REPORT BY THE

Comptroller General

OF THE UNITED STATES

Assessment Of New Chemical Regulation Under The Toxic Substances Control Act

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GAO/RCED-84-84
JUNE 15, 1984

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON D.C 20548

B-214392

The Honorable James J. Florio
Chairman, Subcommittee on Commerce,
Transportation and Tourism
Committee on Energy and Commerce
House of Representatives

The Honorable Dave Durenberger
Chairman, Subcommittee on Toxic Substances
and Environmental Oversight
Committee on Environment and Public Works
United States Senate

As requested, we have reviewed the Environmental Protection Agency's (EPA) process for assessing and regulating risks from new chemical substances under the Toxic Substances Control Act and identified the major differences between this approach and the approach adopted by the European Economic Community.

As arranged with your offices, unless you publicly release its contents earlier, we will make this report available to other interested parties 30 days after the issue date.

Charles A. Bowsher

Comptroller General
of the United States

COMPTROLLER GENERAL'S REPORT

ASSESSMENT OF NEW CHEMICAL REGULATION UNDER THE TOXIC SUBSTANCES CONTROL ACT

D I G E S T

The Toxic Substances Control Act directs the Administrator of the Environmental Protection Agency (EPA) to protect against unreasonable risks to health and the environment from new chemical substances before they occur. To help accomplish this goal the Act requires a manufacturer to notify EPA of its intent to manufacture a new chemical substance. EPA then reviews the information submitted with the premanufacture notification to determine whether there is a reasonable basis to conclude that the new chemical presents or may present an unreasonable risk to health or the environment. If it does, EPA can impose regulatory requirements which might range from requiring labels to banning the product. (See pp. 1 to 3.)

At the request of the Senate Environment and Public Works' Subcommittee on Toxic Substances and Environmental Oversight and the House Energy and Commerce's Subcommittee on Commerce, Transportation, and Tourism, GAO reviewed (1) EPA's program for protecting health and the environment against unreasonable risks from new chemicals, (2) EPA's enforcement of program requirements, and (3) the differences between EPA's program and the new chemicals notification program adopted by the European Economic Community and the potential impact of these differences on trade. (See pp. 5 to 7.)

GAO found that EPA's premanufacture review is limited in scope and that its assessment of risk is frequently made with considerable uncertainties regarding the chemical's toxicity. As a result, EPA needs to take action to monitor changes in the manufacture and use of chemical substances after their premanufacture review. GAO also found that EPA has performed few enforcement inspections and has fallen considerably short of achieving its enforcement inspection goals for the new chemicals program.

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the need for regulatory action to protect against unreasonable risk. EPA's decision on risk and the need for regulatory controls is generally limited to the manufacture and use described in the premanufacture notification. (See pp. 9 to 12.)

The risks posed by a new chemical substance could increase significantly, however, if the exposure situation changes through changes in the volume or method of production or new uses being found for the chemical. Such changes can occur because, after EPA completes its review and manufacturing begins, the chemical can be manufactured by anyone, for any use, and in unlimited quantities without further notification to EPA. The only exception is if EPA has identified specific uses of a chemical or changes in its manufacture for which it will require further notification and clearance, which it had not done for any new chemical through fiscal year 1983. (See pp. 15 to 18.)

Since EPA, during premanufacture review, can generally neither confirm a chemical's toxicity nor foresee and consider all possible applications and uses of a new chemical, EPA needs to establish a procedure for it to be notified when significant changes occur in the initial exposure situations upon which its risk assessments were based. Such notification is necessary to achieve the legislative objective of identifying and controlling unreasonable risks from new chemicals before they occur or become widespread. EPA has the authority under the act to require manufacturers to report such changes in manufacture and use but had not done so through fiscal year 1983, although it has indicated that it intends to do so. (See pp. 12 to 21.)

