

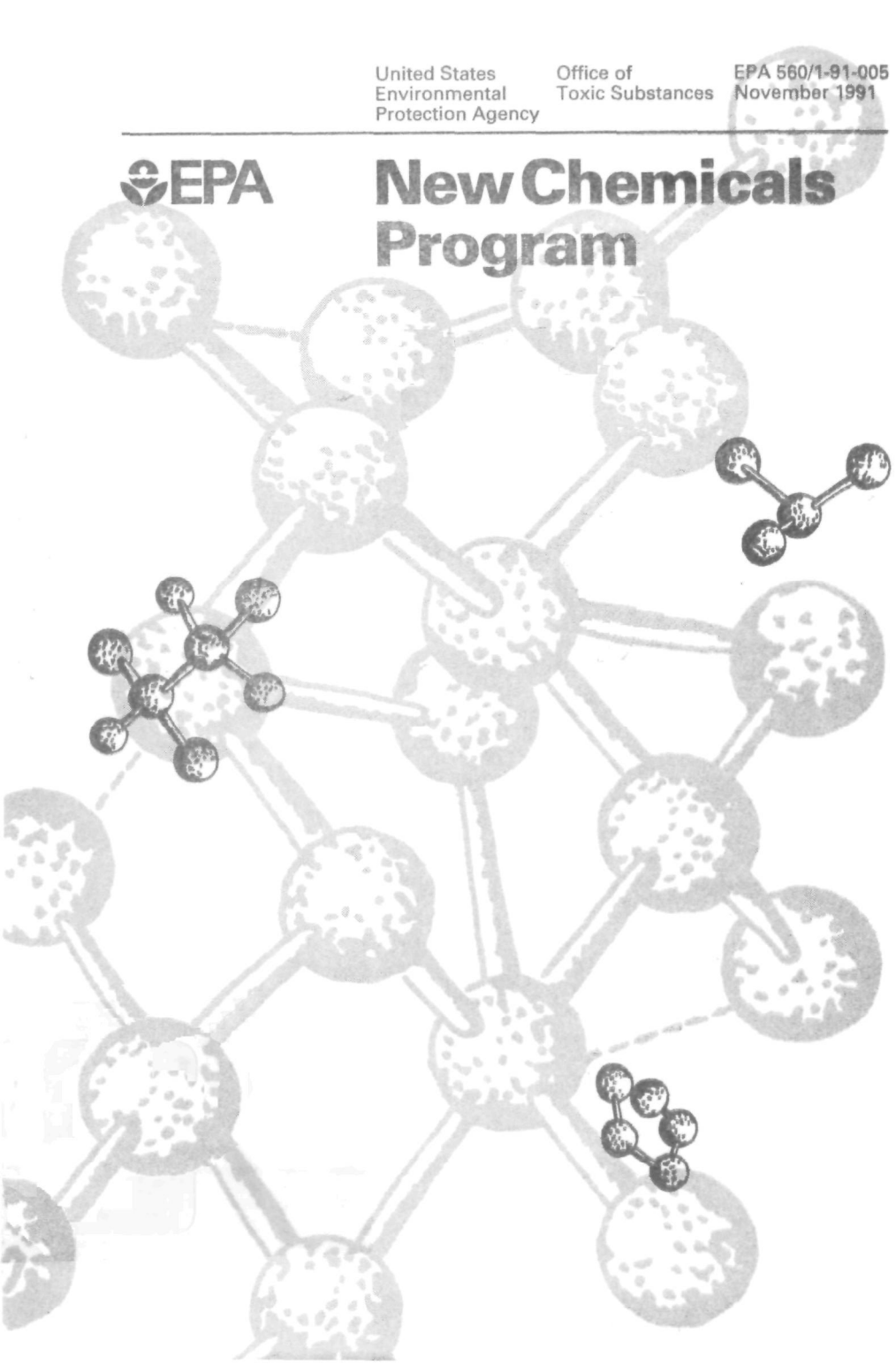
United States
Environmental
Protection Agency

