory purposes. However, recognizing the complexity of the various types of commercial chemical substances that would be reported under TSCA and the need for accurately representing these substances on the Inventory, EPA held numerous meetings with trade associations at the time the Initial Inventory was compiled to develop guidelines for identifying these substances. Before the Inventory was initially compiled, EPA worked with CAS to refine some of the nomenclature policies for certain categories of chemical substances, such as (1) substances of variable composition, (2) natural fats, and (3) polymers.

The TSCA Inventory was initially compiled from information submitted by chemical manufacturers, importers, and processors. Perceived Inventory inconsistencies reflect the different ways in which similar substances were described and reported by submitters. Differences in commercial intent, author emphasis, and level of detail or knowledge of composition resulted in some variation in names. This flexibility in nomenclature was considered necessary by the chemical industry at the time of the Initial Inventory reporting. The Agency checked the original 160,000 reports for the Initial Inventory using a computer program that was designed to identify obvious discrepancies; the Agency then worked with the submitters of problem substances to correct the Inventory reports. If there were no obvious discrepancies, the Agency was not able to identify substances that were identified incorrectly by the submitters, and consequently, some incorrectly identified substances might have been added to the Inventory. However, when the Agency adds substances to the Inventory through the PMN program, it works with the submitters and CAS to attempt to ensure that consistent nomenclature is used.

The Agency will continue using its current nomenclature system, striving to maintain consistency. As discussed above, a series of Inventory nomenclature guidance papers (that will be available through TSCA's Assistance Information Service) is under development at the Agency to publicly articulate Agency nomenclature practices used for Inventory representation of various types of chemical substances.

Comment. CA nomenclature should not be required for TSCA submissions; CAS should not have an exclusive interest.

Response. EPA developed the TSCA Inventory using CA nomenclature and numbers; CAS has been assisting EPA in compiling, maintaining and updating the Inventory since 1977. CA nomenclature and numbers are used by all major industrial countries for their chemical inventories. This form of international harmonization enhances international trade and conserves the resources of chemical industries and governments. Many major chemical manufacturers now utilize CA nomenclature, too. The use of one nomenclature system minimizes confusion in regulatory matters and trade, and facilitates compliance monitoring. Moreover, the Agency has the authority to specify the form of nomenclature for TSCA purposes. Therefore, the Agency believes that the use of CA nomenclature is appropriate. Submitters have the choice of which nomenclature service to use, as long as names are consistent with TSCA nomenclature requirements.

Comment. Problems with nomenclature not provided by CAS should not delay Agency review.

Response. Chemical identification errors by submitters result in wasted resources and significant delays for both EPA and submitters. For this reason, the Agency has determined that it will consider submissions incomplete and thus delay their review if the incorrect nomenclature is received from a source other than CAS. The Agency believes, as a result of its years of experience using CAS nomenclature, that chemical substance identities provided by CAS specifically for TSCA purposes will rarely be in error and that any errors would be relatively minor. EPA has insufficient experience with other chemical nomenclature services to allow EPA to assume that the nomenclature provided by such services would normally be consistent with Inventory nomenclature requirements.

Comment. The burden of supplying CA nomenclature is significant, both in terms of time and financial resources.

Response. The Agency disagrees with this comment. The Agency recognizes that the time and cost of submitting a notice will increase to some extent because of the requirement to use CAS nomenclature. This will be true for those who utilize the TSCA nomenclature services of CAS or other providers or choose to develop CAS nomenclature on their own. EPA does

not believe that this requirement will present significant problems because, in EPA's experience under the section 5 program, some submitters already use CAS private registry services, despite the absence of a requirement to do so under the previous PMN regulations, apparently with minimal added cost or delay.

The Agency recognizes that the lead time required to prepare a PMN may increase. In most cases, submitters can be preparing other sections of their notices pending nomenclature assignments. The added up-front time in compiling a PMN should not be a major factor. According to EPA records many PMN substances are not manufactured until a month or more after the PMN review period ends. The Agency believes that submitters should always take the time necessary to ensure that their chemical substance is correctly identified upfront. The practice of relying on EPA to correct submitter errors, after the fact, has over the years consumed significant Agency resources. The Agency believes that this change in the procedural rule will place this responsibility where it legitimately belongs.

Comment. The burden imposed on small manufacturers and importers is too large.

Response. EPA does not consider this burden to be unreasonable, especially because small companies already save $2,400 on each of their PMN submissions compared with larger companies. Small companies have historically been responsible for a disproportionately large number of errors in chemical identities. The burden of generating CA nomenclature will be offset, in many cases, because with the inclusion of proper chemical names in the initial section 5 notice the review period will not be suspended for problems with chemical identity. Small companies may also benefit significantly from an early knowledge of the correct chemical identity, which may enhance their customer service, Inventory search efforts, and regulatory compliance.

Comment. Requirements to generate CA nomenclature will create problems in protecting confidentiality.

Response. The Agency does not believe that the requirement for CA nomenclature will create undue problems with confidentiality for submitters. All submitters must be responsible for the confidentiality of their information prior to submission to the Agency.

Comment. EPA should not require CA nomenclature for polymers and for *bona fide* inquiries (*bona fides*).

Response. While submitters must report all monomers and other reactants used to manufacture reported polymers, CA nomenclature is required for polymers, in part, because in certain cases the appropriate CA name for the polymer is based on more than just the names of the monomers and other reactants. CA nomenclature for certain polymeric substances may be based on structural repeating units or other important structural features of the polymeric material. Examples include certain block polymers, certain post-treated or functionalized polymers, and siloxanes and silicones. The Agency has chosen to maintain a consistent policy for nomenclature using CA names for all substances, avoiding the potential confusion and compliance problems which could occur if only some substances required CA names.

In a separate rulemaking published concurrently with this document, the Agency has decided not to require CAS nomenclature for polymers that are manufactured under terms of the polymer exemption in accordance with 40 CFR 723.250, since the Agency will no longer review exemption notices for exempted polymers. However, since chemical identity information is required as part of the recordkeeping requirements, persons who are manufacturing polymers under terms of the polymer exemption are encouraged to use standard CA nomenclature in their records.

The Inventory search process is the same for both PMNs and for *bona fides*. In the case of *bona fides*, chemical identity issues frequently have interfered with the Agency's ability to give an accurate response to submitters within the 30–day period to which the Agency has committed itself. In general, there have been more problems with chemical identity for *bona fides* than for PMNs, in part because much less chemical information has been required for *bona fides* than for PMN submissions. Once a correct chemical name is developed for purposes of a *bona fide*, the same name can be used for a subsequent PMN submission without further expense.

B. Revised Requirements for Bona Fides

The Agency is amending §720.25 by revising certain provisions of the procedures to establish a *bona fide* intent to manufacture or import a substance. This amendment reduces or simplifies existing analytical information requirements, modifies and/or clarifies other existing information requirements, and requires some additional types of information in *bona fides*.

