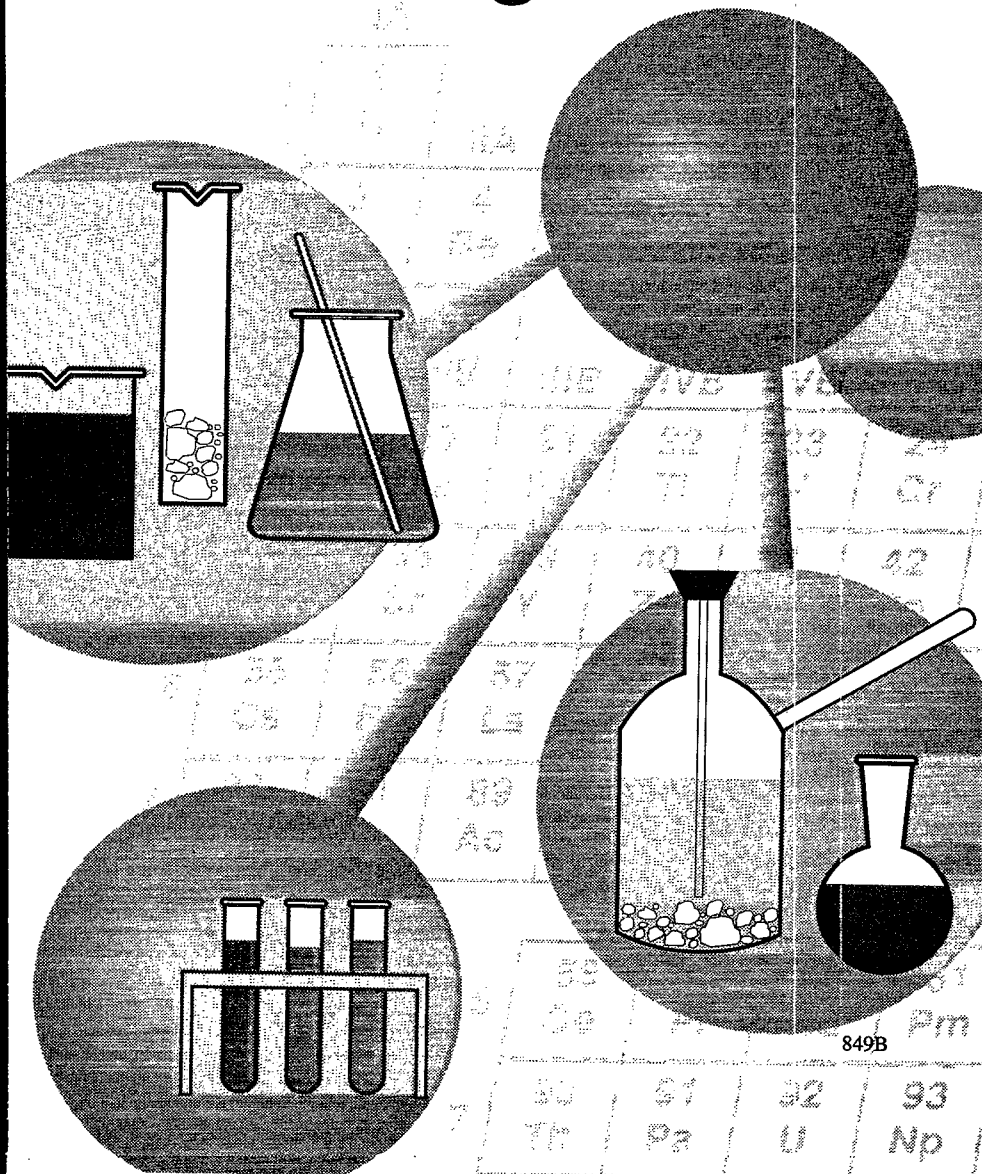
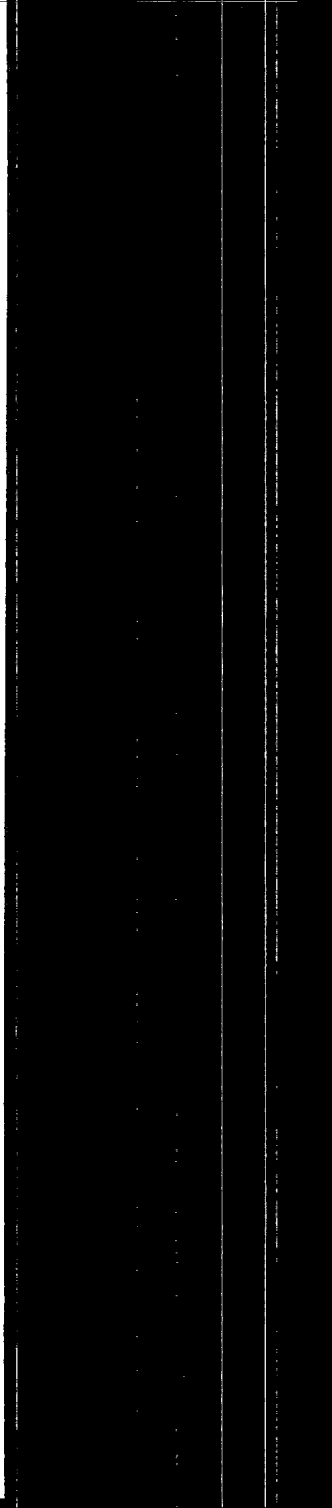




