

40 CFR Part 704

[OPTS-82007A; TSH-FRL 2446-2]

Chlorinated Terphenyl; Submission of Notice of Manufacture or Importation**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This rule requires that the Environmental Protection Agency (EPA) be notified of any manufacture or importation of chlorinated terphenyl, a chemical recommended for testing by the Interagency Testing Committee established under section 4(e) of the Toxic Substances Control Act. Manufacture or importation by a small business (as defined in 40 CFR 704.3(s)) is exempt from this notice requirement. The purpose of the notice requirement is to alert the Agency if the chemical will be manufactured in, or imported into the United States, and to ensure that EPA has the opportunity to investigate the health and environmental impacts of such activity.

EFFECTIVE DATE: May 25, 1984.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, D.C. 20460, Toll free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:**I. Authority**

The Agency is promulgating a rule under section 8(a) of the Toxic Substances Control Act (TSCA) requiring notice of any current manufacture or import of chlorinated terphenyl and notice of any proposed manufacture or import. TSCA section 8(a) authorizes the Administrator to promulgate rules under which each person (other than a small manufacturer or processor) who manufactures or processes or who proposes to manufacture or process a chemical substance or mixture shall submit such reports as the Administrator may reasonably require.

Under this rule, which was proposed in the *Federal Register* of April 29, 1983 (48 FR 19419), the reporting requirement consists of a notice to EPA stating that a person is manufacturing or proposing to manufacture chlorinated terphenyl, or is importing or proposing to import chlorinated terphenyl as a chemical substance in bulk or as part of a mixture. The notice also would include information on uses, production

quantities, and chemical composition. If EPA is notified of chlorinated terphenyl manufacture or import, the Agency will reconsider the need for action to require testing under section 4 of TSCA or for control of the reported activity.

II. Reasons for This Rule**A. ITC Concerns**

The Interagency Testing Committee (ITC) designated the category of polychlorinated terphenyls for testing consideration in April 1978 (43 FR 16684). Chlorinated terphenyl is a member of this category and is the only member of the category on the TSCA Chemical Substance Inventory. Other members of the category are subject to Premanufacture Notification under section 5 of TSCA.

The ITC recommended that polychlorinated terphenyls be tested for carcinogenicity, mutagenicity, teratogenicity, other chronic health effects, and for environmental effects. The recommendations were based on (1) a chemical structure similar to PCBs, (2) increasing quantities imported after domestic production stopped in 1972, (3) wide environmental dispersion from polychlorinated terphenyls' use in waxes for investment casting, (4) chlorinated terphenyl residues found in human blood, fat and milk, and in samples of water and sludge, (5) an indication from available data of a potential for bioaccumulation, and (6) no data on suspected carcinogenic, mutagenic, and teratogenic effects, with incomplete characterization of chronic health and environmental effects.

Chlorinated terphenyl is produced commercially by chlorination of commercial terphenyl, and is a mixture of ortho-, meta-, and para-terphenyl. As a commercial product, chlorinated terphenyl is a mixture of chloroterphenyls having varying numbers and arrangements of chlorine atoms. Commercial-grade chlorinated terphenyl is a light yellow crystalline solid. Chlorinated terphenyl is identified by Chemical Abstract Service registry number 61788-33-8.

Chlorinated terphenyl has been used during this century for various commercial purposes. Before 1973, chlorinated terphenyl was used primarily as a plasticizer in adhesives, inks, sealants, caulking compounds, and waxes. Peak domestic production occurred in 1971 when about 20 million pounds were produced. However, Monsanto, the sole domestic producer, discontinued chlorinated terphenyl production in 1972 because of concern over the environmental effects of the chemically similar polychlorinated

biphenyls (PCBs). After that time, chlorinated terphenyl was imported and used mainly in waxes for investment casting. According to information supplied by the United States Customs Service under Customs Information Exchange 36/72, chlorinated terphenyl was last imported into the United States in November 1979. A 1976 European Economic Community (EEC) law banned its use except under certain conditions such as closed-system electrical equipment. Currently, chlorinated terphenyl is not known to be manufactured anywhere.

Chlorinated terphenyl is very similar in chemical structure to PCBs and could have toxicological properties similar to PCBs. PCBs have a very stable chemical structure, so they persist in the environment. Chlorinated terphenyl, likewise, is known to persist in the environment, and potentially has similar adverse effects as PCBs. However, inadequate data are available on the health and ecological effects of chlorinated terphenyl. PCBs and chlorinated terphenyl were widely used and dispersed into the environment before their potential and real adverse effects were recognized; they are now ubiquitous in the environment, resulting in wide range human exposure.