The amendments eliminate the need for elemental analysis data [former §720.25(b)(2)(iv)] as well as reduce and simplify other analytical information requirements [former §720.25(b)(2)(v)] by identifying an infrared spectrum as the usual practice for characterizing the new chemical substance. Two other parts of this section, regarding chemical identity information, and the description of research and development (R&D) activities and use [former §720.25(b)(2)(i) and (iii), respectively] were modified and/or clarified. There are three new information requirements regarding the most probable manufacturing site and process to be used, as well as an approximate date when the submitter would be likely to submit a section 5 notice for the substance if it is not found in the Inventory. EPA believes that the amendments represent a balanced trade-off of requirements between the former and amended provisions. The amendments will enable submitters to better demonstrate a *bona fide* intent while the Agency will be better able to protect the CBI of the original submitters of Inventory substances. The additional information or data required in the amendment is considered reasonably ascertainable by the submitter, and generally would have been determined already by the time the submitter has developed a *bona fide* intent to manufacture or import a substance for a commercial purpose. Under the amended §720.25(b)(2)(i), submitters of a *bona fide* must provide, as described in the amended provisions of §720.45(a) discussed in unit II.A above, a currently correct CA Index Name or CA Preferred Name, whichever is appropriate, and a currently correct CASRN (if the substance already has a CASRN assigned to it). In addition, the Agency requires a molecular formula and a complete or partial chemical structure diagram if these are known or reasonably ascertainable. Failure to fully comply with the chemical identification elements of this requirement will result in the *bona fide* being declared incomplete by EPA and returned to the submitter.

The amendments modify the requirement for a description of R&D activities conducted to date on the substance and the purpose for manufacture or import [former §720.25(b)(2)(iii)]. Since in the past many submitters have inadvertently omitted one of these two different pieces of information in their notices, EPA is making the requirements clearer by separating the requests for the description of R&D activities and the

purpose for which the submitter will manufacture or import the substance into different subparagraphs of the amended rule [amended §720.25(b)(2)(iii) and (iv), respectively]. In addition, in the amended §720.25(b)(2)(iii)(A), EPA elaborates on the information required by listing some of the general types of R&D activities to be reported. Also, the year in which R&D was started by the submitter on the substance is required. EPA believes that these modifications will enable the submitter to indicate the scope and length of its commitment towards developing the substance for commercial use. EPA expects that this information be briefly stated.

In the amended §720.25(b)(2)(iii)(B), EPA provides an alternative reporting requirement for importers who do not perform R&D activities on the substance and have no knowledge of R&D activities that may have been conducted outside of the United States. Such importers will be allowed, in lieu of presenting R&D information, to indicate for how long, and in which country a given substance has been in commerce outside the United States, as well as to state whether they believe that the substance has already been used outside of the United States for the same commercial applications intended by the submitter. This alternative requirement is similar to the informal EPA practice in the past of allowing such a prospective importer to satisfy the former §720.25(b)(2)(iii) by providing certain information on foreign commercial activity of the substance.

In the amended §720.25(b)(2)(iv), for clarity, the term ''purpose'' used in the former §720.25(b)(iii) has been replaced by the phrase ''major intended application or use'' because some submitters have misunderstood the type of information required and have not provided a description of the intended end use.

EPA has simplified the analytical data requirements in the amended §720.25(b)(2)(v) to reflect the usual practice of submitters providing an infrared spectrum to characterize the chemical substance. An infrared spectrum is required, unless infrared analysis is not suitable for the substance or does not yield good structural information about the substance. In such cases, the amendment requires a spectrum or instrumental readout from another method of spectral or instrumental analysis that yields better structural or compositional information.

Amended §720.25(b)(2)(vi) consists of a minor but new information requirement to estimate the month and year in which the person would intend to submit a section 5 notice for the substance if it is not found in the Inventory. EPA believes that submitters with a *bona fide* interest in a substance would have already considered a future timeframe for reporting the substance under section 5 if in fact it is a new chemical substance. The intent of this requirement is not to legally bind the submitter to a certain date for submission of a PMN. In addition to using this information to determine a demonstration of a *bona fide* intent to manufacture or import the substance, if EPA can anticipate how many *bona fide* submitters may report their substances in PMNs in a given year, the Agency may be able to better allocate resources for reviewing the expected PMNs.

Amended §720.25(b)(2)(vii) requires the address of the facility under the submitter's control where the substance is most likely be manufactured or processed in the future for a commercial purpose. For imported substances it requires the facility at which processing is most likely to occur, if any.

Amended §720.25(b)(2)(viii) requires a manufacturer to briefly describe either in words or with a process flow diagram the manufacturing process that the submitter would most likely use to produce commercial quantities of the substance. The process description does not have to be detailed or comprehensive. Importers are required to briefly describe how the substance would most likely be processed or used at a site controlled by them, or, if no processing or use of the substance is anticipated to occur at a submitter-controlled facility, an importer may state that such commercial activity is not expected to occur. This information is not intended to be legally binding, but rather to assist EPA in determining whether the submitter appears to have serious intentions for commercializing the substance in question.

The Agency has also clarified the procedure for a foreign manufacturer or supplier to provide confidential chemical identity information directly to EPA, to complete a notice when the chemical identity is considered proprietary information by the foreign party and will not be disclosed to the *bona fide* submitter. As amended, it is the importer's responsibility at §720.25(b)(3)(i) to ensure that the foreign supplier provides the required chemical identity information in accordance with §§720.45(a)(1), (2), and (3) to EPA in a timely manner so that EPA can easily link the information to the importer's *bona fide.*

The amendments at §720.25(b)(3)(ii) indicate how to meet chemical identification requirements when submitters of substances to be manufactured or imported do not possess full knowledge of the chemical identity of the substance to be reported because a purchased reactant or component used in the reported material has a confidential chemical identity that is the proprietary information of the supplier. Similar to the procedures specified at §720.45(a)(5) for section 5 notices involving confidential (often trademarked or tradenamed products) reactants or starting materials, the *bona fide* submitter reports all the information known by the submitter about the substance identity. In addition, the supplier must submit a letter of support to EPA providing the specific chemical identity of the proprietary reactant, including the CAS number, if available, and referencing the submitter's *bona fide.* As previously discussed in this Unit under Correct Chemical Identity, correct CA nomenclature is not required when a reported substance involves the use of a purchased proprietary reactant. This is due to logistical obstacles involved in generating correct CA identifications for substances based on multiple submissions of parts of the overall identity from different sources. However, the submitter must coordinate with the supplier to ensure that the remaining specific chemical identity information is sent by the chemical supplier directly to EPA in a timely manner, to complete the *bona fide* request and initiate review by EPA. If the appropriate supporting document from the supplier is not received within 30 days after EPA receives the submitter's *bona fide*, the *bona fide* will be considered incomplete.

Further, EPA has included language in amended §720.25(b)(9) to describe what constitutes an incomplete *bona fide*, and how EPA will handle incomplete ones. When an incomplete *bona fide* is received and identified as such, EPA will immediately return the *bona fide* (minus any supplier-confidential portions) directly to the submitter. The submitter will then have to resubmit the completed *bona fide*, in its entirety, to have EPA perform the Inventory search and respond to the inquiry.