New Chemicals Program



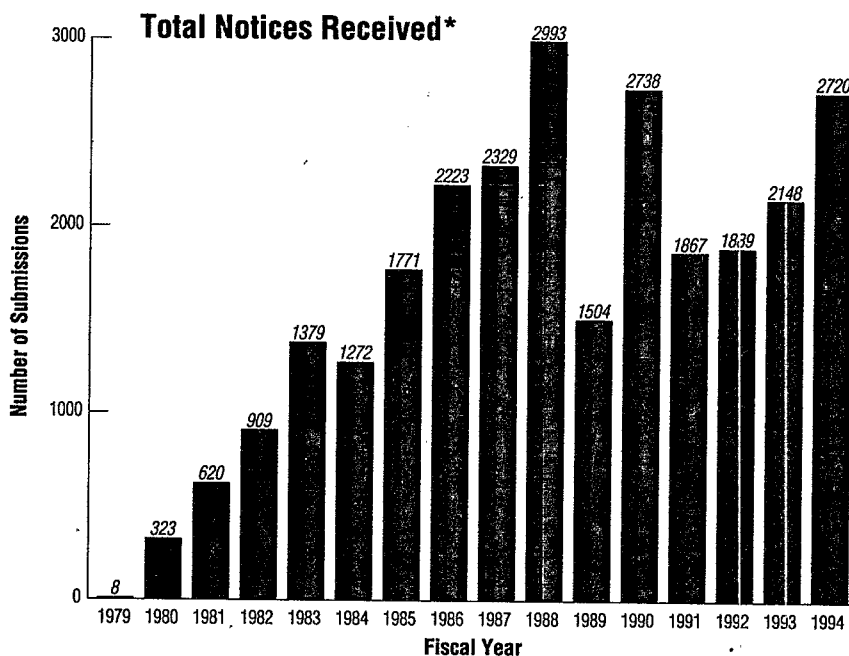


What is the New Chemicals Program?

Anyone who plans to manufacture or import a new chemical substance for a non-exempt commercial purpose 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 Pollution Prevention and Toxics (OPPT), 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 may pose a threat to human health or the environment.

This document incorporates changes made to the PMN program by the 1995 rule amendments (60 FR 16298).



*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 Toxic Substances Control Act Chemical Substance Inventory 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 at (202) 554-1404 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) 512-1800

1985 TSCA Inventory (report form)

Order # 055-000-00254-1

Price \$161

1990 Supplement (report form)

Order # 055-000-00361-1

Price \$24

NTIS: (703) 487-4650

TSCA Inventory

9-track magnetic computer tape

Order # PB95503108

Price \$360 (January 1995)

CD ROM

Order # PB94502168

Price \$250 (May 1994)

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?

