ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[OPTS-82015A; FRL-2973-3]

Partial Updating of TSCA Inventory Data Base; Production and Site Reports

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule, promulgated under the authority of section 8(a) of the Toxic Substances Control Act (TSCA), requires manufacturers and importers of certain chemical substances included on the TSCA Chemical Substances Inventory to report current data on the production volume, plant site, and site-limited status of the substances. After the initial reporting, recurring reporting will be required every 4 years for as long as this rule is in effect. Promulgation of this rule does not affect the status of a chemical substance listed on the Inventory.

DATES: This rule shall be promulgated for purposes of judicial review under section 19 of TSCA at 1 p.m. eastern daylight time on June 26, 1986. This rule is effective on August 25, 1986.

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

SUPPLEMENTARY INFORMATION:

I. Authority

This rule is promulgated under section 8(a) of TSCA, which provides the Administrator of EPA the authority to require, by rule, manufacturers, importers, and processors of chemical substances to submit such information as the Administrator may reasonably require. Failure to comply fully with any provision of this rule is a violation of section 15 of TSCA and will subject the violator to the penalties of TSCA sections 16 and 17.

II. Summary of the Rule

This rule requires manufacturers and importers to report current data on the production volume, plant site, and site-limited status (i.e., whether a chemical substance is manufactured and processed only within a plant site and is not distributed for commercial purposes as a substance or as part of a mixture or article outside the plant site) for certain chemical substances included on the TSCA Chemical Substances Inventory. For the purposes of this rule and preamble, the term "manufacturer" includes importer, unless otherwise specified. A person is considered to be a manufacturer subject to this rule if that person has manufactured or imported a reportable substance in the United States at any time during that person's most recent complete corporate fiscal year preceding the effective date of a relevant reporting period specified in this rule.

This rule requires both initial and recurring reporting. During the initial reporting period, every manufacturer of a chemical substance covered by this rule who produces over 10,000 pounds (4,540 kilograms) of a reportable substance at a plant site will be required to report separately on every such substance. Low-volume substances, i.e., substances with an annual site-specific production volume (or total amount imported) of less than 10,000 pounds, are excluded from this rule. After the initial reporting period, the same type of reporting will be required every 4 years for as long as this rule is in effect.

The substances covered by this rule include those that were initially reported for the Inventory, as well as substances added to the Inventory following TSCA section 5(a) premanufacture notification (PMN) review and the Agency's receipt of a notice of commencement of manufacture or import. Four categories of substances, though on the Inventory, are generally excluded from this rule. These excluded substances are those that are identified as polymers, inorganic substances, microorganisms, and naturally occurring chemical substances as described under § 710.4(b) of the Inventory Reporting Regulations. However, no substance, except one which is naturally occurring, is excluded from this rule if that substance is the subject of an order issued pursuant to TSCA section 5(e) or 5(f), or is the subject of a rule proposed or promulgated under TSCA section 4, 5(a)(2), 5(b)(4), or 6, or is the subject of relief granted under a civil action under section 5 or 7 of TSCA.

In addition to the proposed exclusions of substances, two categories of persons are exempt from certain reporting and recordkeeping requirements: Small manufacturers and persons manufacturing substances in limited circumstances. The small manufacturer exemption, however, does not apply if the substance to be reported by the small manufacturer is the subject of an order issued pursuant to TSCA section 5(e), or is the subject of a rule promulgated under TSCA section 4, 5(b)(4), or 6, or is the subject of relief granted under a civil action under section 5 or 7 of TSCA.

The information reported under this rule includes chemical identity, plant site, annual production volume, and site-limited status of a reportable substance. For each submission, EPA also requires the name, address, and telephone number of a person who can answer technical questions related to the submission. Persons subject to this rule are required to maintain records that support the information in their submissions. Such records are to be kept for 4 years beginning with the effective date of each reporting period.

III. Background

In the **Federal Register** of March 12, 1985 (50 FR 9944), EPA published a proposed rule for reporting of current data on the production volume, plant site, and site-limited status of certain chemical substances included on the TSCA Chemical Substances Inventory. EPA indicated in the proposal that it needs this information to update a critical portion of the TSCA Inventory data base which is used to support a number of TSCA activities. A 60-day public comment period followed the publication of the proposed rule.

This notice discusses the major comments, modifies certain provisions of the proposed rule, and promulgates the final rule under the authority of section 8(a) of TSCA. This rule is promulgated as an amendment to 40 CFR Part 710 which currently contains the Inventory Reporting Regulations of 1977. This amendment formally designates existing §§ 710.1 through 710.8 as Subpart A and adds new Subpart B.

IV. Provisions of the Final Rule

A. Substances Covered by the Rule

Reportable substances under this rule are those that are listed in the Agency's Master Inventory File as of the time of reporting and that are not specifically excluded from this rule. Substances which were originally excluded from the initial Inventory under 40 CFR 710.2 are therefore not reportable under this rule.

As an aid to submitters under this rule, EPA is publishing a 1985 edition of the TSCA Chemical Substances Inventory which supersedes the Initial Inventory published in 1979 and the supplements to the Initial Inventory. This reissued Inventory covers over 63,000 substances, including 6,000 substances which have been added since the last publication in 1982. Since

the printed Inventory can never be as complete as the Agency's Master Inventory File (which also contains specific identities for confidential substances), the Master Inventory File is, therefore, the only source which can conclusively determine whether a substance in question is on the Inventory. Manufacturers who may be subject to the requirements of this rule are urged to first use the printed Inventory for reporting purposes, especially for substances with nonconfidential identities, before requesting EPA to perform a search of the Master Inventory File. Procedures for requesting a search of the Master Inventory File are discussed in the instruction booklet entitled "Instructions for Reporting for the Partial Updating of the TSCA Chemical Inventory Data Base." A copy of this instruction booklet can be obtained by contacting the Agency at the address listed in § 710.39 of this rule.

Since EPA continually adds to the Master Inventory File substances that have undergone PMN review and that are subsequently reported as manufactured or imported, the Agency may publish supplements to the Inventory from time to time covering additions to the Master Inventory File since a previous publication. Substances added to the Master Inventory File after the start of a reporting period become reportable in the next reporting period, unless otherwise excluded from this rule.

B. Substances Excluded From the Rule

Four categories of substances, though included on the Inventory, are generally excluded from the reporting and recordkeeping requirements of this rule. These categories are polymers, inorganics, microorganisms, and naturally occurring chemical substances. However, if a polymer, an inorganic substance, or a microorganism is the subject of an order issued pursuant to TSCA section 5(e) or 5(f), or is the subject of a rule proposed or promulgated under TSCA section 4, 5(a)(2), 5(b)(4), or 6, or is the subject of relief granted under a civil action under TSCA section 5 or 7, that substance is not excluded from the rule.

To assist manufacturers subject to this rule to quickly identify an excluded substance, EPA has labeled with a special "XU" flag in the 1985 edition of the printed Inventory most of the substances that are excluded from this rule. Where a flag is found, manufacturers may rely on it as a signal that labelled substance is not subject to reporting. Where no flag is found and a substance may appear to fall within an excluded category, manufacturers should consult EPA. This is a consequence of technical difficulties with the application of flags by computer.

The four excluded categories are discribed below:

1. *Polymers.* For the purposes of this rule, a polymer is identified by the presence of any one (or more) of the word fragments "*polym*", "*alkyd", or "*oxylated" in the Chemical Abstracts Service (CAS) Index or Preferred Nomenclature of a particular substance, where the asterisk (*) indicates that any set of characters may precede, or follow, the character string defined. The CAS Index or Preferred Nomenclature can be easily obtained from the printed Inventory's "Chemical Substances Identities" section.

Polymers which are UVCB (i.e., chemical substances of unknown or variable composition, complex reaction products, and biological materials) substances, which do not contain one of the aforementioned character strings, can be identified in the hierarchy of subset headings in the printed Inventory's UVCB Index section. These UVCB subset headings are as follows: siloxanes and silicones, silsesquioxanes, proteins (albumin, casein, gelatin, gluten, hemoglobin), enzymes, polysaccharides (starch, cellulose, gums), rubber, or lignin. In general, all individual substances listed under any of the above UVCB subset headings are considered polymers and are therefore excluded from this rule. However, polymers which have been hydrolyzed, depolymerized, or chemically modified to the extent that the final products are no longer polymeric (e.g., a protein which is completely hydrolyzed into amino acids) are reportable.