Comment. Appropriate *bona fide* intent exists even though many *bona fide* substances are never submitted as PMNs.

Response. Each *bona fide* request requires a certification statement about commercial intent. As a result, the Agency believes it is reasonable to expect that most *bona fide* submissions involving substances not found to be on the Inventory would result in

subsequent PMNs. This judgment takes into account the types of factors that could legitimately cause submitters to change their minds. The Agency expects that once the new requirements are in place, a larger percentage of *bona fides* will eventually result in submission of PMNs.

Comment. The proposed *bona fide* requirements are burdensome and the existing requirements need not be changed; EPA should not require process information, specific manufacturing site, the year that research and development started (or the length of foreign use), or the estimated date of PMN submission in order to establish *bona fide* intent.

Response. EPA believes that the information requested does not cause a significant burden because it should be known to or reasonably ascertainable by the submitter without developing or collecting additional data. EPA believes that submitters who have not yet considered these topics or developed this information are not at a commercial development stage consistent with showing *bona fide* intent.

Comment. EPA should focus on abusers of the *bona fide* process rather than increasing the reporting burdens on all submitters.

Response. The Agency believes that the perceived problem of submitter abuse of the *bona fide* process involves more than a few submitters. EPA believes that the best solution is to improve the integrity of the entire process through the new requirements so that all submitters will demonstrate a serious *bona fide* intent prior to receiving confidential Inventory information.

Comment. Greatly increased requirements for *bona fide* intent may lead to more PMN submissions.

Response. Rather than increasing the number of PMNs, EPA believes that the revised procedures will reduce the number of *bona fides* from persons who do not have a *bona fide* intent to manufacture the substance. In any event, persons who intend to manufacture or import a new chemical substance for a commercial purpose are free to submit a PMN without submitting a prior *bona fide*.

C. ''Two percent rule'' for Polymers

Section 720.45(a)(2)(iii) allows submitters to indicate on the PMN form which monomers and other reactants used at 2 weight percent or less (based on the dry weight of the polymer) should be included as part of the polymer description on the Inventory. This gives a manufacturer the flexibility of increasing the weight percent above the 2 percent level without submitting another PMN, but also requires that the monomer or reactant always be present at some level in the polymer. In practice, many polymer manufacturers currently request Agency pre-approval of a consolidated PMN to allow the manufacture of a new polymer with levels of monomers above and below the two percent level (i.e., with and without the monomer in the polymer's chemical identity). As a general rule, if the weight of monomer or reactant charged to the reaction vessel is 2 percent or less, the monomer or reactant is not considered part of the chemical identity of the polymer, unless indicated by the submitter on the PMN form. The 2 percent limit for polymers, referred to as the ''two percent rule'', has been in place since the Inventory reporting regulations were published on December 23, 1977 (see 40 CFR 710.5(c)) and was adopted because the Agency and the regulated community believed it would be difficult to identify the exact amount of monomers or other reactants actually incorporated in the final polymer. Accordingly, polymer manufacturers can use other monomers or reactants at 2 percent or less without changing the chemical identity of an Inventory-listed polymer.

Under the final rule, persons may continue to determine the weight percentage of monomer or other reactant based on the weight of monomer or other reactant actually ''charged'' to the reaction vessel. However, §720.45(a)(iii)(B) now allows persons the flexibility, where technically feasible, to determine the minimum weight of monomer or other reactant required in theory to account for the actual weight of monomer or other reactant molecules or fragments chemically ''incorporated'' (chemically combined) in the polymeric substance manufactured. Consequently, a PMN submitter or a person relying on existing polymer Inventory listings may determine which monomers or other reactants constitute the polymer identity on the basis of either method.

During the compilation of the Inventory, the method of reporting the percent composition of monomers and other reactants ''as charged'' was viewed as a reasonable approach by chemical and polymer industries. However, due to advanced analytical capabilities developed over the intervening years, certain polymer manufacturers asked EPA to revise the ''two percent rule'' to allow manufacturers the option of determining the amounts of monomers and other reactants that are present ''in chemically combined form'' (incorporated) in a polymer as an alternative to the practice of requiring reporting based on the amounts added (charged) to the reaction vessel. The final rule allows this option. The Agency believes that allowing submitters to report on the basis of amounts incorporated in the polymer will provide a better indicator of physical, chemical, and toxicological properties of polymers. At the same time, this action will allow manufacturers greater flexibility in commercial innovation, reduce the number of unnecessary PMNs representing slight variations in polymer composition, and provide greater consistency with international reporting policies. However, the Agency believes that manufacturers should be aware that there may be certain drawbacks and burdens involved in using the method of computation based on incorporated amounts of monomers and other reactants. For example, use of the ''incorporated'' method may have regulatory consequences if process modifications (such as a change in catalyst or solvent used or method and/or order of charging the reactants) affect the degree of chemical incorporation such that the 2 percent level is exceeded for a monomer or other reactant not specified as part of the chemical identity for the polymer, as discussed in the proposed rule (58 FR 7664).

If a person determines those monomers or other reactants used at 2 percent or less on the basis of the amount incorporated in the polymer, EPA believes that it is reasonable to require that such manufacturers maintain in their records analytical data or appropriate theoretical calculations (if it can be documented that an analytical determination is not feasible or not necessary) to demonstrate that the amounts of monomers and other reactants incorporated in the manufactured polymer have been accurately determined [§720.45(a)(2)(iv)]. Additional guidance on appropriate measurements or theoretical calculations is available in EPA's Draft Technical Guidance Document on the Polymer Exemption Rule. That document is in the docket for that rulemaking (OPPTS 50594B) and is available through the TSCA Assistance Information Service.

EPA recognizes that it was a matter of convenience, rather than one of science, to have thus far required reporting of the amounts of polymer reactants charged rather than the amounts incorporated; the former method requires only ''bookkeeping'', while the latter may require extensive and expensive analytical work. After 16 years of experience with the Inventory and PMN

reporting rules, however, EPA has come to realize that the ''amount charged'' approach has drawbacks. In particular, this approach of identifying many polymers based on monomers and other reactants charged to the reactor in quantities significantly larger than the amounts found to be incorporated in the polymer may not adequately represent the physical, chemical, and toxicological properties of the polymer.

Until now under the PMN rule, inefficiently incorporated reactants, reactants charged in large excess, and reactants with other functions besides their reactant ones were often likely to produce reportable polymers, even though the degree of chemical incorporation may have been less than or equal to two percent. For example, free-radical initiators are often charged in quantities greater than two percent to start many polymer chains simultaneously and limit the amount of high-molecular-weight polymer produced. Chemical incorporation of these initiators is inefficient, since many processes other than chain initiation can consume the initiator. The weight of the final polymer that can be attributed to fragments originating from the initiator is often less than 2 percent by weight. In the past, a manufacturer may have used many different initiators, all charged at greater than 2 percent, to produce what would be the same polymer if the ''incorporated'' method of computation was used. The result represented what many manufacturers believed to be excess reporting. Similar problems arose with solvents that have reactive functions, and with neutralizing agents used in excess of their salt-forming capacities. Technical details concerning the ''two percent rule'' are contained in EPA's Draft Technical Guidance Document on the Polymer Exemption Rule, which is available in the public docket for this rulemaking [OPPTS–50593B].