In addition, the commercial chlorinated terphenyl previously manufactured and imported was normally contaminated by PCBs (.05-5 percent). Thus, the manufacture of chlorinated terphenyl is indirectly controlled by section 6(e) of TSCA and the regulations thereunder. That section severely restricts the manufacture, processing, distribution in commerce, or use of PCBs. The history and specific requirements of the rules implementing section 6(e) are explained in the following editions of the *Federal Register*: 44 FR 31514 (May 31, 1979), 47 FR 17426 (April 22, 1982), 47 FR 24976 (June 8, 1982), 47 FR 37342 (August 25, 1982), and 47 FR 46980 (October 21, 1982) (requirements are listed in 40 CFR Part 761).

B. EPA Considerations and Response to Comments

Because domestic production and importation of chlorinated terphenyl apparently has ceased, EPA has concluded that the section 4 testing recommended by the ITC is not warranted at present (see EPA's response to the ITC 46 FR 54482).

In EPA's response to the ITC, several alternatives to testing were discussed and comments were requested on the alternatives. Five alternatives were outlined: (1) Develop a significant new

use rule (SNUR) under section 5(a); (2) list chlorinated terphenyl under section 5(b)(4) in combination with a SNUR (triggering notification requirements under section 5); (3) develop a section 8(a) reporting rule; (4) list chlorinated terphenyl under section 5(b)(4) in combination with a section 8(a) rule and thus require small businesses to report also; and (5) take no further action on chlorinated terphenyl since it appears to be adequately controlled by the PCB regulations. See 48 FR 19420 for a discussion of these alternatives and why EPA chose to propose a section 8(a) rule to track chlorinated terphenyl.

In response to EPA's proposal to subject chlorinated terphenyl to a section 8(a) reporting rule, comments were received from the Chemical Manufacturers Association (CMA) and the Natural Resources Defense Council, Inc. (NRDC).

CMA supports EPA's use of section 8(a) to track chlorinated terphenyl and all other chemicals designated by the ITC for testing consideration but not now produced or imported in measurable quantities. While EPA believes that a section 8(a) rule is appropriate for tracking chlorinated terphenyl because of the reasons stated in the proposal, other chemicals recommended by the ITC that are found to be not produced or imported may be more appropriately subject to a SNUR or section 5(b)(4) listing (with an accompanying SNUR and section 8(a) rule). Alternatively, EPA may decide that some of these chemicals require no follow-up activity. A chemical's production and use history, other regulations (both foreign and domestic), existing health and environmental effects data, and its likelihood of manufacture in the future (especially by small business), are all factors that must be considered in addition to the lack of current production. Thus, the facts surrounding each chemical must be examined before proposing a particular course of action; a section 8(a) rule will not always be the outcome.

Finally, CMA seems to suggest that EPA must develop a full scientific record before subjecting a chemical to a SNUR or section 5(b)(4) listing and that section 8(a) can monitor future commercial activities without making risk determinations that unjustifiably restrict future manufacture or use.

EPA will not forgo the use of a SNUR or section 5(b)(4) listing in the absence of a full scientific record. If EPA has sufficient data to show that a chemical may pose an unreasonable risk for example, the Agency would be justified in pursuing section 5(b)(4) listing. Very few chemicals have full scientific

records. Waiting until records are fully developed would needlessly delay appropriate regulatory action.

While in partial agreement with EPA's decision to track chlorinated terphenyl with a section 8(a) rule, NRDC believes that chlorinated terphenyl should also be subject to section 5(b)(4) listing and an accompanying SNUR. EPA rejected this alternative and its reasoning is set forth at 48 FR 19420 and 19421. However, some additional discussion is appropriate.

For a chemical that is no longer in commercial use, NRDC is recommending three rulemakings: A section 8(a) rule, a section 5(b)(4) listing, and a SNUR. NRDC's scheme would appear to reserve section 8(a) reporting for chlorinated terphenyl's previous uses, in waxes for investment casting, tooling compounds, etc., and the SNUR for unknown new uses, which conceivably could be any use not identified in EPA's section 8(a) proposal. Since chlorinated terphenyl would be on the section 5(b)(4) list under NRDC's scheme, any person wanting to manufacture chlorinated terphenyl for any significant new use would be required to submit data that show that "the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment."