EPA has labeled with an "XU" flag in the 1985 edition of the Inventory all of those polymers which contain one of the aforementioned character strings. UVCB biopolymers, except for those that contain a character string or polymer code, are generally not flagged. Therefore, users of the printed Inventory should be aware that substances other than those labeled with the "XU" flag may also be excluded from this rule.

EPA believes that the coverage for polymers for the purposes of this rule is sufficiently broad to include virtually all those substances that are generally considered as polymers.

2. *Inorganics.* For the purposes of this rule, inorganic substances are those that do not contain a carbon atom, or contain carbon only in the form of carbonato [= CO_3], cyano [–CN], isocyano [–NC], cyanato [–OCN], or isocyanato [–NCO] groups, or the chalcogen analogues of these groups.

In the 1985 edition of the Inventory, "XU" flags are applied to all inorganic substances that have molecular formulas which do not contain the element carbon. UVCB inorganics with no molecular formulas or inorganics containing carbon are not flagged on the Inventory, although they are considered inorganics and not reportable under this rule.

3. *Microorganisms.* For the purposes of this rule, this category includes bacteria, eimeria, fungi, and yeasts which are easily identifiable in the hierarchy of UVCB subset headings and are also identified on the Inventory by their corresponding CAS Preferred Names which are usually standard names for the species. Products of microorganisms are, however, reportable unless otherwise excluded. In the 1985 edition of the Inventory, "XU" label flags are applied to all substances listed under one of these three UVCB subset headings.

4. *Naturally occurring chemical substances.* Chemical substances, as described in § 710.4(b) of the Inventory Reporting Regulations (40 CFR Part 710) of 1977, are considered "naturally occurring" and are not reportable under this rule. However, persons who produce a substance in a manner other than as described in § 710.4(b) are required to report unless otherwise excluded.

This exclusion covers chemical substances which are naturally occurring and which are unprocessed or processed only by manual, mechnical, or gravitational means, by dissolution in water, by flotation, or by heating solely to remove water or which are extracted from air by any means. Examples of such substances include raw agricultural commodities, water, air, natural gas, crude oil, minerals, ores, and rocks.

Since whether a substance is considered as "naturally occurring" depends on the manner in which it is produced, it is impossible to label such substances with the "XU" flags because "naturally occurring" substances are not included on the Inventory.

C. Persons Subject to the Rule

Except for those persons described in unit IV.D below, a person is a manufacturer subject to this rule if that person has manufactured or imported for commercial purposes 10,000 pounds or more of a reportable substance at a particular site at any time during that person's most recent complete corporate fiscal year immediately preceding the

effective date of the rule or the start of any recurring reporting period.

D. Persons Exempt from the Rule

Two categories of persons are exempt from the reporting and recordkeeping requirements of this rule, provided that they qualify for one of the exemptions during a reporting period. Since a person who qualifies for an exemption during one reporting period may no longer qualify during the next reporting period, each person who may be subject to this rule must determine the person's exemption status during each succeeding reporting period.

1. *Small manufacturers.* Persons qualify as small manufacturers under this rule if, at the time of reporting, they meet one of the two standards specified in the TSCA section 8(a) Small Manufacturer Exemption Rule (40 CFR 704.5(d)) which was published in the **Federal Register** of November 16, 1984 (49 FR 45425). However, no person is considered a small manufacturer for the purposes of reporting a chemical substance that is the subject of an order issued pursuant to TSCA section 5(e), or is the subject of a rule proposed or promulgated under TSCA section 4, or 5(b)(4), or 6, or is the subject of relief granted under a civil action under TSCA section 5 or 7. Such persons must comply with the reporting and recordkeeping requirements under this rule for that particular substance.

2. *Persons manufacturing substances in limited circumstances.* Persons who manufacture reportable substances either in limited ways or through coincidental manufacture are exempt from the requirements of this rule for those substances. Therefore, persons who manufacture or import substances solely in small quantities for research and development or persons who import substances as part of articles, are exempt from this rule for those activities. Furthermore, persons who manufacture substances as impurities, byproducts, or in a manner incidental to another operation or upon end use of another substance or mixture, as described under § 720.30 (g) and (h) of the Premanufacture Notification Rule of 1983, are also exempt from the requirements of this rule for those substances.

E. Low-Volume Threshold

For the purposes of this rule, a low-volume reporting threshold is established to exempt from reporting those substances that are produced at low volumes. If a person's site-specific annual production volume for a reportable substance is below 10,000 pounds during the person's most recent complete corporate fiscal year before a reporting period, no reporting will be required for that substance for that period. In the case of importers, the measurable volume is the total amount of a substance imported during that year by each site which contains an operating unit responsible for the import. Thus a company which allows each plant to conduct its own import operations would make the determination for each such plant; a company which handles imports through its corporate headquarters would make the determination for all imports handled through the headquarters on an aggregate basis. Similarly, reports would be made by the site which actually conducts the import operation—either the specific plant or the corporate headquarters. If a substance's site-specific annual production volume or total amount annually imported increases to 10,000 pounds or more during the fiscal year preceding a subsequent reporting period, the person would be required to comply with the reporting requirements of this rule for that substance at that site.

F. When to Report

Current data, as described under unit IV.G below, must be submitted for each reportable substance at each plant site once every 4 years. For each round of reporting, submitters will have 120 calendar days to submit a report. Therefore, the first reporting period will commence on the effective date of this rule and will end 120 days after the effective date. Recurring reporting will take place on the fourth anniversary of the effective date and every 4 years thereafter. EPA plans to publish in the **Federal Register** a brief reminder announcement 2 months prior to the beginning date of each recurring reporting period.

G. What to Report

Persons who are subject to this rule are required to report by completing original numbered copies of the reporting form designated in § 710.39 of the rule, or by submitting the information in a computer tape. No other types of submissions will be acceptable. Detailed instructions for filling out the reporting form as well as specifications for submitting computer tape are discussed in the reporting instruction booklet. Persons who report via computer tape must follow the specifications discussed in the instruction booklet. Otherwise, the tape cannot be processed, will be rejected, and must be resubmitted.

To further simplify reporting procedures, EPA has combined the two previously proposed reporting forms into one form. Submitters, however, must not mix on one form information for substances with confidential chemical identities and information for those with nonconfidential chemical identities. Parts I, II, and III of the reporting form include the certification to be signed by the submitter and other basic submitter information. The extent to which Part IV of the form is completed will depend on the number of chemical substances reported on that form. Copies of the reporting forms can be obtained by contacting EPA at the address listed in § 710.39 of this rule.

The information requirements for this rule are discussed below.

1. *Chemical identity.* For each chemical substance covered by this rule, a submitter is required to provide certain specific information which will enable the Agency to identify quickly and uniquely that substance. Where known, such information must include the CAS Registry Number and a chemical name that is not a trade name. For most of the nonconfidential substances, the corresponding CAS Registry Number can be easily obtained from the 1985 edition of the Inventory. If the identity of the substance is claimed as confidential and no CAS Registry Number has been assigned to that substance, a submitter should provide a chemical name and an EPA-designated Accession Number for that substance. Each substance with a confidential identity has been assigned an Accession Number. Accession Numbers for confidential substances are listed in the generic names section of the printed Inventory. If a person does not know whether a substance is covered by one of the generic names, the person should contact EPA by following the procedures described in the aforementioned instruction booklet to determine whether the substance in question is reportable.

Other identifying numbers, i.e., PMN Case Number, original Inventory Reporting Form Number, Bona Fide Document Control Number, or Test Market Exemption Application Case Number, should be used only if a submitter cannot identify a particular substance by either its corresponding CAS Registry Number or EPA Accession Number.

2. *Plant site.* Manufacturers are required to report by specific plant site name and street address. Corporate headquarters, business, or Post Office Box addresses are not acceptable for reporting. However, if a corporation has a number of plant sites and wishes to have the corporate headquarters

coordinate the submission of reports, it may do so as long as information for different plant sites is reported on separate reporting forms.