Office of
Toxic Substances

EPA 560/1-91-005
November 1991



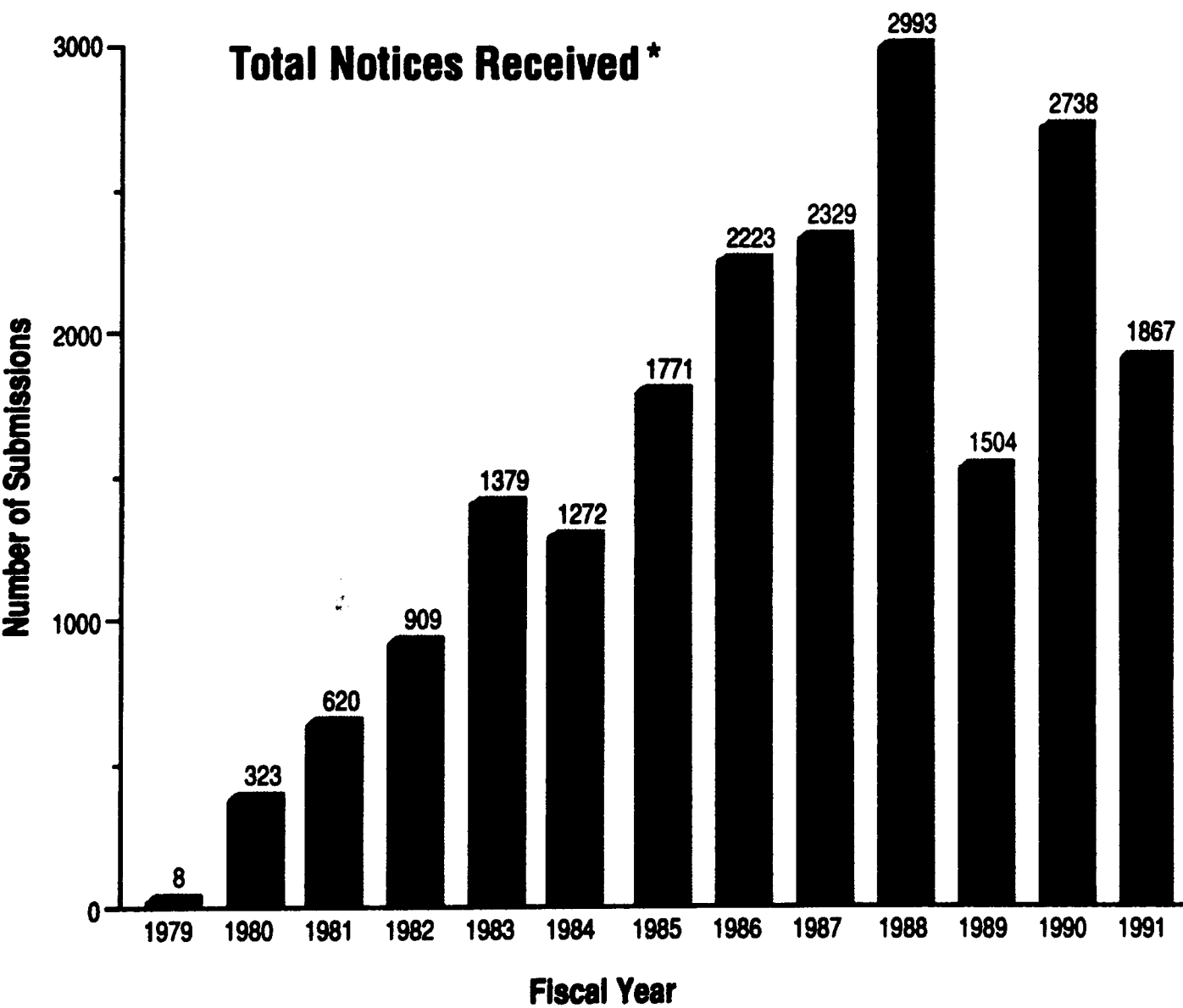
New Chemicals Program



What is the New Chemicals Program?

Anyone who plans to manufacture or import a new chemical substance is required to provide the Environmental Protection Agency (EPA) with a pre-manufacture notice (PMN) at least 90 days prior to the activity. EPA's New Chemicals Program, which is part of the Office of Toxic Substances (OTS), is responsible for reviewing PMN submissions and identifying new substances that require regulatory action.

The PMN program is mandated by section 5 of the Toxic Substances Control Act (TSCA). The law, enacted by Congress in 1976, gives EPA broad authority to identify and control substances that pose a threat to human health or the environment.



*Total includes PMNs, low-volume exemptions, test-market exemptions, and polymer exemptions.

What chemical substances are “new” chemicals?

EPA classifies chemical substances as either “existing” chemicals or “new” chemicals. The only way to determine if the substance you are working with is a new chemical is by consulting EPA’s Inventory of Chemical Substances, which is commonly referred to as the TSCA Inventory. Any substance that is not on the TSCA Inventory is classified as a new chemical.

Note to importers: Many chemical substances that are manufactured in other countries are not on the TSCA Inventory. If you intend to import any of these chemical substances into the United States, you must follow all U.S. laws and regulations pertaining to new chemicals.