The Agency has always believed the actual content of a polymer is a better indicator of its physical, chemical, and toxicological properties, but adopted the ''amount charged'' method of computation as a matter of convenience to industry. The Agency believes that, in light of advanced analytical capabilities, it is now reasonable to also allow the submitter to optionally use the amounts of monomers and other reactants incorporated, as an alternative to the ''amounts-charged'' method.

Comment. Several comments supported EPA's proposal to modify the ''two percent rule'' by allowing polymer manufacturers to determine the amounts of monomers and other reactants that are ''incorporated'' in the polymer, as an alternative to the current practice of reporting based on the ''amounts charged'' to the reaction vessel. One comment stated that the use of the incorporation method, where the technology is available and feasible, more accurately represents the actual properties of the polymer. Commenters also stated that PMN submitters and/or manufacturers relying on existing listings of polymers on the Inventory should be able to use either method as long as they are in compliance with the ''two percent rule.''

Response. The proposed amendment was intended to allow this flexibility. Persons relying on existing Inventory listings of polymers or persons submitting PMNs may use either method as long as they can demonstrate the percentage of monomers or other reactants either charged to the reaction vessel or incorporated in the polymer.

Comment. The amendment to the ''two percent rule'' should be clearly stated to be an option rather than a regulatory requirement. EPA should abandon the proposed rule's arbitrary distinction and clarify that, for purposes of TSCA compliance, a polymer should be described either by analysis or by calculation.

Response. EPA has clearly indicated in this preamble and in the regulatory text that a manufacturer may use either method to determine which monomers or other reactants constitute the polymer identity.

Comment. EPA should establish a ''five percent rule'' for non-monomer reactants such as free radical initiators, chain transfer reagents, and pH neutralizing agents. These reactants are known to correlate poorly with the amounts charged and incorporated. Routine analytical testing would be inconclusive.

Response. EPA continues to believe, as stated in the preamble to the proposed rule (58 FR 7672), that a 5 percent rule would create a larger potential variation in those physical and chemical properties of a polymer that may have toxicological implications. Further, adopting a ''five percent rule'' would not be consistent with the Agency's goal of harmonizing, to the extent possible, the reporting of polymers with other international reporting practices that use a 2 percent standard.

In the past, industry has asserted that free radical initiators were not expected to be incorporated, so allowing a company to use the ''incorporated'' method should already provide a greater measure of flexibility. Manufacturers who are unable to develop reliable analytical data or reasonable theoretical calculations to support their use of the ''incorporated'' method should continue to follow the current practice of calculating 2 percent based on the monomers and other reactants ''charged'' to the reaction vessel.

Comment. EPA should allow use of any scientifically sound and technically appropriate incorporation measurement or theoretical calculation method. The proposal should be modified so that analytical and recordkeeping requirements for the incorporation method are not so onerous as to virtually negate the advantage of its use. A company that uses the ''incorporated'' method would be required to maintain analytical data to support this determination at the site of manufacture.

Response. The rule does not specify any particular analytical methodology for the ''incorporated'' method. The Agency would also allow theoretical calculations if it can be documented that an analytical determination is not technically feasible or not necessary as discussed above. Further, EPA believes that it is reasonable to require that manufacturers who use the ''incorporated'' method maintain records of analytical data or appropriate theoretical calculations that demonstrate compliance with the ''two percent rule'' at the site of manufacture to verify compliance in a straightforward manner.

D. Multiple photocopies of section 5 submissions

The Agency is amending §720.40(d)(2) to require submitters to provide EPA with one original and two complete copies of section 5 notices, in addition to a sanitized copy in which CBI has been deleted under §720.80. Submitters are also required to provide one original and two additional copies of any test data.

Comment. EPA should not require the submission of copies of test data. Test reports range from hundreds to thousands of pages and submitting extra copies would result in excessive volumes of material for EPA to handle.

Response The two extra copies of test data will reduce the Agency's administrative burden and will facilitate scientific reviews of the data submitted. The Agency's request for these test results falls clearly within the General Information Collection Guidelines, 5 CFR 1320.6 of the rules on the Paperwork Reduction Act of May 10, 1988 promulgated by the Office of Management and Budget. Under these guidelines, the Agency is allowed to request an original and two copies of

any document that satisfies its statutory requirements.

E. Electronic Transmission of Section 5 Notices; Removal of PMN from the CFR

EPA is amending the PMN rule at §720.40(a) to allow for future reporting via magnetic or other electronic media. This amendment is designed to promote the use of electronic media for data submission. EPA is investigating the use of magnetic tape, floppy diskettes, and electronic data interchange as means to submit information, and is participating in a nation-wide trend toward reducing reliance on paper for information transfer. EPA has already taken steps in TSCA and other program areas to encourage electronic submission, and intends to expand this effort to the PMN review program.

Information may be submitted electronically (on magnetic or other media) once EPA publishes a format for electronic submissions. Pilot projects using electronic submissions for the Inventory Update Rule (40 CFR part 710) and Toxic Release Inventory Rule (40 CFR part 372) will be used as a baseline for enhancements to developing a standard Agency-wide format. Such submissions will have to meet this format and all other media specifications published by EPA.

EPA is taking this opportunity to remove the full text of EPA form 7710–25 (PMN form) from the Code of Federal Regulations (CFR)(40 CFR part 720, Appendix A) and also correct the address for availability (40 CFR 720.40). The PMN form, which has been printed each year in the CFR, requires approximately 10 pages of publication and does not represent the most current document in use by PMN submitters. Removing the form from the CFR reflects standard Agency policy of not printing the full text of final forms in the CFR and will result in a significant cost savings for the Agency. In general, EPA has determined that it is not legally obligated to publish forms in full text. Under the Administrative Procedure Act (APA), 5 U.S.C. 552(a)(1)(c), EPA is obligated to describe forms and give a source of availability. In addition to removing the form, EPA is making conforming amendments to those sections that reference part 720, Appendix A to remove reference to Appendix A.

In addition, the PMN form that appears in the CFR has been photo reduced and cannot be used in a practical sense by those who must comply with the reporting requirements. More importantly, the Agency has continued to implement editorial revisions to the form since it was first published as part of the final rule in 1983. These revisions are intended to reflect PMN regulations and the policy initiatives implemented during the intervening years. Any substantive removal or addition of reporting requirements is accomplished by notice and comment rulemaking.

Comment. Comments were generally supportive of developing an electronic data interchange (EDI) with the Agency, although some reservations and concerns were expressed. Comments questioned (1) how practical it might be to submit some information, such as toxicity studies, electronically, (2) signature certification and (3) the security of CBI submissions. One comment suggested holding a workshop to address CBI concerns.