With regard to importers, the definition under § 710.2(1) of the Inventory Reporting Regulations applies. Therefore, an importer means "* * * any person who imports a chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the United States," and includes "* * * the person primarily liable for the payment of any duties on the merchandise * * *". For the purposes of this rule, as discussed in Unit IV.E. above, certain importers must report by the United States headquarters or similar central office. However, if a plant site imports a substance directly from a foreign supplier and is "primarily liable for the payment of any duties" on that substance, the plant is then the importer of that substance. In that case, the imported substance must be reported directly by that plant site. This approach allows companies to report consistent with the conduct of their importing.

Each submitter is also required to provide a Dun & Bradstreet Number for each site reported under this rule.

3. *Manufacturer/importer.* Every submitter is required to indicate whether that person is a manufacturer and/or an importer for each of the substances reported for each site.

4. *Site-limited status.* Manufacturers are required to indicate whether a chemical substance manufactured at a plant site is distributed for commercial purposes outside that site, as a substance or as part of a mixture or an article. Imported substances cannot be site-limited.

5. *Production volume.* Respondents to this rule must report the plant site production volume (or total quantity imported) of each substance for which reporting is required. Quantities must be reported in pounds. Reporting must be accurate to the extent that the information is known to or reasonably ascertainable by the submitter, or to two significant figures. Production volume information reported within ±10 percent of the actual value will be acceptable for purposes of this rule. Manufacturers are required to report the annual production volume of each reportable substance at each plant site at which it is produced. Importers may report volume by plant site or as the total quantity imported by the company.

6. *Technical contact.* For each report submitted under this rule, a submitter is required to identify the name, address, and telephone number of an individual who can answer questions concerning the information on the reporting form.

H. Confidentiality

1. *Asserting claims.* While information submitted under this rule can generally be claimed as confidential, EPA strongly encourages respondents to this rule to carefully consider the necessity of asserting such claims. As provided by section 14 of TSCA, claims of confidentiality can be asserted only if release of the information would reveal company trade secrets or other confidential commercial or financial information. Furthermore, claims of confidentiality must be asserted at the time information is submitted to EPA in the manner specified in the rule and reporting instructions. EPA's procedures for processing and reviewing confidentiality claims are set forth at 40 CFR Part 2, Subpart B.

To claim information as confidential, a submitter is required to check the appropriate box and sign the certification statement on the reporting form. If a submitter fails to do so, EPA may release the information to the public without further notice to the submitter. By signing the certification statement the submitter certifies that its claims of confidentiality are made in good faith and that the statements on the back of the reporting form are true for each claim. Procedures for claiming as confidential information submitted by computer tape are contained in the instruction booklet.

2. *Chemical identity.* If a submitter wishes to claim the specific identity of a reportable substance as confidential business information, the submitter must report on the form (not by computer tape) and must check the "confidential" box for chemical identity under Column IV d of the reporting form and provide the required substantiation by answering the questions in § 710.38(c)(2) of this rule. A submitter, however, may not assert a claim of confidentiality for the identity of a substance if such identity is not already held confidential on the Inventory as of the time of the report. For each of the recurring reporting periods under this rule, a submitter is required to resubstantiate each claim of confidentiality even if the circumstances with regard to that claim have not changed since the last report.

If a manufacturer reports information under this rule for a chemical substance whose identity is held confidential on the Inventory and the manufacturer does not claim the chemical identity confidential, EPA will consider the identity of that substance no longer confidential for the purposes of the Inventory and may therefore disclose the identity of that substance. EPA strongly encourages industry to reconsider the necessity of retaining those claims. If a submitter decides not to assert again a claim of confidentiality for the identity of a substance which is on the Inventory, that submitter will simply submit the required data under this rule for that substance, and will check the "nonconfidential" box for chemical identity on the reporting form.

Submitters are required to segregate information on substances with confidential identities from the information on those with nonconfidential identities by using separate forms for each.

I. Recordkeeping Requirements

Persons subject to this rule are required to maintain records for a period of 4 years beginning with the effective date of a reporting period. As long as the records are maintained in a manner consistent with normal business practice, each submitter may determine the exact format in which the records are to be kept. The records that are required include those that show the production volume, plant site, and site-limited status of each of the substances reported. If a substance is not reported because its site-specific annual production is less than 10,000 pounds, only the site-specific production records for that substance need to be kept. Persons who qualify as exempt small manufacturers are not required to keep records.

V. Discussion of Major Comments

EPA received comments from 37 organizations. Although many of the comments were received after the closing date of the comment period, the Agency fully considered all of them in promulgating the final rule. While almost all of the commenters agreed that EPA needs current data to update the Inventory data base, many presented suggestions regarding specific provisions of the proposed rule. Some commenters requested that EPA grant more chemical exclusions under this rule. One commenter, however, argued that the proposed chemical exclusions are not justified and urged the Agency to broaden the scope of the update by including all Inventory substances under the rule.

This unit discusses the major comments that have the greatest impact on the rule, and gives EPA's response for each of these comments. EPA has also classified into generic categories all comments received and summarized the Agency's response to these comments. This summary, together with copies of

the public comments, is included in the public record for this rulemaking [docket number OPTS-82015A]. Therefore, EPA's response to comments that are not specifically discussed in this unit can be found in the rulemaking record.

A. Reporting Actual Production Volume

Comments. Eighteen commenters objected to the proposed requirement that production volume information be reported in pounds, rather than in ranges as used in reporting for the 1977 Inventory. These commenters urged EPA to reconsider its position toward precise production data for the following reasons:

First, the commenters noted that reporting of precise production volume would significantly increase the number of confidentiality claims on production information. They pointed out that such a reporting requirement would directly contradict EPA's expressed desire that industry exercise restraint to reduce the number of confidentiality claims for data to be submitted under this rule.

Second, some commenters argued that if the primary purpose of the Inventory data base is to provide basic information for priority setting or chemical screening, as EPA indicated in the preamble to the proposed rule, the need for precise production data for these purposes is not fully justified because these uses of the data would not require such a level of accuracy.

Third, certain commenters pointed out that it would be technically difficult to report precise production data for certain types of substances. For example, precise production data would be difficult to calculate for ingredients in formulated products or mixtures, especially for imported mixtures. They maintained that a submitter would have to review each product or mixture to determine the percentage composition of each of the ingredients. From the percentage composition and total production volume, the production volume of each ingredient would be calculated.

Fourth, some commenters noted that precise production data would, in some cases, create even more uncertainty than production ranges because a particular annual production may be atypical. Furthermore, initial precision could degrade substantially over time. Reporting in exact figures would create, at best, a false precision. They also maintained that it is inconsistent for EPA to require such a degree of accuracy when the low-volume threshold provision of this rule would allow production data up to 10,000 pounds to be excluded entirely.

Almost all of the 18 commenters agreed that the production ranges used for the 1977 Inventory reporting are too broad, and recommended that EPA consider using ranges that are narrower. As a minimum, they suggested that EPA allow reporting of precise production data to one or two significant figures or rounding the figures to the nearest 10,000 pounds.

EPA's response. EPA is aware that requiring precise production data under this rule could result in more frequent claims of confidentiality for production data than were asserted under the original Inventory rule. However, the same result is likely if production data were required to be reported under this rule in ranges that are narrower than those required under the oriqinal Inventory. If broad ranges were required, the data would be of diminished use to EPA. Therefore, EPA believes that the advantages of requiring production data to be reported in specific numbers will far outweigh the possible disadvantage of increased confidentiality claims. It should be noted that EPA will closely monitor claims of confidentiality asserted under this rule.

EPA disagrees with the commenters' contention that precise production data are not justified under this rule. In the preamble to the proposed rule, EPA stated that the Agency "needs production data to set priorities for further investigation, to perform first-level screening of chemical substances for testing under TSCA section 4, to estimate, along with other data, the potential for human and environmental exposure to specific substances, to support the implementation of various TSCA regulations, and to perform economic impact analyses for potential TSCA regulations." These uses will require data that are reasonably accurate. The ranges used for reporting the 1977 production data for the original Inventory were so broad that the resulting uncertainty became unacceptable in many applications including priority setting.

Many commenters perceived that they would be required to count every pound of a chemical substance produced at a plant site. This is not the intent of the Agency. In fact, the preamble to the proposed rule clearly states that "a submitter should provide the best available information, i.e., production figures normally maintained at a plant site for business purposes and known to, or reasonably ascertainable by, a submitter * * *." Some commenters urged EPA to permit the reporting of production data to two significant figures. EPA agrees with this comment and has included such a requirement in the final rule.