Although additional reporting will be required to accomplish this objective, GAO believes the additional burden on industry will not be extensive because the majority of new chemicals manufactured do not achieve a high degree of commercial success (i.e. multiple uses are not found for the chemicals, and/or are not produced in large quantities). Furthermore, as of September 30, 1983, manufacturing had begun for only 1,124 (about 37 percent) of the 3,012 new chemicals for

This could be accomplished by amending the act to establish a separate inventory of new chemical substances for which EPA has made a premanufacture review and require that additional premanufacture notification be made when significant changes are planned in manufacture and use. Movement of a chemical from this separate inventory to the existing inventory could occur when EPA has sufficient information to determine that the substance is not significantly toxic.

The approach could place some additional burden on industry and EPA. However, because of the lack of information on changes in manufacture and use of new chemicals after the premanufacture review, it is difficult to predict what the increased burden will be. Implementation of GAO's reporting recommendation should generate data that would enable EPA to assess what the increased burden would be. Congress may wish to require EPA, after it implements GAO's reporting requirement, to assess how the use of an interim inventory of chemicals will change the burden on itself and industry. This would provide the Congress an improved information base for considering the magnitude of the regulatory burden that would be associated with this type of legislative change. (See pp. 24.)

EPA'S ENFORCEMENT INSPECTIONS GOALS FOR THE NEW CHEMICALS PROGRAM ARE NOT BEING ACHIEVED

Enforcement inspections are necessary to provide assurance that (1) new chemical notifications are being submitted, as required by the Act, (2) EPA-imposed control actions are being implemented by the manufacturers, and (3) data required to be submitted is reliable. However, EPA had performed few inspections prior to fiscal year 1983 to determine compliance with these requirements. For example, in fiscal year 1982, EPA made only 33 (about 10 percent) of 318 planned new chemical inspections. Although inspections increased in fiscal year 1983, they still fell about 52 percent short of the goal of 265 inspections. (See pp. 27, 30, and 32-33.)

The primary reason cited by EPA enforcement officials for their limited inspection effort through fiscal year 1983 was that resources

--The European program requires anyone who markets a chemical not on the existing chemicals inventory to comply with the premarket notification requirement. If the chemical was not on the established inventory it will always be classified as a new chemical requiring notification. The U.S. program generally only requires notification by the initial manufacturer. After initial notification and manufacture in the U.S. program the chemical is reclassified as an existing chemical. (See pp. 36-37.)

--The European program requires additional notification and testing when the quantity being marketed reaches specified annual or cumulative levels. Through fiscal year 1983, the U.S. program has not required any additional notification after the premanufacture notification. (See pp. 41-42.)

It is too early to tell how international trade might be affected by the differences between the two systems. However, GAO discusses several situations under which trade could be affected. (See pp. 43-44.)

AGENCY COMMENTS AND GAO EVALUATION

In commenting on a draft of this report, EPA stated that (1) the report fairly deals with a complicated set of issues and accurately points out the problems the EPA is committed to resolving and (2) the report's recommendations to the EPA Administrator are among options being examined for the new chemicals program.

However, EPA commented that the report overstated EPA's reliance on exposure assessment and, as a result, gives the impression that there are a large number of chemicals that EPA believes may be highly toxic, but which were not regulated because exposure is low. It was not GAO's intent to imply nor does GAO believe that the report either states or implies that EPA has chosen not to regulate a large number of chemicals it believed to be highly toxic because of low exposure. In citing the relationship between exposure and toxicity, GAO's focus is on those chemicals for which the chemical's toxicity