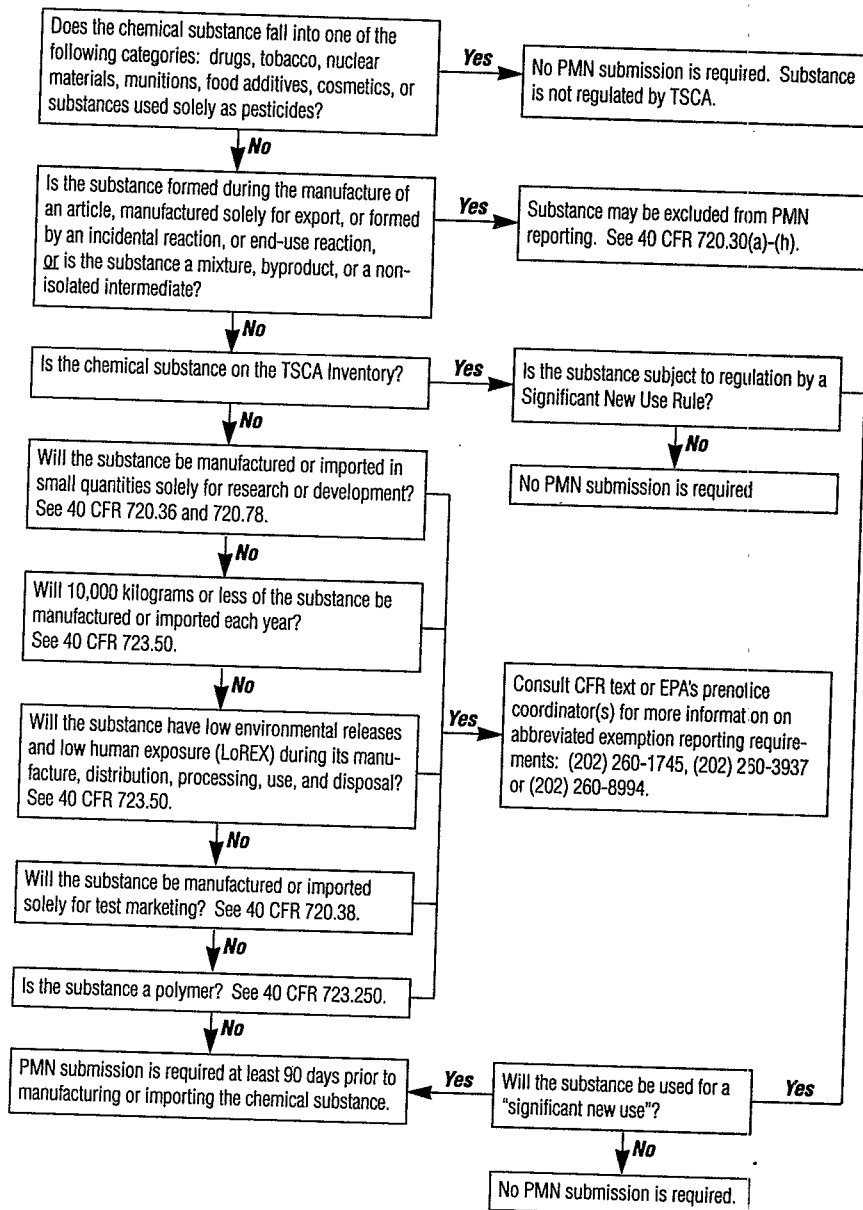
Some new chemical substances are not subject to PMN reporting. These substances are either exempt from TSCA, or EPA has determined that they do not warrant review or require only a short review.

EPA does not review new substances in the following product categories, which are excluded 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 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 (40 CFR 720.36 and .78);
- 10,000 kilograms or less of the substance will be manufactured or imported each year (40 CFR 723.50);
- the substance is expected to have low releases and low exposures (40 CFR 723.50);
- the substance is being manufactured or imported for test marketing (40 CFR 720.38); or
- the substance is a polymer that meets certain specified criteria where the substance is not considered chemically active or bioavailable (40 CFR 723.250).

When Are You Required to Submit a PMN?



What information must be submitted about new chemical substances?

PMN submissions must be made on EPA form 7710-25 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 Instruction Manual for Premanufacture Notification of New Chemical Substances 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. OPPT 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 OPPT.

- 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 an acknowledgement letter that includes the PMN number assigned to your submission and the date the PMN review began. If the agency has any concerns about the substances, you will be notified before 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 (sales are less than \$40 million/year), 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 consolidated PMN, as approved by a prenotice coordinator, 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(s) at (202) 260-1745, (202) 260-3937 or (202) 260-8994.

For information about PMN fees see 40 CFR 700, or 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 (EPA Form 7710-56) 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?