The NRDC scheme has merit only if it is likely that chlorinated terphenyl will be manufactured for new uses; as stated in the proposal, EPA believes that this is unlikely. If chlorinated terphenyl were manufactured again for known uses, e.g., investment casting, then, except for the exemption of small businesses, EPA's and NRDC's schemes would yield the same data because chlorinated terphenyl's inclusion on the section 5(b)(4) list would have no impact since there is no data-generating link between section 5(b)(4) and section 8(a) as there is with a SNUR. Placing a chemical on the section 5(b)(4) list does, however, allow EPA to remove the small manufacturer exemption from section 8(a) rules. While this does not require a different level of reporting, as does the section 5(b)(4) and SNUR link, it does expand the respondent population. However, EPA believes that small businesses are unlikely to manufacture chlorinated terphenyl because of the expense of preparing chlorinated terphenyl free of PCB contamination and the need to manufacture large quantities to capture lost markets (see 48 FR 19420).

Thus, in the absence of the likelihood of new uses, NRDC's scheme would in effect mirror EPA's approach. However, NRDC's scheme would be resource

intensive and require EPA to develop three rules instead of one.

NRDC's comments close with the statement that "it [EPA] does not seem to recognize that if use and exposure levels had been high enough at this time, all requisite section 4(a) findings could have been made and a test rule issued."

It was just this recognition that led us to propose that chlorinated terphenyl be tracked with a section 8(a) rule. In the event production is resumed for any use, EPA will consider a section 4 test rule or other regulatory action.

III. Requirements

This rule requires notice of any current or proposed manufacture or import of chlorinated terphenyl. Chlorinated terphenyl means a chemical substance, CAS No. 61788-33-6, comprised of various proportions of chlorinated ortho-, meta-, and para-terphenyl. Chlorinated terphenyl is produced by the chlorination of terphenyl. Consequently, the reaction product of the chlorination process (which under TSCA is a chemical substance) is composed of the mixed chlorinated isomers of terphenyl.

Persons who propose to manufacture or import chlorinated terphenyl must notify EPA within 15 days of the date they make this decision. Persons who are manufacturing or importing chlorinated terphenyl on the effective date of the rule must submit a notice within 30 days of the effective date. The notice must include company name and address, principal technical contact, and, to the extent that it is known to or reasonably ascertainable by the company, a description of the use or intended use of the chlorinated terphenyl; chemical composition information (including PCB impurity level); estimated production volume; and, as appropriate, the proposed date for initiating manufacture or import. This rule does not require testing to determine chemical composition information. However, for subsequent rules, similar information may be required to be submitted which EPA believes is reasonably ascertainable even if it involves testing to determine the information.

After receiving notice of current or proposed manufacture or import, EPA will carry out a follow-up investigation to determine whether the activity may present a risk to health or the environment. If a significant risk may result, EPA will consider additional regulatory action to investigate or control the proposed chlorinated terphenyl activity.

The codified material following this preamble will appear in Part 704 of Title 40 of the Code of Federal Regulations. Part 704 was recodified in the **Federal Register** of May 25, 1983 (48 FR 23420). The scope and compliance, general definitions, exemptions, and confidentiality claim sections of the proposal are now part of Subpart A of recodified 40 CFR Part 704. Therefore, this material will not be published again today. Persons should familiarize themselves with Part 704 so that they are aware of all the provisions of this rule.

IV. Exempt Persons

Small manufacturers and importers are not subject to this rule. The small business exemption standards are set out in the rule and have been designed to reduce the paperwork burden on small chemical manufacturers, while ensuring that EPA will receive a sufficient amount of chemical use, production, and exposure information to support an assessment of chemical risks. EPA believes that these standards serve the purpose of this rule. The rule also exempts persons who manufacture or import chlorinated terphenyl solely for research and development, as part of an article, or as a byproduct or impurity.

EPA is exempting importers of articles from this rule for several reasons. Past imports of chlorinated terphenyl were only in bulk form, and importing of the chemical in articles is unlikely. In addition, EEC countries forbid production of chlorinated terphenyl for use in articles, and known imports of chlorinated terphenyl originated in an EEC country. Moreover, EPA believes that it would be a significant and needless burden on importers of articles to try to ascertain if they contain chlorinated terphenyl. The exemption also is consistent with previous Agency reporting provisions for the Inventory (42 FR 64572 *et seq.*) and the Premanufacture Notification Regulations (48 FR 21722 *et seq.*).