Response. EPA will not implement an EDI application for TSCA section 5 submissions until an Agency policy is developed for EDI standard practices. Thus, submitters would not have to develop unique interchange devices for section 5.

Electronic authentification technology is commercially available to address signature certification concerns and general security concerns. The Agency is required to protect CBI, and any EDI practices will ensure the confidentiality of data transmissions. The Agency is receptive to working with industry and other concerned parties to develop an EDI application for the New Chemicals Program, including CBI procedures. In the interim, the Agency encourages the use of PMN software developed by industry and approved for use by the Agency for generating hardcopy section 5 notices.

In addition to EDI, the Agency is analyzing other electronic reporting media to determine which is most appropriate for these submissions, given the variety of documents and materials involved. All comments on electronic reporting are welcome.

F. Mandatory Form for Notice of Commencement of Manufacture or Import (NOC)

Under this amendment, all PMN submitters are required to use a standard one-page form to submit a NOC. In addition, the NOC information requirements at §720.102(c) have been slightly expanded; however, all information can be provided on the one-page standard form (EPA Form 7710–56).

Every NOC received at EPA on or after the effective date of these final rule amendments must contain the required information on the new standard NOC reporting form. This form will automatically be provided to each PMN submitter as an attachment to EPA's letter acknowledging PMN receipt letter sent to submitters shortly after each PMN is received. Persons who have not submitted NOCs for PMNs that have been previously submitted to EPA can obtain copies of the NOC form from the TSCA Assistance Information Office. Many submitters are already reporting voluntarily using a similar form.

Previous NOC information reporting requirements, which are unaffected by these amendments, include specific chemical identity of the PMN substance, PMN number, the date manufacture or import commenced, and substantiation of CBI claims for chemical identity, which is required at the time a NOC is submitted. The amendment at §720.102(c)(ix) requests a clear indication of whether the submitter identity and/or other information on the form are also claimed as confidential. Confidentiality claims can only be asserted by the submitter if corresponding claims were made in the PMN.

EPA is amending NOC reporting to require that complete submitter identity information be provided on the form. This would include the name and address of the submitter, the name and dated signature of the authorized official, and the name and telephone number of a technical contact in the United States.

The amended NOC provisions also require a generic chemical name for a substance whose chemical identity is claimed as CBI. This name could either be (1) the same generic name provided in the PMN, (2) a generic name as revised by the submitter, as long as it masks no more of the chemical identity than the original generic name provided, or (3) an improved or corrected generic name agreed to via negotiation with EPA.

Because the initial intention to manufacture or import a substance sometimes changes between the time of PMN submission and the NOC, submitters are required to specify in the NOC whether commencement occurred via manufacture or import and the address of the site(s) at which manufacture commenced.

All of the above amendments to information requirements for NOCs involve information that the submitter will already know by the time manufacture or importation of the substance has commenced. Consequently, providing this information in the NOC will not constitute a significant reporting burden. EPA will not process a NOC that does not contain the chemical

identity, the date of commencement, and the PMN number.

Comment. EPA needs to define in the regulations or form the ''date of commencement.'' Is this the first date that a chemical reaction occurs in the manufacturing operation; the date that the last amount of final product is produced in a batch operation; the first date that the PMN chemical is drummed off; or another date?

Response. The Agency considers the date of commencement to mean the date of completion of manufacture for non-exempt commercial purposes of the first amount (e.g., batch, drum, etc.) of the chemical substance identified in the PMN. The Agency chose not to use the date on which the manufacturing process is started because that particular process may in some instances not result in the successful manufacture of the PMN substance. For importers, the date of commencement is the date the new chemical substance clears United States Customs. The final rule contains this definition.

Comment. The information required for an NOC duplicates that already submitted in the PMN: site of manufacture, name and telephone number of technical contact. This information should not be required, since a manufacturer is free to change any of these items after the PMN review period has expired. The Inventory Update Rule is the appropriate vehicle for the Agency to gather this information.

Response. An NOC may be filed years after the PMN was submitted. In the interim, the information provided in the original PMN may have changed due to change of location, change in ownership, etc. Up-to-date telephone numbers are important when problems need to be resolved. The Agency believes that the site of first manufacture or import is an important compliance monitoring tool. Although the Agency recognizes that a company may switch from import to domestic manufacture (or vice versa) after the PMN review period has expired, the Agency may find cause to investigate such changes that occur shortly after the expiration of the PMN review period.

Comment. The NOC form should be made available for public comment prior to finalization.

Response Although the form was not published in the **Federal Register** as part of the proposed rulemaking, it was available in the public docket and at the public hearings for this rulemaking held on April 26–27, 1993. Draft copies of the form have been available through the TSCA Assistance Information Office. The form has also been routinely distributed to all PMN submitters for use on a voluntary basis during the past year.

Comment. EPA should clarify its statement that an NOC will be declared incomplete if any required information is missing. It is possible that EPA could declare an NOC incomplete past the 30–day period, potentially resulting in a compliance problem. EPA should provide that the original NOC filing date will be considered the effective date for determining compliance with the requirement that the NOC be filed within 30 days after the first day of commercial manufacture or importation. For example, if EPA determines that responses to CBI claims are inadequate, the NOC should not be declared untimely because it is considered incomplete.

Response. EPA will continue its practice of adding a PMN substance to the Inventory as of the date the Agency receives the NOC from the PMN submitter with the correct chemical identity, date of commencement and PMN number. Further, EPA does not believe it is a significant burden for companies to submit a completed standard one-page NOC form that requests information that should be known to the submitter when manufacture or importation commences.

Comment. The NOC form should be computer compatible or the submitter should be allowed to use a computer facsimile as long as it has the same format as the NOC form. Companies should not be required to receive advance approval of computer facsimiles.

Response. The Agency will allow submitters to use a computer generated form, as long as the form is readable by Agency staff.

Comment. EPA should allow an ''authorized official or designated representative'' to sign the NOC form. The term ''authorized official'' might be construed to mean a corporate vice president. This type of form should not require a corporate vice president's signature.

Response. The ''authorized official'' has always been designated by the submitting company and should be a person that the submitting company deems responsible for the truth and accuracy of each statement in the certification.

Comment. The NOC form and/or accompanying instructions should indicate clearly that a sanitized version must be submitted if any information is claimed confidential and that all submitter identification information will be treated as CBI. Furthermore, the submitter must be permitted to claim the signature of the authorized official as CBI.

Response. EPA does not require submission of a sanitized copy of the NOC form because NOC submissions are not placed in the public files. Information on the NOC form that was claimed confidential in the original PMN submission may also be claimed confidential on the NOC form, although new confidentiality claims cannot be made in an NOC for information not claimed as confidential in the original PMN submission.