Hazard x Exposure = Risk

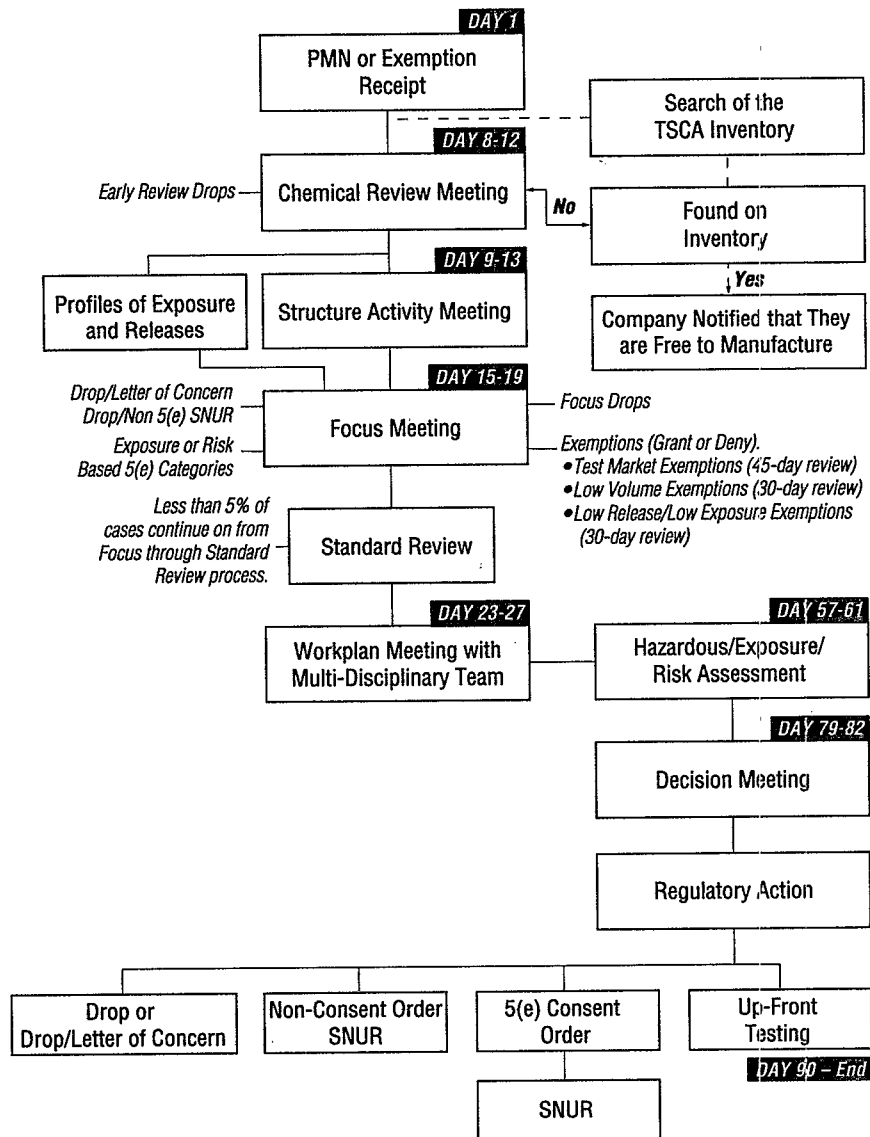
What are the possible outcomes of PMN review?

EPA toxicologists, chemists, biochemists, engineers, and experts 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, less than half of the PMN forms submitted include toxicological data. In these cases, OPPT scientists assess the chemical's structural similarity to chemicals for which data are available—called a structure-activity relationship—to predict toxicity.

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 and lacks sufficient toxicological information; 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 (risk-based consent order) or (2) permit the PMN submitter to suspend the review period while developing additional test data. In the absence of a risk finding and sufficient toxicological data and faced with the potential for substantial human or environmental exposure—section 5(e) of TSCA allows EPA to enter into a consent order to collect data that will better characterize the substance's toxicity and risk (exposure-based consent order). 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.

Premanufacture Notification (PMN) 90 day review process



What are consent orders and significant new use rules?

An occasional outcome of the PMN review is the negotiation of a section 5(e) consent order, which allows the PMN submitter to manufacture or import the new substance under specified conditions (e.g., use of worker protective equipment or release controls). EPA may develop a consent order based on a finding of potential unreasonable risk or substantial exposure. A section 5(e) consent order is not binding, however, on other companies that may manufacture or import the substance. Consequently, after signing a section 5(e) consent order, EPA generally promulgates a significant new use rule (SNUR).