Regarding the technical difficulty in obtaining production figures for ingredients in formulated products or mixtures, EPA believes that this difficulty is overstated. Regardless of whether production volume is reported in ranges or in actual figures, a submitter will have to do almost the same amount of work to calculate the production volume for each of the ingredients in a product or a mixture. Furthermore, the provision of two significant figures will sufficiently lessen the burden associated with that calculation.

EPA recognizes that actual production data, like production ranges, will inevitably degrade over time. Actual figures, however, are initially more accurate than ranges. Over a period of time, the initial uncertainty associated with production ranges will be compounded by degradation, thus making the ranges less desirable.

EPA disagrees with the contention that there is an inconsistency between requiring precise production data to be reported and exempting from reporting those substances with an annual site-specific production volume of less than 10,000 pounds. EPA established the low-volume threshold for this rule to better focus its information collection effort on substances representing a greater potential exposure concern and to provide certain reporting relief for those who manufacture only a small amount of a reportable substance. However, if a company's production volume of a reportable substance increases to 10,000 pounds annually at a particular site, reporting will be required. This provision bears no relationship to the level of accuracy at which the data are reported.

B. Recurring Reporting and Reportable Events

In the March 12 **Federal Register** notice, EPA proposed that recurring reporting be required every 2 years if a reportable event has occurred. Reportable events generally reflected what EPA considered as significant changes in production volume or site-limited status of a reportable substance. In addition to the proposed approach, two possible alternatives were discussed in the preamble. One of these two alternatives would require automatic reporting periodically on all reportable substances, regardless of whether a reportable event has occurred.

Comments. Seventeen commenters addressed the issue of recurring

reporting in their comments on the proposed rule. While all of these commenters agreed that some kind of recurring reporting is necessary to maintain a current data base, they all disagreed with EPA's proposed approach. Major points of their comments are summarized below:

First, many commenters contended that recurring reporting at 2-year intervals is not justified because production does not change that frequently for many chemicals. For chemicals that are produced in batches, such an approach would provide misleading information. Many maintained that EPA has underestimated the burden that would be imposed by this approach while it has overestimated the degree of data obsolescence for the 2-year period. They suggested that the frequency for recurring reporting be determined after the Agency has obtained initial submissions under this rule and compared the new data against the 1977 data to determine the extent to which the information has become out-of-date.

Second, a number of commenters indicated that EPA has underestimated the burden associated with the determination of whether a reportable event has occurred. They maintained that, in many cases, it would be less burdensome to simply submit a report. Some commenters argued that reporting triggers would penalize smaller companies more because they are less equipped to make a determination of whether reporting is necessary and would therefore tend to overreport.

Third, most of the commenters suggested that, if EPA decides that it must include a recurring reporting provision in the final rule, the Agency should consider requiring recurring reporting on all reportable chemicals every 5 years regardless of whether a reportable event has occurred during that period. The 5-year interval corresponds to the period used by the U.S. Census Bureau for its Census of Manufacturers. The commenters argued that this approach would provide EPA with a more complete update each time, though less frequently. EPA will be able to maintain a relatively current data base. The commenters contended that, even using EPA's own estimate, the Inventory would only be 62.5 percent obsolete and would still be more current than the present Inventory which EPA has been using for the past 8 years. The commenters also pointed out that this approach would be less burdensome to both EPA and industry, because the absence of reporting triggers would further simplify the reporting and recordkeeping requirements under this rule and would make EPA's compliance monitoring much easier.

EPA's response. EPA's original proposal that recurring reporting be triggered by the occurrence of a reportable event was based on the belief that this approach would allow the Agency to maintain a current data base without imposing an unreasonable burden on both the Agency and the submitters. After carefully reviewing the comments on this issue, EPA concludes that the proposed approach may not offer as many advantages as the Agency previously believed. Therefore, EPA agrees with the commenters that compliance with the requirements of this rule will be simpler and more straightforward if recurring reporting is not event-triggered.

The question of whether the determination of the occurrence of a reportable event is more burdensome than actual reporting will most likely vary from submitter to submitter. The Agency still believes that the reportable events governing recurring reporting, as proposed in the March 12 **Federal Register** notice, are not overly complicated. In most cases, it would simply require the comparison of production data every 2 years against the data previously reported. For those submitters who have the capability of storing the information in a computerized system, such a comparison should not be difficult. However, smaller companies which do not have access to computerized systems would have to perform such comparisons manually. Furthermore, recordkeeping requirements could, in most cases, become open-ended because current production data would be compared against the data last reported reqardless of its age.

If recurring reporting is triggered by events, EPA's compliance monitoring effort could become, in many cases, difficult and resource-intensive. The Agency would have to inspect production records before it could conclude that a manufacturer had a legitimate reason not to report during a particular reporting period. On the other hand, if recurring reporting is automatic, there will be fewer records to inspect because more manufacturers will have to report each time.

EPA believes that the provision governing recurring reporting should be part of the final rule and therefore disagrees with the recommendation that the frequency of recurring reporting be determined at a later date. By the time the initial submissions under this rule can be analyzed and compared against the 1977 data, the existing data would be almost 10 years old. There could have been successive changes at a plant site which could make such a comparison both difficult and inconclusive.

Based on these comments, EPA has adopted the concept of automatic recurring reporting every 4 years on all reportable substances with a site-specific production volume of 10,000 pounds or more. Although recurring reporting will occur less frequently, as compared to the originally proposed 2-year interval, each round of reporting will provide a much more complete update of the information. Based on its experience with the 1977 Inventory data, EPA believes that the 4-year reporting interval would be reasonable, since this would enable the Agency to maintain a relatively current data base without imposing an unreasonable reporting burden on industry.

C. Definition of Polymer

Comments. Eleven commenters urged EPA to broaden the "definition" of polymer by including such terminologies as "homopolymer," "copolymer," and "terpolymer," and/or to add the definition for polymer used under the section 5(h)(4) premanufacture notification polymer exemption rule (40 CFR 723.250(b)(11)).

EPA's response. EPA disagrees with these comments for two reasons. First, the terminologies used to describe polymers, as discussed in the proposed rule, already provide sufficiently broad coverage of substances with a polymeric structure. Some of the terminologies suggested by the commenters, i.e., "homopolymer," "copolymer," and "terpolymer," are already covered.

Second, the definition used for identifying polymers for consideration under the section 5(h)(4) polymer exemption rule, (40 CFR 723.250(b)(11)) is not the only criterion which determines whether a substance is qualified for exemption under that rule. Additional criteria must also be satisfied before a substance can be considered as eligible for exemption. Some of the criteria require that an eligible polymer not contain certain reactive functional groups or elements, not be a biopolymer or its synthetic equivalent, not contain less than 32.0 weight percent of atomic carbon, and must have a number-average molecular weight of at least 1,000. A substance that does not fully satisfy all of the criteria listed in the polymer exemption rule will not qualify for consideration even if it is a polymer defined under 40 CFR 723.250(b)(11). Therefore, it would

not be appropriate to include that definition without the accompanying criteria. If the criteria are also used, many polymers that are currently excluded from this rule would no longer be eligible for exclusion.

Since issuing the March 12 Federal Register notice, EPA has closely examined the completeness of the terminologies that were used in the proposed rule to identify polymers. As a result of this review, EPA has refined the terminologies for the final rule. The refined terminologies, which are discussed in Unit IV. above, identify virtually all those substances on the Inventory that are generally considered as polymers.

D. Chemical Exclusions

Comments. Almost all of the commenters agreed with the four chemical exclusion categories proposed by EPA. One commenter, however, strongly opposed excluding any chemical categories from the requirements of this rule. This commenter contended that the Inventory data base is too important to update only partially, and that section 8(b) of TSCA requires that the entire Inventory be kept current.

EPA's response. EPA believes that the exclusions proposed in the March 12 Federal Register notice are justified. Section 8(b) of TSCA requires the Agency to "* * * compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States." EPA has already been fulfilling this mandated obligation of keeping the Inventory current by continually adding to the list those newly manufactured substances that have completed section 5 PMN review, and by periodically removing from the Inventory those substances which were misreported when the Inventory was compiled and replacing them with the corrected chemical identities. The production volume and plant site data associated with the substances on the Inventory were not collected for the purposes of the section 8(b) Inventory. Rather, these data were reported under the authority of section 8(a). The "keep current" provision under section 8(b) is restricted to the addition of newly manufactured substances and does not apply to the production volume and plant site data associated with Inventory substances.