How can the TSCA Inventory be consulted?

The TSCA Inventory is available in report form or on computer tape. The TSCA Inventory in report form was updated in 1990 and does not reflect additions to the inventory since then. The computer tape is updated every six months. EPA does not provide searches of the TSCA Inventory, but there are a number of ways you can research whether a chemical is listed on the TSCA Inventory:

- Many public libraries and company libraries have copies of the TSCA Inventory. In addition, the inventory is available at federal depository libraries. To find the closest federal depository library, call your local library or look in the *Directory of U.S. Government Depository Libraries*.
- Assistance in determining whether a chemical substance is on the TSCA Inventory is available from two companies: CAS Online and Dialog. To request assistance, phone CAS Online at (800) 848-6533 or Dialog at (800) 334-2564. Other companies may offer similar services in the future; contact the TSCA Assistance Information Service for an up-to-date list.

- Online access to the TSCA Inventory is available through Dialog. To open an account, call (800) 334-2564.
- A copy of the TSCA Inventory can be purchased from the Government Printing Office (GPO) or the National Technical Information Service (NTIS).

GPO: (202) 783-3238

1985 TSCA Inventory (report form)

Order# 055-000-00254-1

Price \$161

1990 Supplement (report form)

Order# 055-000-00361-1

Price \$15

NTIS: (703) 487-4650

TSCA Inventory (computer tape)

Order# PB90504226

Price \$450 or \$560 (depending on type of tape)

How can it be determined whether a substance is a new chemical if its identity is a trade secret?

The identity of an existing chemical that has been claimed as confidential business information will not be listed on the public portion of the TSCA Inventory. In these cases, EPA will search the confidential portion of the TSCA Inventory for you if a bona fide intent to manufacture or import a chemical substance is demonstrated.

For more information about submitting a bona fide inquiry, see 40 CFR 720.25 or contact the TSCA Assistance Information Service.

Are any new substances exempt from PMN reporting?

Some new chemical substances are not subject to PMN reporting. These substances are either exempt from TSCA, or EPA has determined that they do not warrant review or require only a short review.

EPA does not review new substances in the following product categories, which are exempt from TSCA authority: tobacco, nuclear materials, munitions, food additives, drugs, cosmetics, and substances used solely as pesticides. These new substances fall under the jurisdiction of other federal laws and are reviewed by other federal programs. In addition, the following are excluded from PMN reporting under certain conditions: products of incidental reactions, products of end-use reactions, mixtures, byproducts, substances manufactured solely for export, nonisolated intermediates, and substances formed during the manufacture of an article. See 40 CFR 720.30(a)-(h) for more information about exclusions from PMN reporting.

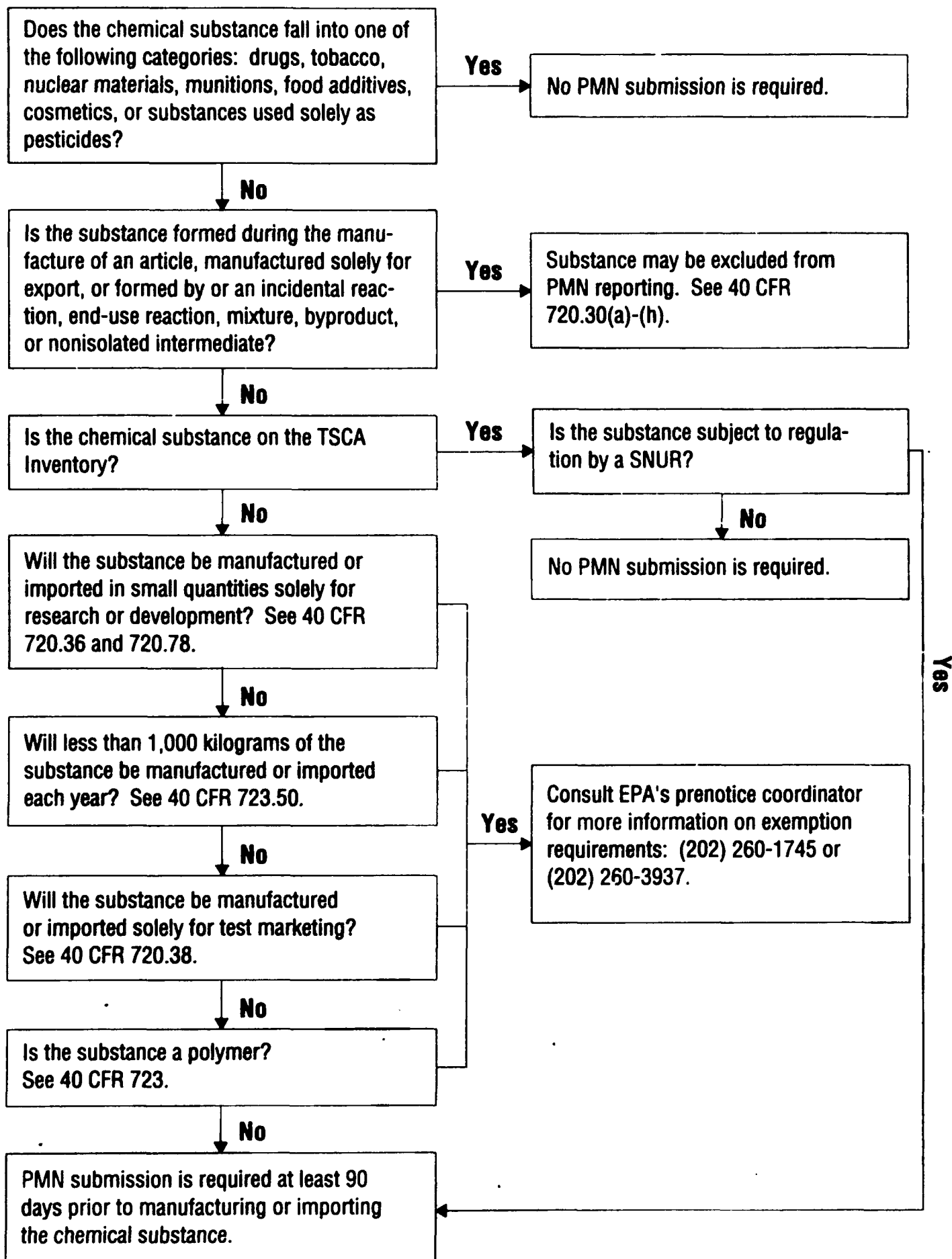
EPA has limited the reporting requirements for new chemical substances in the following cases:

- the substance is manufactured in small quantities for research and development, and special procedural and recordkeeping requirements are met;
- less than 1,000 kilograms of the substance will be manufactured or imported each year;
- the substance is being manufactured or imported for test marketing; or
- the substance is a polymer that meets certain specified criteria.

For information about PMN exemptions, contact the prenotice coordinator at (202) 260-1745 or (202) 260-3937.

Materials Belong To:
OPPT Library
401 M Street, SW (TS-793)
EPA 20460

When Are You Required to Submit a PMN?



What information must be submitted about new chemical substances?

PMN submissions must be made on a specific form which requires all available data on chemical identity, production volume, byproducts, use, environmental release, disposal practices, and human exposure. EPA also requires that the following information be submitted with the PMN: all existing health and environmental data in the possession of the submitter, parent company, or affiliates, and a description of any existing data known to or reasonably ascertainable by the submitter.

The PMN instruction manual explains all reporting requirements. When you request a PMN form, an instruction manual is included. Both are available from the TSCA Assistance Information Service.

How does EPA handle proprietary information submitted in a PMN?

Under section 14 of TSCA, EPA is required to protect from disclosure confidential business information (CBI) that is explicitly claimed by a submitter. Substantiation of CBI claims for chemical identity is required when a Notice of Commencement of Manufacture or Import is submitted. OTS reviews CBI claims to determine whether they meet the legal definition of CBI. If the answer to any of the following questions is "no," a submission probably will not meet the legal definition of CBI when reviewed by OTS.

- Is the information that is claimed as confidential known only to the company that is making the CBI claim?
- Has the company made reasonable efforts to ensure that the information is and will remain confidential?
- Is the information obtainable only from the submitter?
- Is disclosure of the information likely to cause substantial harm to the company's competitive position?

How are you notified of the outcome of the PMN review?

When EPA receives your PMN form, you will be sent a letter that includes the PMN number assigned to your submission and the expiration date of the PMN review period. If the agency has any concerns about the substance, you will be notified by the end of the review period. Otherwise, you will receive no subsequent notification, and you are free to manufacture or import the substance the day after the review period ends.

What is the fee for submitting a PMN?

The fee for most PMN submissions is \$2,500. The fee is reduced under certain conditions: (1) if your company qualifies as a small business, the fee is \$100; (2) if a PMN for an intermediate substance is submitted with a final product PMN, the fee for the intermediate substance is \$1,000; and (3) if a PMN is filed for multiple chemicals that are related, the total fee is \$2,500.

For information about filing a notice for multiple chemicals, contact the prenotice coordinator at (202) 260-1745 or (202) 260-3937.