SNURs require that manufacturers, importers and processors of certain substances notify EPA at least 90 days before beginning any activity that EPA has designated as a "significant new use." These new use designations typically correspond with activities prohibited by the section 5(e) consent order and are generally promulgated on an expedited (i.e., "direct final," see 54 FR 31299) basis. The advance notification required by SNURs allows EPA to prevent or limit potentially adverse exposure to, or effects from, the new use of the substance.

In cases where EPA does not issue a section 5(e) consent order, the Agency may promulgate an expedited SNUR when potential new uses—not identified in the PMN—could result in increased exposures to or releases of the substance, and in turn an unreasonable risk to health or the environment. The 1995 TSCA PMN rule amendments expanded the types of significant new use designations that EPA may promulgate in expedited SNURs. This change is intended to improve the efficiency of the SNUR procedure for both EPA and the chemical industry.

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 or eliminating 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. A guidance document on how to report pollution prevention activities is included as an attachment to the PMN Instruction Manual.

As with all the exemptions to full PMN reporting, the low release and low exposure (LoREX) chemicals exemption was especially designed with EPA's overall pollution prevention strategy. This exemption encourages companies to develop manufacturing, processing, use, and disposal techniques which minimize exposures to workers, consumers, the general public, and the environment.

Summary of accomplishments

Since 1979, EPA's New Chemicals Program has reviewed almost 30,000 new chemical substances. This figure includes nearly 22,000 PMNs that have undergone full review and approximately 5,500 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 2,700 new substances.

New Chemicals Program Activities Through December 31, 1994

TYPE OF SUBMISSION	NO. SUBMITTED	TIME PERIOD
Premanufacture notices	21,599	7/1/79-12/31/94
Test Marketing Exemption Applications	604	7/1/79-12/31/94
Low-volume exemptions.....	2,868	6/10/85-12/31/94
Polymer exemptions*	2,054	1/4/85-12/31/94
Total.....	27,125	

REGULATORY ACTION	NO. ISSUED
Section 5(e) orders	677
SNURs.....	417
Section 5(f) actions	4
PMNs withdrawn in face of action	1,093
Voluntary testing actions	871
Total cases regulated**	2,645

* As of 5/30/95 reporting for exempt polymers will no longer be required.

** Total does not include order-related SNURs, as these are already counted under Section 5(e) orders.

New Chemicals and Existing Chemicals

Why does EPA regulate a new chemical and not a similar chemical already on the market? This issue is sometimes referred to as a "new chemical bias." Before 1976, there was no comprehensive chemical law like TSCA to require the review of new chemicals. Under TSCA, industrial chemicals in commerce in 1975-1977 were "grandfathered" into the Inventory without considering if the chemicals were hazardous. Once on the Inventory, a substance is considered an "existing" chemical and for EPA to control its use, a legal finding has to be made that the chemical will

New Chemicals and Existing Chemicals

(Continued)

present an unreasonable risk to human health or the environment. This is a standard which requires EPA to have conclusive data on that particular chemical. By comparison, newly introduced chemicals can be regulated under TSCA based on whether they may present an unreasonable risk and this finding of risk can be based on data for structurally similar chemicals.

Existing chemicals are oftentimes of similar toxicity to new chemicals being controlled by EPA under the PMN program. Lack of controls on the older chemicals may cause a misunderstanding that since there are less (or no) requirements that they are considered safer than new, regulated chemicals. In fact, the same protective measures would probably be imposed on the older chemicals if they were submitted as "new" chemicals to EPA today.

EPA continues to work to lessen the apparent inequity between its regulation of new and existing chemicals. EPA screens and selects from among the 15,000 chemicals in commerce (of the total of 70,000 chemicals on the Inventory) that appear to be of greatest concern to human health and the environment. The Agency then uses a variety of approaches to reduce risks from chemicals that appear to pose problems. These approaches include voluntary agreements, alone or in combination with regulatory approaches; regional, federal, state and local partnerships; dissemination of risk management information to assist the selection of safer substitutes; emphasis on pollution prevention and innovative control technology to reduce exposure and environmental release; use of chemical emission data from the Toxics Release Inventory (TRI) to help address site-specific chemical concerns; refined risk assessment and cost/benefit analysis; and the challenge to industry to meet its Product Stewardship and Responsible Care principles.

**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 (7408)
Office of Pollution Prevention and Toxics
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 a PMN prenotice coordinator at (202) 260-1745, (202) 260-3937, or (202) 260-8994.