EPA must independently determine the need for collecting current data for these substances under section 8(a) of TSCA. The reasons for excluding the four categories were given in the March 12 Federal Register notice. If EPA were to require manufacturers to report data on every substance listed on the Inventory, this would result in an unnecessary reporting burden for the submitters, and the additional information would be "of no practical utility" to the Agency, thus violating the Paperwork Reduction Act's standards for information collection. However, the Agency has included in the final rule a provision which requires the reporting of current data on an excluded substance if such substance is the subject of a rule or an order issued under TSCA section 4, 5, 6, or 7. This provision will ensure the availability of current information if EPA has expressed a concern in the form of regulatory action on any of the substances otherwise excluded from the rule.

E. Petroleum Refinery Streams

Comments. Six commenters responded to EPA's request for comment on whether petroleum refinery streams should be excluded from this rule. They pointed out that, for TSCA purposes, EPA should be concerned about the potential health and environmental effects of products rather than intermediate process streams. The petroleum refinery streams are by their nature site-limited and maintained within closed systems. It is normally only the final petroleum products that leave the refinery and enter into commerce. The commenters argued that production volume data for refinery streams are unnecessary to the evaluation of products, and can be used inappropriately to give misleading results because they do not necessarily reflect the production volumes for commercial petroleum products. Furthermore, they also pointed out that the refining and manufacture of petroleum products is a mature technology, and no new refinery streams or petroleum products have ever been added to the Inventory through the PMN process. Nor are major changes in refinery technology anticipated which would significantly change the composition of refinery streams. Therefore, the commenters believed that a broad-based Inventory update of petroleum production statistics would serve little purpose in the absence of technological developments or volume changes with potential impacts on human exposure or environmental release. Even if EPA can establish a need for such data, reporting under this rule will not be necessary because the data are already reported to the Department of Energy (DOE).

In addition to petroleum refinery streams, fifteen commenters also suggested additional substances for exclusion. EPA's responses to these suggestions are included in the public record for this rule and are not discussed in this unit.

EPA's response. EPA disagrees with the contention that intermediate process streams are inappropriate subjects of risk identification activities under TSCA. EPA has never limited its focus to only final products sold in commerce. Since intermediate products can raise concerns with regard to occupational exposure and release to the environment during production and processing operations, it is often necessary to know the total production volume of a stream which may appear as a fraction of numerous products. If such a fraction is hazardous, it is important to know the total volume in commerce. EPA routinely uses total production volume as a decision factor in preliminary risk identification activities.

Regarding the availability of production data at DOE, as claimed by these commenters, EPA has reviewed reports published by the DOE Energy Information Administration (EIA) and concluded that site-specific production volume information on refinery streams is not available. EPA believes that the rationale for site-specific information on petroleum refinery streams and products is basically the same as the rationale for any other types of substances. For the purposes of TSCA, EPA needs site-specific production volume information to support assessment of the number of workers who may be exposed at a site, the general population at risk in the area surrounding a site, and the chemical concentration in waterways downstream from each site. Site-specific information is also needed to support the assessment of economic impacts on affected companies in rulemaking under TSCA, and to determine the number of reports that can be expected for each reporting rule. Aggregated production data, which are readily available from EIA, do not provide useful information for any of the aforementioned analyses.

F. Duplicative Reporting

Comments. Two commenters requested that EPA clarify the potential duplicative reporting requirements between this rule and other TSCA section 8(a) rules including the yet-to-be proposed Comprehensive Assessment Information Rule (CAIR).

EPA's response. EPA recognizes that there could exist a potential for duplicative reporting among the various section 8(a) reporting rules, especially regarding production volume data. The Agency has decided that if similar information has been submitted under a

section 8(a) rule for a substance within the year preceding the start of a reporting period under this rule, the submitter will not be required to report the same information again for that reporting period.

G. Reporting by Importers

Comments. One commenter asked EPA to clarify in the final rule which person has the responsibility to report as the "importer" of a particular substance as was done in the PMN rule.

EPA's response. EPA recognizes that more than one person might meet the definition of "importer" in § 710.2(1) of the original Inventory Reporting Rule and § 704.3 of the general section 8(a) definitions for a particular import transaction involving a particular substance. For PMN purposes, to address the same problem, EPA decided to define a "principal importer" (40 CFR 720.3(z)), which in most cases will be the person most knowledgeable about a new chemical substance, and to require that person to submit the PMN. For this rule EPA has decided not to designate which "importer" should report for a particular import transaction involving a specific chemical substance. Rather, EPA will leave it to the parties to the transaction to determine which will report. Section 710.35(b) of the rule makes clear that EPA wants only a single report for such a transaction and that EPA will hold each "importer" liable if a required report is not submitted or does not contain the required information. Thus, if a company imports a substance several times in a single year at a particular site and uses different agents each time, the company could choose to submit the report combining all the imports, or it could designate one of the agents to submit the report, provided the agent had all the necessary information about all shipments.

H. Definition of "Parent Company" for Small Manufacturer Exemption

Comments. One commenter raised several concerns about the Agency's definition of the terms "parent company" and "small manufacturer," specifically, the commenter noted that the total annual sales criterion of the small manufacturer definition should not include sales revenue of parent and/or subsidiary companies. In addition, the commenter noted that majority stock ownership should not be a determining factor in either the definition of "parent company" or the determination of responsibility for compliance with reporting requirements.

EPA's response. In an effort to simplify this final rule, EPA has deleted the text of several definitions from the rule, including the definitions of "parent company" and "small manufacturer." However, these definitions still are applicable to the final rule because they are incorporated by reference from the list of standard section 8(a) definitions contained in 40 CFR 704.3. The definitions in § 704.3 are not substantively different from the definitions which were contained in the proposed rule. Since this rule adopts the definitions contained in 40 CFR 704.3, the commenter's points remain relevant and are addressed by EPA below.

The Agency's definitions for the terms "parent company" and "small manufacturer" are part of the generic reporting provisions for section 8(a) rules, and already have been the subject of public comment. EPA received relatively few adverse comments on the generic definitions. The definition of "parent company" is based on the concept of ownership or control, which often is determined by majority stock ownership. This interpretation of the relationship between parent firm and subsidiary reflects prevailing judicial views on the issue.

The "small manufacturer" definition includes the total annual sales of parent firms and subsidiaries, if any, because EPA believes that a broadly defined sales criterion is the best available measure of a diversified firm's full financial resources available for regulatory compliance. For a more detailed discussion of this definition, see the preamble discussions of both the proposed and final Small Manufacturer Exemption Rules (proposed rule at 47 FR 27206, June 23, 1982; final rule at 49 FR 45425, November 16, 1984).

EPA does not intend that a parent firm owning a majority of stock in a subsidiary report on behalf of the subsidiary. Any company that is subject to reporting requirements under the terms of this rule (and that does not qualify for any of the exemptions in the rule) must submit the requisite information, even if that firm is a subsidiary of a larger company; it is up to the companies involved to determine internally who compiles the requisite data for submission. In the event of noncompliance, the legal principles of liability in parent-subsidiary relationships will govern.

I. Recordkeeping Requirements

Comments. Nine organizations expressed concern that the proposed recordkeeping requirements would be unnecessarily burdensome. In general, there are two main objections. First, the commenters believed that the proposed 5-year record retention time is not justified. A 2-year period would be consistent with standard practice. Second, they objected to the requirement that the submitters must document decisions not to report. Some indicated that this requirement would take away the benefits of the various exclusions and exemptions. Furthermore, all of the commenters urged EPA to provide detailed guidance regarding how and what records should be kept.

EPA's response. EPA agrees that, as proposed, the actual recordkeeping time could be open-ended. This is because a submitter, in order to make a determination of whether recurring reporting is necessary, would have to compare, for each reportable substance, current data against the information that was last reported. To make that comparison, the submitter would have to maintain records of the last reporting almost indefinitely, or until a reportable event occurs. This is one of the major disadvantages of the event-triggered approach for recurring reporting. Since the Agency has abandoned the previously proposed event-triggered approach, recordkeeping time for the purpose of this rule will no longer be open-ended. However, there must be adequate time from the closing of a reporting period for the Agency to analyze the submissions and to examine the corresponding records if an inspection of a particular plant site is found to be necessary. For this reason, EPA believes that a 2-year recordkeeping period, as suggested by the commenters, will not be sufficient. As a minimum, relevant records for a reporting period must be retained until the start of the next round of reporting, i.e., for the entire 4 years between 2 reporting periods.