EPA is exempting manufacture and import of chlorinated terphenyl as a byproduct because it was the intentional use of chlorinated terphenyl in products which caused the wide environmental dispersion of chlorinated terphenyl. EPA is not aware of any chemical manufacture that would lead to the production of chlorinated terphenyl as a byproduct. Chlorinated terphenyl may have been manufactured as a byproduct during the production of PCBs, but since the manufacture of PCBs has been banned, any manufacture of chlorinated terphenyl as a byproduct from this source has ceased.

This rule does require reporting from importers of mixtures containing chlorinated terphenyl. Since TSCA defines manufacture as importation, EPA considers an importer of a mixture as the manufacturer of each chemical substance contained in the mixture. Therefore a person intending to import a mixture containing chlorinated terphenyl is required by this rule to submit a notice to EPA. An importer of a mixture may be exempt from reporting if the small business exclusion is applicable. Thus, if a person with annual sales of less than \$40 million but more than \$4 million is importing a mixture containing chemicals A and B, the importer is a small manufacturer and need not submit notice to EPA. However, if chemical A is subject to a section 8(a) rule, and more than 45,400 kilograms of chemical A were imported, (not 45,400 kilograms of mixture AB), then the small business exclusion would no longer apply and the importer must submit notice.

V. Confidentiality

Any person submitting a notice may claim any part or all of the notice as confidential. Information which is claimed confidential will be disclosed by EPA only to the extent and by means of the procedures set forth in 40 CFR Part 2.

VI. Economic Impact

EPA estimates that compliance costs will range from \$225-\$716 for each notice. The cost estimate for Data Acquisition below assumes that the data are known to or reasonably ascertainable by the person submitting the notice. It does not include the laboratory cost of determining isomeric ratios for example. Costs include:

Data Acquisition.....	\$107-\$430
Notice Preparation (Typing).....	17-51
Managerial Review.....	101-235
Total.....	225-716

Because available information shows that there was only one manufacturer and one importer of chlorinated terphenyl, EPA expects to receive few notices under this rule.

Because the cost of this rule is expected to be low and because it will effectively alert the Agency to commercial activity involving a potentially hazardous chemical, thereby allowing EPA to take appropriate action to require testing or control risks, the Agency believes that this action will benefit the public.

Upon receipt of a notice under this rule, EPA will decide what, if any, further information gathering, testing, or

control actions are needed. Estimates of the costs of some possible actions are included in the economic support document that is contained in the public record for this rule. The actual costs of such actions will be assessed by EPA in the development of the appropriate follow-up rulemaking.

VII. Public Record

EPA has established a public record (docket number OPTS-82007) for this rulemaking document which, along with a complete index, is available for inspection in Rm. E-107, 401 M St., SW., Washington, D.C., 20460, from 8:00 a.m. to 4:00 p.m. Monday through Friday, except legal holidays. This record includes basic information considered by the Agency in developing this rule. Following is a list of the documents which constitute the record for this rulemaking. Public comments on the proposed rule are not individually listed, but will be available upon request in the OPTS Reading Room. EPA requests that it be notified of any additions to or deletions from this record within the next 30 days.

- (1) Polychlorinated Terphenyls; Response to the Interagency Testing Committee (46 FR 54482) and all comments received thereon.
- (2) 2nd Report of the Interagency Testing Committee (ITC) (43 FR 16684).
- (3) Polychlorinated Biphenyls (PCBs); Manufacturing, Processing, Distribution in Commerce and Use Prohibitions Rule (44 FR 31514).
- (4) Polychlorinated Biphenyls (PCBs); Use in Electrical Equipment; Proposed Rules (47 FR 17426).
- (5) Chlorinated Biphenyls (PCBs); Manufacture, Processing, Distribution, and Use in Closed and Controlled Waste Manufacturing Processes; Proposed Rule (47 FR 24976).
- (6) Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce and Use Prohibitions; Use in Electrical Equipment (47 FR 37342).
- (7) Chlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce and Use Prohibitions; Use in Closed and Controlled Waste Manufacturing Processes (47 FR 46980).
- (8) Economic Analysis of Section 8(a) Rule on Chlorinated Terphenyl.
- (9) Economic Analysis of Final Section 8(a) Rule on Chlorinated Terphenyl.

VIII. Regulatory Assessment Requirements

A. Paperwork Reduction Act

The information collection requirements in this rule will be submitted for approval to the Office of

Management and Budget (OMB) under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* Once the requirements have been approved and assigned an OMB control number a technical amendment to this rule will be published in the **Federal Register**.