G. Comments on Other Issues

The Agency also discussed certain issues relating to CBI claims in the proposed rule (58 FR 7665) but did not propose any additional PMN rule amendments at that time. The Public Docket for this rulemaking contains a complete set of comments on this issue, as well as comments received in response to a discussion on use of geographic locators by section 5 reporting facilities. Several industry commenters expressed concern about the discussion in the proposal regarding enhanced review of all confidential claims. Specifically, some commenters were concerned that the discussion signalled a change of rules on making CBI claims in the PMN process. As stated in the proposal, the purpose behind the discussion of CBI claims filed in PMNs was to remind the regulated community of its obligations concerning CBI claims. As noted at that time, there are no changes to the CBI procedures included in the PMN rule amendments.

Industry submitters have an obligation to insure that only that information which needs to be kept confidential is claimed as CBI. Further, CBI claims are routinely reviewed and submitters who make broad, indiscriminate CBI claims will be contacted and requested to substantiate their claims pursuant to 40 CFR part 2.

III. Economic Analysis

EPA has evaluated the potential costs of the amendments for potential submitters of section 5 notices. The Agency's complete economic analysis is available in the public record for this rule (OPPTS–50593B).

The regulatory impact analysis estimates the costs and benefits attributable to the regulation. In this case, the analysis also contains estimates for the three additional amendments to section 5 regulations that are published elsewhere in this **Federal Register**. These new provisions amend the PMN Exemptions for Polymers, Chemical Substances

Manufactured in Quantities of 1,000 Kilograms or Less per Year (40 CFR part 723), and the Expedited Process for Issuing Significant New Use Rules (40 CFR part 721). Because these regulations are amendments to current regulations, their costs and benefits are incremental as compared to the current regulations.

The costs and benefits associated with these amendments are partially quantified; many of the benefits are unquantified but are of significant importance. Considering only the quantified costs and benefits, there is a slight cost increase for industry and a slight cost savings for EPA. Assuming either 1,000, 2,000, or 3,000 annual section 5 submissions, the savings as compared to the current regulation are estimated to be:

Annual Number of Submissions	Annual Cost Savings ($ Million)	
	Industry	Government
1,000	-0.1	0.1
2,000	-0.3	0.2
3,000	-0.4	0.2 – 0.3

The aspects of the amendments that have the greatest quantified cost impact on industry are the change in requirements for a *bona fide* TSCA Inventory search request and the requirement to provide correct chemical identification. Both requirements are expected to enable the Agency to utilize resources more effectively, thereby providing better service to industry. One of the major unquantified benefits of this amendment is increased flexibility under the ''two percent rule,'' allowing industry to make minor compositional changes, providing more manufacturing latitude to the submitter and possibly reducing the number of section 5 submissions. Another unquantified change is the requirement to use a standardized form for NOCs, the impact of which is expected to be minimal as many submitters are already using a similar form.

IV. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPPTS–50593B). The record includes basic information including public comments considered by the Agency in developing this rule amendment. A public version of the record without any confidential information is available in the TSCA Public Docket Office from 12 noon to 4 p.m., Monday through Friday, except legal holidays. The TSCA Public Docket Office is located in Rm. NE–G307 (Northeast Mall), 401 M St., SW., Washington, DC.

V. Other Regulatory Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51835, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the Order defines a ''significant regulatory action'' as an action that is likely to (1) have an annual effect on the economy of $100 million or more, or adversely and materially affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant'') (2) create serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to Executive Order 12866, it has been determined that this rule is not a ''significant regulatory action'' under section 3 (f) of the Order. This action is therefore not subject to OMB review.

B. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Agency has determined that this regulatory action will not impose any adverse economic impacts on small entities. EPA believes that, even if all of the section 5 notice submitters were small firms, the number of small businesses affected by this action will not be substantial.

C. Paperwork Reduction Act

The information collection requirements in this rule have been approved by the OMB under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3502 et seq and have been assigned OMB control number 2070–0012. The public reporting burden for this collection of information is estimated to vary from 18 to 21 hours per response, with an average of 20 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

List of Subjects

40 CFR Part 704

Chemicals, Confidential business information, Environmental protection, Hazardous substances, Imports, Reporting and recordkeeping requirements.

40 CFR Part 720

Chemicals, Environmental protection, Premanufacture notification, Hazardous materials, Reporting and recordkeeping requirements.

40 CFR Part 721

Administrative practice and procedure, Chemicals, Environmental protection, Hazardous substances, Imports, Labeling, Occupational Safety and Health, Reporting and Recordkeeping requirements.

Dated: March 21, 1995.

Carol M. Browner,

Administrator.

Therefore, 40 CFR chapter I, subchapter R, parts 704, 720 and 721 are amended as follows:

1. In part 704:

PART 704—[AMENDED]

a. The authority citation for part 704 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

b. Section 704.25 is amended by revising paragraph (d) to read as follows:

§704.25 11-Aminoundecanoic acid.

* * * * *

(d) *What information to report.* Persons identified in paragraph (b) of this section must submit a Premanufacture Notice Form (EPA Form 7710–25).

* * * * *

c. Section 704.104 is amended by revising paragraph (d) to read as follows:

§704.104 Hexafluoropropylene oxide.

* * * * *

(d) *What information to report.* Persons identified in paragraph (b) of this section must submit a Premanufacture Notice Form (EPA Form 7710–25).

* * * * *

2. In part 720:

PART 720 — [AMENDED]

a. The authority citation for part 720 continues to read as follows:

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

b. Section 720.25 is amended by revising paragraphs (a), (b)(1), (2)(i),

(2)(iii), (2)(iv), (2)(v), (3), and by adding paragraphs (b)(2)(vi), (2)(vii), (2)(viii), and (b)(9) to read as follows:

§720.25 Determining whether a chemical substance is on the Inventory.

(a) A new chemical substance is any chemical substance that is not currently listed on the Inventory.

(b)(1) A chemical substance is listed in the public portion of the Inventory by a specific chemical name (either a Chemical Abstracts (CA) Index Name or a CA Preferred Name) and a Chemical Abstracts Service (CAS) Registry Number if its identity is not confidential. If its identity is confidential, it is listed in the public portion of the Inventory by a TSCA Accession Number and a generic chemical name that masks the specific substance identity. The confidential substance is listed by its specific chemical name only in the confidential portion of the Inventory, which is not available to the public. A person who intends to manufacture or import a chemical substance not listed by specific chemical name in the public portion of the Inventory may ask EPA whether the substance is included in the confidential Inventory. EPA will answer such an inquiry only if EPA determines that the person has a *bona fide* intent to manufacture or import the chemical substance for commercial purposes.

(2) * * *

(i) Except as provided in paragraphs (b)((3)(i) and (ii) of this section, the specific chemical identity of the substance that the person intends to manufacture or import, using the currently, correct CA name for the substance and the other correct chemical identity information in accordance with §§720.45(a)(1), (2)), and (3).