The proposed requirement that submitters document decisions that reporting is not necessary was also closely related to the proposed event-triggered approach for recurring reporting. This requirement meant that the submitters should be able to show evidence, upon request, that recurring reporting was not necessary because a reportable event had not occurred during a particular period of time. Since most of the reportable events relate to production, the submitter's production records would have been sufficient evidence. Contrary to what many commenters believed, the Agency had never intended to extend the scope of this requirement to cover persons who are not subject to this rule or the excluded chemical categories. For the purposes of this rule, only those records that show the production volume, plant

site, and site-limited status of each reportable substance are to be maintained. In the case of low-volume substances, only production records must be kept to establish evidence that those substances are not reportable at the current production levels.

J. Data Aggregation and Confidentiality

Comments. Several commenters suggested that EPA publish prior to the effective date of the final rule methodologies that the Agency will use to aggregate production volume data for public disclosure. One commenter claimed that even aggregated data could be sensitive information, and thus EPA has no right to publish aggregated data.

A number of commenters urged that EPA allow confidentiality claims for the signing official of the reporting firm and the name and address of the technical contact. They also urged EPA to exempt submitters from resubstantiating claims for confidential chemical identities if such has been submitted to the Agency within 2 years before the final rule takes effect.

EPA's response. EPA has yet to determine which of the several data aggregation methodologies it is investigating will be used for production volume data collected under this rule. Even after a methodology is selected, it is unlikely that EPA will be able to describe it in great detail and still preserve the confidentiality of the information to be aggregated. EPA's rationale for not publishing a detailed description of the aggregation is to protect the confidentiality of the information.

EPA agrees with the comments on confidentiality claims for the signing official and the technical contact. The reporting form has been revised to permit these claims to be asserted.

EPA disagrees, however, with the comment that resubstantiation of confidentiality claims for chemical identity is unnecessary under this rule if such substantiation has been submitted within 2 years before the rule takes effect. EPA is actively reviewing claims of confidentiality asserted for information on substances added to the Inventory via the PMN process, and will also actively review claims asserted under this rule. This review requires up-to-date substantiation for the claims asserted. If the substantiation previously submitted is no longer valid, EPA must have new substantiation for the purposes of this rule. If the substantiation is still valid, the burden for resubmitting it should be minimal.

VI. Rulemaking Record

EPA has established a public record for this rulemaking (docket number OPTS 82015A), which is available for inspection in Rm. E-107, 401 M St., SW., Washington, DC 20460, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. These records include all basic information considered by the Agency in developing this rule.

The following documents are included in the rulemaking record:

(1) Analysis of Reporting Requirements for the Partial Update of the TSCA Inventory Data Base.

(2) Whether and How the TSCA Inventory Data Base Should Be Updated.

(3) Analysis of TSCA Section 8(a) Small Manufacturer Exemption.

(4) All comments on proposed rule and relevant documents and studies submitted in support of these comments.

(5) A summary of EPA's responses to the comments on the proposed rule.

(6) U.S. General Accounting Office Fact Sheet for the Chairman, Subcommittee on Commerce, Transportation and Tourism, Committee on Energy and Commerce, House of Representatives: Chemical Inventory—Environmental Protection Agency's Proposed Inventory Update, December 1985, GAO/RCED-86-47FS.

(7) A Summary of EPA's Responses to the GAO Report on the TSCA Inventory Update.

(8) Records of all communications between EPA personnel and persons outside the Agency pertaining to the development of this rule. (This does not include inter- or intra-agency memoranda unless specifically noted in the index of the rulemaking record.)

VII. Economic Impact

Based on exclusions and exemptions discussed in this preamble, EPA estimates that a total of 4,800 plant sites will be required to submit an initial report on at least one chemical substance.

EPA estimates that chemical manufacturers subject to this rule will spend approximately $5.5 million to report for the initial reporting period. These estimates include both fixed and variable costs.

The fixed costs per plant site to comply with the initial reporting requirements of this rule are estimated at $946. This includes time to become familiar with the reporting requirements, time to determine which of the substances produced at the site are covered by the rule, and time to develop an ongoing reporting mechanism. Maximum variable costs of compliance with the initial reporting are estimated at an additional $251 per reporting form that must be submitted. The variable costs include time to gather necessary data, and time to complete and review a reporting form including a determination of whether the information should be claimed as confidential.

The fixed and variable cost estimates were based on the number of hours that would be required to complete a reporting form. EPA estimates an average of 19 hours for a submitter to become familiar with the rule, determine which of the substances produced at a plant site is reportable, and develop a reporting mechanism. A maximum of 5 additional hours are estimated for a submitter to gather the necessary information and to complete and review a reporting form. At an average of one report per plant site, these estimates allow 24 hours for an average plant site's compliance. This figure could be lower or higher depending on the number of forms involved at a plant site.

For subsequent reporting years (every fourth year following the initial reporting year), all plant sites manufacturing a reportable substance will have to file a new reporting form. The total cost of reporting in subsequent reporting years is projected at $2.2 million. This estimate includes costs for reviewing the rule, for making the determination, and for completing a reporting form.

A more detailed economic impact analysis of the requirements of this rule is included in the rulemaking record.

VIII. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must determine whether a regulation is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this regulation is not "major" because it will not have an annual effect of $100 million or more on the economy. It is not anticipated to have a significant effect on competition, costs, or prices.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

This rule contains a small manufacturer exemption which generally exempts small manufacturers and importers from all reporting requirements. Therefore, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, EPA has determined

that this rule will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The information collection requirements contained in this rule were submitted for approval to OMB under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* The information collection requirements in this final rule were approved by OMB and assigned control number 2070–0070.

List of Subjects in 40 CFR Part 710

Environmental protection, Chemicals, Inventory, Hazardous materials, Reporting and recordkeeping requirements.

Dated: May 29, 1986.

Lee M. Thomas,

Administrator.

PART 710—[AMENDED]

Therefore, 40 CFR Part 710 is amended as follows:

1. The authority citation for Part 710 continues to read as follows:

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

2. By designating the existing §§ 710.1 through 710.8 as Subpart A, the heading for which reads as follows:

Subpart A—Compilation of the Inventory

3. By adding a new Subpart B, to read as follows:

Subpart B—Partial Updating of the Inventory Data Base

Sec.

Subpart B—Partial Updating of the Inventory Data Base

§ 710.23 Definitions.

The definitions in § 704.3 of this chapter and § 710.2 of this Part apply except as provided in this section.

(a) "Master Inventory File" means EPA's comprehensive list of chemical substances which constitute the Chemical Substances Inventory compiled under section 8(b) of the Act. It includes substances reported under Subpart A of this Part and substances reported under Part 720 of this chapter for which a Notice of Commencement of Manufacture or Import has been received under § 720.120 of this chapter.

(b) "Nonisolated intermediate" means any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

(c) "Site-limited" means a chemical substance is manufactured and processed only within a site and is not distributed for commercial purposes as a substance or as part of a mixture or article outside the site. Imported substances are never site-limited.

§ 710.25 Chemical substances for which information must be reported.

Any chemical substance which is in the Master Inventory File at the beginning of a reporting period described in § 710.33, unless the chemical substance is specifically excluded by § 710.26.

§ 710.26 Chemical substances for which information is not required.

The following categories of chemical substances are excluded from the reporting requirements of this subpart. However, a chemical substance described in paragraphs (a), (b), or (c) of this section is not excluded from the reporting requirements of this subpart if that substance is the subject of a rule proposed or promulgated under section 4, 5(a)(2), 5(b)(4), or 6 of the Act, or is the subject of an order issued under section 5(e) or 5(f) of the Act, or is the subject of relief that has been granted under a civil action under section 5 or 7 of the Act.

(a) *Inorganic chemical substances.* Any chemical substance which does not contain carbon or contains carbon only in the form of carbonato [$=CO_3$], cyano [$-CN$], cyanato [$-OCN$], isocyano [$-NC$], or isocyanato [$-NCO$] groups, or the chalcogen analogues of such groups.