B. Regulatory Flexibility Act

This rule will not have a significant economic impact on a substantial number of small entities. Only two companies manufactured or imported chlorinated terphenyl since 1971. Currently, no company is known to manufacture or import chlorinated terphenyl. This rule also contains a small manufacturer exemption (see definitions "Small Manufacturer"). Therefore, in accordance with the Regulatory Flexibility Act (Pub. L. 95-354), EPA has determined that this rule will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this regulation is not major because it does not have an effect of \$100 million or more on the economy. It is expected to have an annual cost of less than \$2,000. It does not have a significant effect on competition, costs, or prices.

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

IX. List of Subjects in 40 CFR Part 704

Environmental protection, Hazardous materials, Imports, Recordkeeping and reporting requirements.

Dated: March 16, 1984.

William D. Ruckelshaus,
Administrator.

PART 704—[AMENDED]

Therefore, 40 CFR Part 704 is amended as follows:

1. By redesignating the existing Subpart E as Subpart D.
2. By adding a new § 704.85 to read as follows:

§ 704.85 Chlorinated terphenyl.

(a) *Definitions.* (1) "Chlorinated terphenyl" means a chemical substance, CAS No. 61788-33-6, comprised of

chlorinated ortho-, meta-, and paraterphenyl.

(2) "Extent of chlorination" means the percent by weight of chlorine for each isomer (ortho, meta, and para).

(3) "Isomeric ratio" means the ratios of ortho-, meta-, and parachlorinated terphenyls.

(4) "Polychlorinated biphenyl" means any chemical substance that is limited to the biphenyl molecule that has been chlorinated to varying degrees.

(5) "Small manufacturer" means a manufacturer (importers are defined as manufacturers under TSCA) who meets either of the following standards under this rule:

(i) *First standard.* A manufacturer of an existing chemical substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$40 million. However, if the annual production volume of a particular chemical substance at any individual site owned or controlled by the manufacturer is greater than 45,400 kilograms (100,000 pounds), the manufacturer shall not qualify as small for purposes of reporting on the production of that chemical substance at the site, unless the manufacturer qualified as small under paragraph (a)(5)(ii) of this section.

(ii) *Second standard.* A manufacturer of an existing chemical substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$4 million, regardless of the quantity of chemicals produced by that manufacturer.

(b) *Persons who must report.* Except for small manufacturers and as provided in § 704.5, the following persons are subject to the rule:

(1) Persons who manufacture or propose to manufacture chlorinated terphenyl.

(2) Persons who import (importers) or propose to import chlorinated terphenyl as a chemical substance in bulk or as part of a mixture.

(c) *What information to report.* Persons subject to this rule as described in paragraph (b) of this section must notify EPA of current or proposed manufacture or import of chlorinated terphenyl. The notice must include, to the extent that it is known to the person making the report or is reasonably ascertainable, the following information:

- (1) Company name and address.
- (2) Name, address, and telephone number of principal technical contact.

(3) A description of the use(s) or intended use(s) for chlorinated terphenyl.

(4) A description of the isomeric ratio and extent of chlorination of the chlorinated terphenyl and the impurity level of polychlorinated biphenyls.

(5) The quantity (by weight) manufactured or imported within 12 months prior to the effective date of the rule, if any, and the estimated quantity (by weight) to be manufactured or imported for the first three years following the date of the report or the date of the intended start of production, whichever occurs later.

(6) The proposed date for the initiation of manufacturing or importation of chlorinated terphenyl, if appropriate.

(d) *When to report.* Persons who are manufacturing or importing chlorinated terphenyl on the effective date of the rule must notify EPA within 30 days of the effective date of the rule. Persons who propose to manufacture or import chlorinated terphenyl must notify EPA within 15 days after making the management decision described in § 704.3(p).

(e) *Where to send reports.* Notices must be submitted by certified mail to the United States, Environmental Protection Agency, Document Processing Center, P.O. Box 2070, Rockville, Md. 20852. Attn: Chlorinated terphenyl notification.

[FR Doc. 84-9023 Filed 3-23-84; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 171 and 172

[Docket HM-145D; Amdt. Nos. 171-78, 172-90]

Hazardous Waste Manifest; Shipping Papers

Correction

In FR Doc. 84-7167 beginning on page 10507 in the issue of Tuesday, March 20, 1984, make the following correction:

On page 10510, in the third column, in the third line in § 172.205(a), "Forms" should read "Form".

BILLING CODE 1505-01-M