* * * * *

(iii)(A) A brief description of the research and development activities conducted to date related to the substance, including the year in which the person first started to conduct research or development activity on the substance, and the general types of research and development activities conducted thus far (e.g., synthesis, substance isolation/purification, formulating, product development, process development, end-use application, toxicity testing, etc.). The person must also indicate whether any pilot plant or production-scale plant evaluations have been conducted involving the manufacture or processing of the substance.

(B) If an importer is unable to provide the information requested in paragraph (b)(2)(iii)(A) of this section from the foreign manufacturer or supplier, the following information shall be submitted:

(*1*) A brief statement indicating how long the substance has been in commercial use outside of the United States.

(*2*) The name of a country in which it has been commercially used.

(*3*) Whether the importer believes that the substance has already been used commercially, in any country, for the same purpose or application that the importer is intending.

(iv) A specific description of the major intended application or use of the substance.

(v) An infrared spectrum of the substance, or alternative spectra or other data which identify the substance if infrared analysis is not suitable for the substance or does not yield a reasonable amount of structural information. When using alternative spectra or instrumental analysis, the person must submit a spectrum or instrumental readout for the substance.

(vi) The estimated date (month/year) in which the person intends to submit a Premanufacture Notice (PMN) for this substance if EPA informs the notice submitter that the substance is not on the Inventory.

(vii) The address of the facility under the control of the submitter at which the manufacture or processing of the substance would most likely occur. For an imported substance, the facility under the control of the importer at which processing of the substance would likely occur, if any.

(viii)(A) For substances intended to be manufactured in the United States, a description of the most probable manufacturing process that would be used by the submitter to produce the substance for non-exempt commercial purposes.

(B) For substances intended to be imported, a brief description of how the submitter is most likely to process or use the substance for a commercial purpose. If the substance is not expected to be processed or used at any facility under the importer's control, a statement to this effect must be included along with a description of how the substance will be processed or used at sites controlled by others, if this information is known or reasonably ascertainable.

(3)(i) If an importer cannot provide the chemical identity information required by paragraph (b)(2)(i) and (v) of this section because it is claimed confidential by its foreign manufacturer or supplier, the foreign manufacturer or supplier must supply the required information directly to EPA in accordance with §720.45(a)(1), (2), and (3) and reference the importer's notice. If the appropriate supporting document from the foreign party is not received within 30 days after EPA receives the importer's notice, the notice will be considered incomplete.

(ii) If a manufacturer cannot provide all of the required information in accordance with §720.45(a)(1), (2), and (3) because the new chemical substance is manufactured using a reactant that has a specific chemical identity claimed as confidential by its supplier, the notice must contain chemical identity information that is as complete as known by the manufacturer. In addition, a letter of support for the notice must then be sent to EPA by the chemical supplier of the confidential reactant, providing the specific chemical identity of the proprietary reactant. The letter of support must reference the manufacturer's notice. If the appropriate supporting document from the supplier is not received within 30 days after EPA receives the manufacturer's notice, the notice will be considered incomplete.

* * * * *

(9) If the required chemical identity information has not been reported correctly or completely in the notice (except as provided under paragraph (b)(3)(ii) of this section) or if any other required data or information has been omitted or is incomplete, EPA will consider the whole notice to be incomplete. As soon as an incomplete notice is identified as such by EPA, the Agency will immediately return the notice directly to the submitter. The submitter must then resubmit the whole, completed *bona fide* notice to EPA in order to have the Agency perform the desired Inventory search and respond to the notice.

c. Section 720.40 is amended by revising paragraphs (a) and (d) to read as follows:

§720.40 General.

(a) *Use of the notice form; electronic submissions.* (1) Each person who is required by subpart B of this part to submit a notice must complete, sign, and submit a notice containing the information in the form and manner specified in this paragraph. The information submitted and all attachments (unless the attachment appears in the open scientific literature) must be in English. All information submitted must be true and correct.

(2) Information may be submitted on paper, or electronically, as follows:

(i) Information submitted on paper must be submitted in the form and manner set forth in EPA Form No. 7710–25, which is available from the

Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Information which is not submitted on the EPA Form No. 7710-25 or a photocopy thereof (e.g., on a form created by commercial form-making software) must be in a format pre-approved by the Agency.

(ii) Information may be submitted electronically (on magnetic or other media) pursuant to an EPA published format for electronic submissions. Such submissions must comply with this format and all other media specifications published by EPA. Persons submitting electronically must still complete and submit on paper the Certification and Submitter Identification sections of Form 7710–25.

* * * * *

(d) *General notice requirements.* (1) Each person who submits a notice must provide the information described in §720.45 and specified on the notice form, to the extent such information is known to or reasonably ascertainable by the person. In accordance with §720.50, the notice must also include any test data in the person's possession or control, and descriptions of other data which are known to or reasonably ascertainable by the person and which concern the health and environmental effects of the new chemical substance.

(2) A person who submits a notice to EPA under this part must provide EPA with an original and two complete copies of the notice, including all test data and any other information attached to the notice form. If information is claimed as confidential pursuant to §720.80, a sanitized copy must also be provided.

* * * * *

d. Section 720.45 is amended by revising paragraph (a) to read as follows:

§720.45 Information that must be included in the notice form.

* * * * *

(a)(1) The specific chemical identity of the substance that the person intends to manufacture or import, which includes the following:

(i) The currently correct Chemical Abstracts (CA) name for the substance, based on the Ninth Collective Index (9CI) of CA nomenclature rules and conventions, and consistent with listings for similar substances in the Inventory. For each substance having a chemical composition that can be represented by a specific, complete chemical structure diagram (a Class 1 substance), a CA Index Name must be provided. For each chemical substance that cannot be fully represented by a complete, specific chemical structure diagram (a Class 2 substance), or if the substance is a polymer, a CA Index Name or CA Preferred Name must be provided (whichever is appropriate based on CA 9CI nomenclature rules and conventions). In addition, for a Class 2 substance, the notice must identify the immediate chemical precursors and reactants by specific chemical name and Chemical Abstracts Service Registry Number (CASRN), if the number is available. Tradenames or generic names of chemical precursors or reactants are not acceptable as substitutes for specific chemical names.

(ii) The currently correct CASRN for the substance if a CASRN already exists for the substance.

(iii) For a Class 1 substance and for any Class 2 substance for which a definite molecular formula is known or reasonably ascertainable, the correct molecular formula.

(iv) For a Class 1 substance, a complete, correct chemical structure diagram; for a Class 2 substance or polymer, a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.

(2) For a polymer, the submitter must also report the following:

(i) The specific chemical name and CASRN, if the number is available, of each monomer and other reactant used, at any weight percent, to manufacture the polymer. Tradenames or generic names of chemical reactants or monomers are not acceptable as substitutes for specific chemical names.

(ii) The typical percent by weight of each monomer and other reactant in the polymer (weight of the monomer or other reactant expressed as a percentage of the weight of the polymeric chemical substance manufactured), and the maximum residual amount of each monomer present in the polymer.