(b) *Polymers.* (1) Any chemical substance described with the word fragments "*polym*", "*alkyd*", or "*oxylated" in the Chemical Abstracts Service Index or Preferred Nomenclature in the Chemical Substance Identities section of the 1985 edition of the Inventory or in the Master Inventory File, where the asterisk (*) indicates that any sets of characters may precede, or follow, the character string defined.

(2) Any chemical substance which is identified in the 1985 edition of the Inventory or the Master Inventory File as siloxane and silicone, silsesquioxane, a protein (albumin, casein, gelatin, gluten, hemoglobin), an enzyme, a polysaccharide (starch, cellulose, gum), rubber, or lignin. This exclusion, however, does not apply to a chemical substance which has been hydrolyzed, depolymerized, or chemically modified to the extent that the final product is no longer polymeric in structure.

(c) *Microorganisms.* Any combination of chemical substances that is a living organism, such as bacteria, eimeria, fungi, and yeasts. Any chemical substance produced from such a living organism is reportable unless otherwise excluded.

(d) *Naturally occurring chemical substances.* Any naturally occurring chemical substance, as described in § 710.4(b). The applicability of this exclusion is determined in each case by the specific activities of the person who manufactures the substance in question. Some chemical substances can be manufactured both as described in § 710.4(b) and by means other than those described in § 710.4(b). If a person described in § 710.28 manufactures a chemical substance by means other than those described in § 710.4(b), the person must report regardless of whether the substance also could have been produced as described in § 710.4(b). Any chemical substance that is produced from such a naturally occurring chemical substance described in § 710.4(b) is reportable unless otherwise excluded.

§ 710.28 Persons who must report.

Except as provided in §§ 710.29 and 710.30, the following persons are subject to the requirements of this subpart. Persons must determine whether they must report under this § 710.28 for each chemical substance that they manufacture at an individual site.

(a) *Persons subject to initial reporting.* Any person who manufactured for commercial purposes 10,000 pounds (4,540 kilograms) or more of a chemical substance described in § 710.25 at any single site owned or controlled by that person at any time during the person's latest complete corporate fiscal year before August 25, 1986.

(b) *Persons subject to recurring reporting.* Any person who manufactured for commercial purposes

10,000 pounds (4,540 kilograms) or more of a chemical substance described in § 710.25 at any single site owned or controlled by that person at any time during the person's latest complete corporate fiscal year before August 25, 1990, or before August 25 at four-year intervals thereafter.

(c) *Special provisions for importers.* For purposes of paragraphs (a) and (b) of this section, the site for a person who imports a chemical substance described in § 710.25 is the site of the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction. The import site may in some cases be the organization's headquarters in the U.S. (See also § 710.35(b).)

§ 710.29 Persons not subject to this subpart.

A person described in § 710.28 is not subject to the requirements of this subpart if that person qualifies as a small manufacturer as that term is defined in § 704.3(r) of this chapter. Notwithstanding this exclusion, a person who qualifies as a small manufacturer is subject to this subpart with respect to any chemical substance that is the subject of a rule proposed or promulgated under section 4, 5(b)(4), or 6 of the Act, or is the subject of an order in effect under section 5(e) of the Act, or is the subject of relief that has been granted under a civil action under section 5 or 7 of the Act.

§ 710.30 Activities for which reporting is not required.

A person described in § 710.28 is not subject to the requirements of this subpart with respect to any chemical substance described in § 710.25 that the person manufactured or imported under the following circumstances:

(a) The person manufactured or imported the chemical substance described in § 710.25 solely in small quantities for research and development,

(b) The person imported the chemical substance described in § 710.25 as part of an article,

(c) The person manufactured the chemical substance described in § 710.25 in a manner described in § 720.30 (g) or (h) of this chapter.

§ 710.32 Information to be reported.

Any person who must report under this subpart must submit the information prescribed in this section for each chemical substance described in § 710.25 that the person manufactured for commercial purposes in an amount of 10,000 pounds (4,540 kilograms) or more at a single site during a corporate fiscal year described in § 710.28. (The site for a person who imports a chemical substance is the site of the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction, and may in some cases be the organization's headquarters office in the U.S.). A respondent to this subpart must report information in writing or by computer tape as prescribed in this section, to the extent that such information is known to or reasonably ascertainable by that person. A respondent to this subpart must report information that applies to the specific corporate fiscal year for which the person is required to report. Information on chemical substances for which the chemical identities are claimed confidential under § 710.38 must be submitted in writing.

(a) *Reporting in writing.* Any person who chooses to report information to EPA in writing must do so by completing the reporting form contained in § 710.39, and must submit a separate form for each site for which the person is required to report. Information on substances for which the chemical identity is claimed confidential under § 710.38 must be submitted in writing on a separate reporting form; a respondent to this subpart must not report confidential and non-confidential chemical substance identities on the same reporting form.

(b) *Reporting by computer tape.* Any person who chooses to report information to EPA by means of computer tape must submit the information prescribed in this paragraph (b), and must report separately for each plant site for which the person is required to report. Computer tape submitted in response to this subpart must meet EPA specifications, as described in the instruction booklet identified in § 710.39(b). Persons reporting by means of computer tape also must submit a separate reporting form, with certain basic data elements completed, as specified below, for each site for which the person is required to report. The information to be reported is as follows:

(1) On the reporting form, the name, address, city, State, Zip code, and telephone number of a person who will serve as technical contact for the respondent company, and will be able to answer questions about the information submitted by the company to EPA.

(2) On the reporting form, a certification statement signed and dated by an authorized official of the respondent company, and a written statement on the form that information is being submitted by means of computer tape. The computer tape shall be enclosed with the reporting form.

(3) On the computer tape, the specific chemical name and Chemical Abstracts Service (CAS) Registry Number of each chemical substance for which reporting is required under this subpart. A respondent to this subpart may use other chemical identification numbers in lieu of CAS Registry Numbers when a CAS Registry Number is not known to the respondent as provided in the instruction booklet identified in § 710.39(b), including EPA-designated Accession Numbers for confidential substances, EPA-assigned numbers for bona fide or Premanufacture Notification submissions or Test Market Exemption Applications, or original Inventory form numbers.

(4) On the computer tape, the name, street address, city, State, and Zip code of each site at which 10,000 pounds (4,540 kilograms) or more of a chemical substance for which reporting is required under this subpart is manufactured or imported. (The site for a person who imports a chemical substance is the site of the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction, and may in some cases be the organization's headquarters office in the U.S.). A respondent to this subpart must include the appropriate Dun and Bradstreet Number for each plant site reported.

(5) On the computer tape, a statement for each substance for which information is being submitted indicating whether the substance is manufactured in the United States or imported into the United States.

(6) On the computer tape, a statement for each substance for which information is being submitted indicating whether the substance is site-limited.

(7) On the computer tape, the total volume (in pounds) of each subject chemical substance manufactured or imported at each site. This amount must be reported to two significant figures of accuracy provided that the reported figures are within ±10 percent of the actual volume.

§ 710.33 When to report.

All information reported to EPA in response to the requirements of this subpart must be submitted during an applicable reporting period. The following reporting periods are prescribed for this subpart.

(a) *Initial reporting period.* The first reporting period is from August 25, 1986

to October 10, 1986. Any person described in § 710.28(a) must report during this period for each chemical substance described in § 710.25 that the person manufactured during the corporate fiscal year described in § 710.28(a).

(b) *Recurring reporting periods.* The first recurring reporting period is from August 25, 1990 to October 10, 1990. Subsequent recurring reporting periods are from August 25 to October 10 at 4-year intervals thereafter. Any person described in § 710.28(b) must report during the appropriate reporting period for each chemical substance described in § 710.25 that the person manufactured during the applicable corporate fiscal year described in § 710.28(b).

§ 710.35 Duplicative reporting.

(a) *With regard to section 8(a) rules.* Any person subject to the requirements of this subpart who previously has complied with reporting requirements of a rule under section 8(a) of the Act by submitting the information described in § 710.32 for a chemical substance described in § 710.25 to EPA, and has done so within one year of the start of a reporting period described in § 710.33, is not required to report again on the manufacture of that substance at that site during that reporting period.