For information about PMN fees, contact the TSCA Assistance Information Service.

When is a new chemical substance added to the TSCA Inventory?

A new chemical is eligible for addition to the TSCA Inventory after the PMN review has been completed. To add a substance to the TSCA Inventory, the company that submitted the PMN must provide a Notice of Commencement of Manufacture or Import to EPA within 30 days of the date the substance is manufactured or imported for nonexempt commercial purposes. Once a substance is listed on the TSCA Inventory, it is considered an existing chemical.

How does EPA assess potential risk?

EPA toxicologists, chemists, biochemists, engineers, and scientists in other disciplines work together to predict the potential risks to humans or the environment from each new substance. In doing so, they draw on data submitted with the PMN form, other information available to the agency, and exposure and release modeling.

TSCA does not require prior testing of new chemicals. Consequently, more than half of the PMN forms submitted do not include toxicological data. In these cases, OTS scientists assess the chemical's structural similarity to known toxic chemicals—called a structure-activity relationship—to predict toxicity.

What are the possible outcomes of PMN review?

Almost 90 percent of the PMNs submitted to the program complete the review process without being restricted or regulated in any way. If the agency determines that a new chemical substance may pose a risk to health or the environment, however, section 5(e) of TSCA allows EPA to (1) enter into a consent order permitting the PMN submitter to manufacture or import the new substance under specified conditions or (2) allow the PMN submitter to suspend the review period while developing additional test data. In cases where the agency determines that a new substance will present an unreasonable risk, section 5(f) of TSCA allows EPA to issue an injunction to prohibit the manufacture, processing, or distribution in commerce of the substance.

What is a significant new use rule?

A frequent outcome of PMN review is the negotiation of a section 5(e) consent order to allow the PMN submitter to manufacture or import the new substance under specified conditions. A section 5(e) consent order, however, is not binding on other companies that may manufacture or import the substance. Consequently, EPA generally follows the signing of a section 5(e) consent order with a significant new use rule (SNUR).

SNURs require that manufacturers, processors, and importers notify EPA 90 days before beginning any activities that are defined as new uses. These typically are those activities not permitted by the section 5(e) consent order. EPA also uses SNURs when use of a new substance may present risks to health or the environment if exposures or releases are significantly different from those described in the PMN. The advance notification required by SNURs allows EPA to prevent potentially adverse exposure to or effects from the new use of the substance.

How is the New Chemicals Program related to EPA's pollution prevention efforts?

By assessing new chemical substances before they are manufactured or imported, the New Chemicals Program is actively carrying out EPA's strategy to prevent pollution before it can occur. The program also supports development of safer chemical substances by minimizing regulatory burdens on new chemicals if they will replace riskier substances already in the marketplace.

The New Chemicals Program strongly encourages industry efforts to prevent pollution. One of the ways this is accomplished is through the PMN form, which requests industry to voluntarily provide information about steps taken to reduce exposures to or releases of chemical substances. During the PMN review, EPA carefully considers this information in evaluating potential risks.

Summary of accomplishments

Since 1979, EPA’s New Chemicals Program has reviewed almost 20,000 new chemical substances. This figure includes nearly 16,000 PMNs that have undergone full review and approximately 4,000 low-volume, test-market, and polymer exemptions. In that time, the agency has taken action to prevent potential risks to people and the environment from nearly 1,700 new substances.

New Chemicals Program Activities Through September 30, 1991

TYPE OF SUBMISSION	NO. SUBMITTED	TIME PERIOD
Premanufacture notices	15,901 7/1/79-9/30/91
Test marketing exemption applications	547 7/1/79-9/30/91
Low-volume exemptions	1,941	... 6/10/85-9/30/91
Polymer exemptions	1,547 1/4/85-9/30/91
Total	19,936	

REGULATORY ACTION	NO. ISSUED
Section 5(e) orders	504
Section 5(f) actions	4
PMNs withdrawn in face of action	779
Voluntary testing actions	401
Total cases regulated	1,688



For more information

The TSCA Assistance Information Service (TSCA hotline) is available to answer general questions about the PMN process or filing a PMN form. The TSCA hotline operates Monday through Friday, from 8:30 a.m. to 5:00 p.m. Eastern time. Call (202) 554-1404. FAX requests for documents are received every day, at all times, on (202) 554-5603. To request assistance by mail, write

Environmental Assistance Division (TS-799)
Office of Toxic Substances
U.S. EPA
401 M Street, S.W.
Washington, D.C. 20460

For answers to questions about procedural, technical, or regulatory requirements prior to submitting a PMN, call the PMN prenotice coordinator at (202) 260-1745 or (202) 260-3937.