(iii) For monomers and other reactants used at 2 weight percent or less (based on the dry weight of the polymer manufactured), indicate on the PMN form any such monomers and other reactants that should be included as part of the polymer description on the Inventory, where the weight percent is based on either (A) the weight of monomer or other reactant actually charged to the reaction vessel, or (B) the minimum weight of monomer or other reactant required in theory to account for the actual weight of monomer or other reactant molecules or fragments chemically incorporated (chemically combined) in the polymeric substance manufactured.

(iv) For a determination that 2 weight percent or less of a monomer or other reactant is incorporated (chemically combined) in a polymeric substance manufactured, as specified in paragraphs (a)(2)(iii)(B) of this section, analytical data or appropriate theoretical calculations (if it can be documented that analytical measurement is not feasible or not necessary) to support this determination must be maintained at the site of manufacture or import of the polymer.

(v) Measured or estimated values of the minimum number-average molecular weight of the polymer and the amount of low molecular weight species below 500 and below 1,000 molecular weight, with a description of how the measured or estimated values were obtained.

(3) The person must use one of the following two methods to develop or obtain the specified chemical identity information reported under paragraphs (a)(1) and (2) of this section and must identify the method used in the notice:

(i) *Method 1.* Obtain the correct chemical identity information required by paragraphs (a)(1) and (2) of this section directly from the Chemical Abstracts Service (CAS), specifically from the CAS Registry Services Inventory Expert Service, prior to submitting a notice to EPA. A copy of the chemical identification report obtained from CAS must be submitted with the notice.

(ii) *Method 2.* Obtain the correct chemical identity information required by paragraphs (a)(1) and (2) from any source. The notice will be incomplete according to §720.65(c)(1)(vi) if the person uses Method 2 and any chemical identity information is determined to be incorrect by EPA.

(4) If an importer submitting the notice cannot provide all the information specified in paragraphs (a)(1) and (2) of this section because it is claimed as confidential by the foreign supplier of the substance, the importer must have the foreign supplier follow the procedures in paragraph (a)(3) of this section and provide the correct chemical identity information specified in paragraphs (a)(1) and (2) of this section directly to EPA in a joint submission or as a letter of support to the notice, which clearly references the importer's notice and PMN User Fee Identification Number. The statutory review process will commence upon receipt of both the notice and the complete, correct information.

(5) If a manufacturer cannot provide all the information specified in paragraphs (a)(1) and (2) of this section because the new chemical substance is

manufactured using a reactant having a specific chemical identity claimed as confidential by its supplier, the manufacturer must submit a notice directly to EPA containing all the information known by the manufacturer about the chemical identity of the reported substance and its proprietary reactant. In addition, the manufacturer must ensure that the supplier of the confidential reactant submit a letter of support directly to EPA providing the specific chemical identity of the confidential reactant, including the CAS number, if available, and the appropriate PMN or exemption number, if applicable. The letter of support must reference the manufacturer's name and PMN User Fee Identification Number under §700.45(c)(3) of this chapter. The statutory review period will commence upon receipt of both the notice and the letter of support.

* * * * *

e. Section 720.80 is amended by revising paragraph (b)(2) to read as follows:

§720.80 General provisions.

* * * * *

(b) * * *

(2) If any information is claimed as confidential, the person must submit, in addition to the copies specified by §720.40, a sanitized copy of the notice form (or electronic submission) and any attachments.

(i) The original and two copies of the notice, specified at §720.40 (or electronic submission) and attachments must be complete. The submitter must designate that information which is claimed as confidential in the manner prescribed on the notice form (or in EPA's electronic submission instructions).

(ii) The sanitized copy must be complete except that all information claimed as confidential in the original must be deleted. EPA will place this sanitized copy in the public file.

(iii) If the person does not provide the sanitized copy, or information in a health and safety study (except information claimed as confidential in accordance with §720.90), the submission will be deemed incomplete and the notice review period will not begin until EPA receives the sanitized copy or the health and safety study information is included, in accordance with §720.65(c)(1)(vii).

* * * * *

f. Section 720.95 is amended by revising the third sentence to read as follows:

§720.95 Public file.

* * * Any of the nonconfidential material described in this subpart will be available for public inspection in the TSCA Nonconfidential Information Center, Room B607, Northeast Mall, 401 M St., SW., Washington, DC between the hours of 1 p.m. and 4 p.m., weekdays, excluding legal holidays.

g. Section 720.102 is amended by revising paragraphs (c) and (d) to read as follows:

§720.102 Notice of commencement of manufacture or import.

* * * * *

(c) *Information to be reported on form.* (1) The notice must be submitted on EPA (Form 7710–56), which is available from the Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. The form must be signed and dated by an authorized official. All information specified on the form must be provided. The notice must contain the following information:

(i) The specific chemical identity of the PMN substance.

(ii) A generic chemical name (if the chemical identity is claimed as confidential by the submitter).

(iii) The premanufacture notice (PMN) number assigned by EPA.

(iv) The date of commencement for the submitter's manufacture or import for a non-exempt commercial purpose (indicating whether the substance was initially manufactured in the United States or imported). The date of commencement is the date of completion of non-exempt manufacture of the first amount (batch, drum, etc.) of new chemical substance identified in the submitter's PMN. For importers, the date of commencement is the date the new chemical substance clears United States customs.

(v) The name and address of the submitter.

(vi) The name of the authorized official.

(vii) The name and telephone number of a technical contact in the United States.

(viii) The address of the site where commencement of manufacture occurred.

(ix) Clear indications of whether the chemical identity, submitter identity, and/or other information are claimed as confidential by the submitter.

(2) If the submitter claims the chemical identity confidential, and wants the identity to be listed on the confidential portion of the Inventory, the claim must be reasserted and substantiated in accordance with §720.85(b). Otherwise, EPA will list the specific chemical identity on the public Inventory. Submitters who did not claim the chemical identity, submitter identity, or other information to be confidential in the PMN cannot claim this information as confidential in the notice of commencement.

(d) *Where to submit.* Notices of commencement of manufacture or import should be submitted to:

TSCA Document Control Office (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

* * * * *

Appendix A [Removed]

h. Appendix A to part 720 is removed.

3. In part 721:

PART 721—[AMENDED]

a. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2652(c).

b. Section 721.25 is amended by revising the last sentence of paragraph (a) to read as follows:

§721.25 Notice requirements and procedures.

(a)* * * The notice must be submitted on EPA Form 7710–25, and must comply with the requirements of part 720 of this chapter, except to the extent that they are inconsistent with this part 721.

* * * * *

[FR Doc. 95–7709 Filed 3–24–95; 3:32 pm]
BILLING CODE 6560–50–F

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40 CFR Part 721

[OPPTS–50595B; FRL–4921–9]

RIN 2070–AC14

Amendment for Expedited Process To Issue Significant New Use Rules for Selected New Chemical Substances; Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating an amendment to the regulations governing significant new uses of chemical substances. The amendment authorizes EPA to impose any of the ''significant new use'' designations in 40 CFR part 721 subpart B using expedited rulemaking procedures to promulgate ''significant new use'' rules (SNURs) for