(b) *With regard to importers.* This subpart requires that only one report be submitted on each import transaction involving a chemical substance described in § 710.25. When two or more persons are involved in a particular import transaction and each person meets the Agency's definition of "importer" as set forth in § 710.2(l) and § 704.3 of this chapter, they may determine among themselves who should submit the required report; if no report is submitted as required under this subpart, EPA will hold each such person liable for failure to report.

§ 710.37 Recordkeeping requirements.

Each person who is subject to the reporting requirements of this subpart must maintain records that document any information reported to EPA. For substances that are manufactured or imported at less than 10,000 pounds annually, volume records must be maintained as evidence to support a decision not to submit a report. Records relevant to reporting during a reporting period described in § 710.33 must be retained for a period of four years beginning with the effective date of that reporting period.

(Approved by the Office of Management and Budget under control number 2070-0070)

§ 710.38 Confidentiality.

(a) Any person submitting information under this subpart may assert a business confidentiality claim for the information. The procedures for asserting confidentiality claims are described in the instruction booklet identified in § 710.39. Information claimed as confidential in accordance with this section and those instructions will be treated and disclosed in accordance with the procedures in Part 2 of this chapter.

(b) A person may assert a claim of confidentiality for the chemical identity of a specific chemical substance only if the identity of that substance is treated as confidential in the Master Inventory File as of the time the report is submitted for that substance under this subpart.

(c) To assert a claim of confidentiality for the chemical identity of a specific chemical substance, the person must take the following steps:

(1) The person must report on the form contained in § 710.39, not by computer tape.

(2) The person must submit with the report detailed written answers to the following questions signed and dated by an authorized official.

(i) What harmful effects to your competitive position, if any, do you think would result from the identity of the chemical substance being disclosed in connection with reporting under this subpart? How could a competitor use such information? Would the effects of disclosure be substantial? What is the causal relationship between the disclosure and the harmful effects?

(ii) How long should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

(iii) Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential?

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

(v) Is the fact that the chemical substance is being manufactured or imported for a commercial purpose available to the public, for example in technical journals, libraries, or State, local, or Federal agency public files?

(vi) What measures have you taken to prevent undesired disclosure of the fact that this chemical substance is being manufactured or imported for a commercial purpose?

(vii) To what extent has the fact that this chemical substance is manufactured or imported for commercial purposes been revealed to others? What precautions have been taken regarding these disclosures? Have there been public disclosures or disclosures to competitors?

(viii) Does this particular chemical substance leave the site of manufacture in any form, as product, effluent, emission, etc.? If so, what measures have you taken to guard against discovery of its identity?

(ix) If the chemical substance leaves the site in a product that is available to the public or your competitors, can the substance be identified by analysis of the product?

(x) For what purpose do you manufacture or import the substance?

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

(3) If any of the information contained in the answers to the questions is asserted to contain confidential business information, the person must mark that information as "trade secret," "confidential," or other appropriate designation.

(d) If no claim of confidentiality accompanies information at the time it is submitted to EPA under this subpart or if substantiation required under paragraph (c) of this section is not submitted with the reporting form, EPA may make the information available to the public without further notice to the submitter.

§ 710.39 Reporting form and instructions for submitting information.

(a) All persons submitting written information in response to the requirements of this subpart must use original copies of the form contained in this § 710.39.

(b) Complete instructions for completing the reporting form and

preparing a computer tape report are given in the EPA publication entitled "Instructions for Reporting for the Partial Updating of the TSCA Chemical Inventory Data Base." Reporting forms and instruction booklets may be obtained from the following address:

OTS Document Control Officer (Room E-201), U.S. Environmental Protection Agency, Office of Toxic Substances (TS-790), 401 M Street, SW., Washington, DC 20460, Attention: Inventory Update Rule, Telephone: (202) 382-3698 or (202) 755-4880.

(c) Completed reporting forms and computer tapes must be submitted to the address specified in § 710.39(b) above.

(d) The reporting form is as follows:

BILLING CODE 6560-50-M

IMPORTANT: Before completing this form, carefully read the accompanying instructions

Form Approved OMB 2070-0070
Approval expires 11-30-87

US Environmental Protection Agency

EPA

Partial Updating of TSCA Inventory Data Base Production and Site Report

(Section 8(a) Toxic Substances Control Act 15 USC 2607)

Report Number

FORM **U**

I. Certification Statement: I hereby certify to the best of my knowledge and belief that (1) all information entered on this form is complete and accurate, and (2) the confidentiality statements on the back of this form are true as to that information for which I have asserted a confidentiality claim.

Signature	Date	Name/Title *(Type or Print)*

II. Technical Contact *(Name, Company, Street address, City, State, ZIP Code)*

III. Plant Site *(Name, Street address, City, State, ZIP Code)*

Telephone No *(Include Area Code)* CBI ☐

Dun & Bradstreet Number

IV. Chemical Substance Identity/Activity/Confidentiality

a	b	c	d	e	f	g	h
LINE NO	CAS Registry and/or Other Identifying Number / Original Inventory Report Line No	A, B, C, F, P or T Codes A: Accession No B: Bona Fide No C: CAS Registry No F: Original Inventory Report No P: PMN No T: TMEA No	All Chemical Substance Identities on This Form Are Claimed ☐ Confidential ☐ Nonconfidential — Specific Chemical Name	Activity M Manufacture I Import	Site Limited	Plant Site CBI Claim	Production Volume (pounds)
1				CBI ☐	CBI ☐	CBI ☐	CBI ☐
2				CBI ☐	CBI ☐	CBI ☐	CBI ☐
3				CBI ☐	CBI ☐	CBI ☐	CBI ☐
4				CBI ☐	CBI ☐	CBI ☐	CBI ☐
5				CBI ☐	CBI ☐	CBI ☐	CBI ☐
6				CBI ☐	CBI ☐	CBI ☐	CBI ☐
7				CBI ☐	CBI ☐	CBI ☐	CBI ☐
8				CBI ☐	CBI ☐	CBI ☐	CBI ☐
9				CBI ☐	CBI ☐	CBI ☐	CBI ☐
10				CBI ☐	CBI ☐	CBI ☐	CBI ☐

EPA Form 7740-8 (12-85)

Where To Get Supplies and Send Completed Forms:

TSCA Inventory Update Form U and a copy of the instruction booklet may be obtained from, and completed forms should be sent to:

OTS Document Control Officer (TS-790)
U.S. Environmental Protection Agency
401 M Street, S.W., Washington, DC 20460
Attn: Inventory Update Rule
(202) 382-3698 or (202) 755-4880

Concerning EPA Disclosure of Information

If you submit information to EPA and claim any of it as confidential, EPA will publicly disclose that information only as allowed by the procedures set forth in 40 CFR Part 2. If no such claim accompanies the information when it is received, EPA may make that information public without further notice to you.

Confidentiality Statements

Chemical substance identity and other information reported to EPA on the front of this form may be claimed confidential by checking the appropriate CBI boxes in Blocks II and IV. In certifying this form, the person signing in Block I attests to the truth of the following four statements concerning all information claimed as confidential:

1. My company has taken measures to protect the confidentiality of the information, and it intends to continue to take such measures.

2. The information is not, and has not been, reasonably obtainable without our consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding).

3. The information is not publicly available elsewhere.

4. Disclosure of the information would cause substantial harm to our competitive position.

The person signing in Block I also attests to the truth of the appropriate statement(s) below concerning the information specifically claimed confidential for the particular chemical substance. By checking the CBI box under:

(IIb) Technical Contact/Company Identity: I assert that the linkage between my company identity (including the names appearing in Blocks I and II) and the information submitted on this form is confidential. (Note: checking this box does not claim plant site as confidential).

(IVd) Chemical Identity: I assert that the identities of all of the chemical substances on this form are confidential.

(IVe) Manufacture/Import: I assert that whether I manufacture or import the specific chemical substance is confidential.

(IVf) Site Limited: I assert that whether the specific chemical substance is distributed for a commercial purpose outside the plant site identified in Block III is confidential.

(IVg) Plant Site: I assert that the link of the specific chemical substance to the plant site identified in Block III is confidential.

(IVh) Production Volume: I assert that the production volume of the specific chemical substance for the plant site identified in Block III is confidential.

When claiming that the identity of a chemical substance is confidential, you must provide written substantiation for such claim (see reporting instructions). Failure to do so may result in EPA making that information public without further notice to you.

[FR Doc. 86-13036 Filed 6-11-86; 8:45 am]
BILLING CODE 6560-50-C