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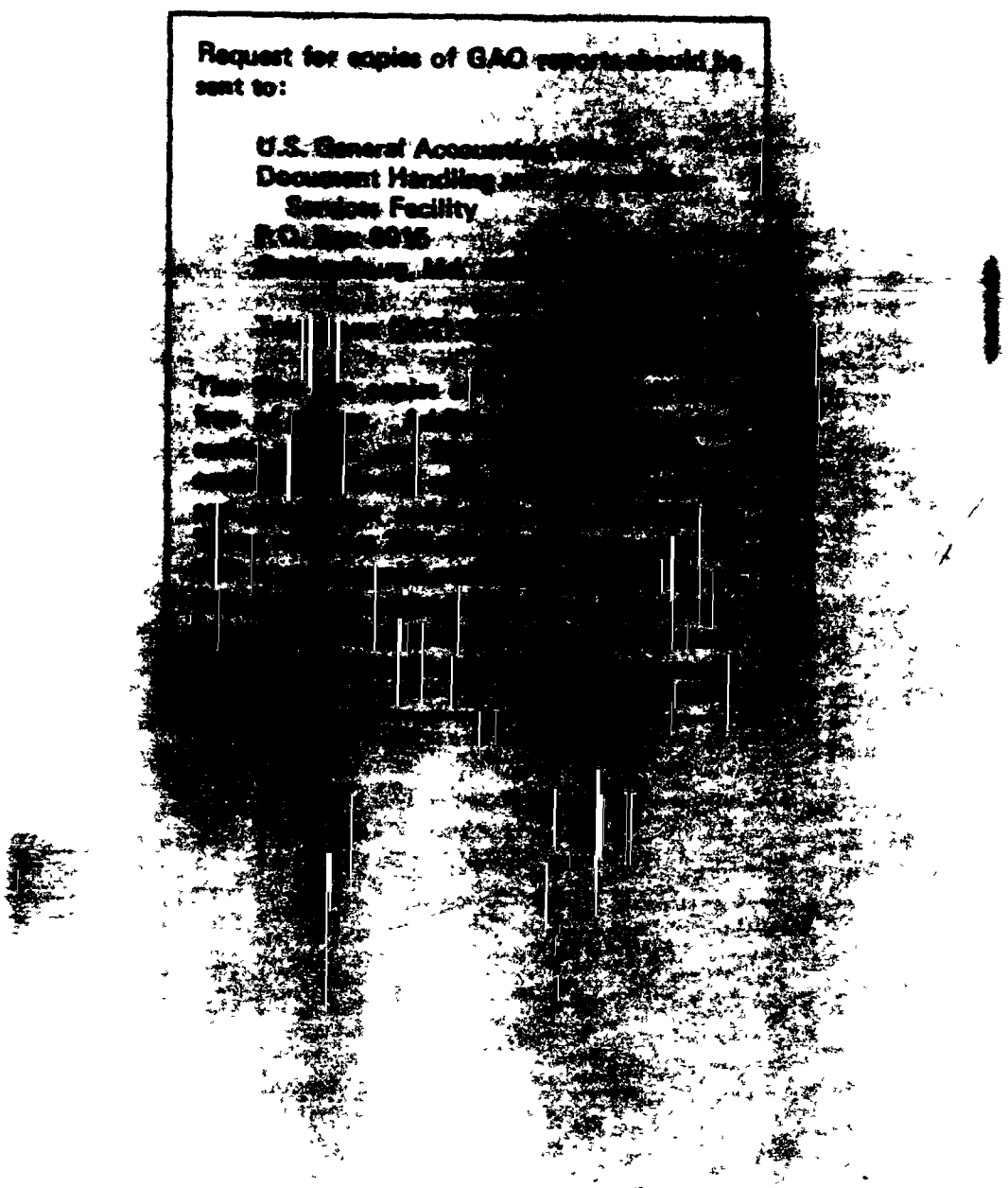
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CHAPTER 1

INTRODUCTION

The Toxic Substances Control Act (TSCA), which became effective on January 1, 1977, gives the Administrator of the Environmental Protection Agency (EPA) a broad mandate to protect public health and the environment from unreasonable risks associated with the manufacturing, processing, commercial distribution, use, or disposal of chemical substances. The act applies to all chemical substances except pesticides, tobacco, nuclear material, firearms and ammunition, food, food additives, drugs, and cosmetics which are regulated under other laws. The scope of TSCA's authority is broad enough to fill protection gaps existing in other environmental and public health laws.

A major objective of TSCA is to deal with the effects that chemicals may have on human health with particular emphasis on their potential for causing cancer, birth defects or genetic mutations through either direct human contact with the chemical substance or indirect human contact through environmental contamination. TSCA also provides EPA with the authority to deal with other chronic and acute health effects and with the ecological effects of chemicals.

One of EPA's initial efforts under TSCA was to compile an inventory of those chemical substances subject to TSCA that were manufactured or processed in the United States during calendar years 1975 through 1977. The chemicals included in the inventory were classified as existing chemicals. Chemicals not on this inventory were to be considered to be new chemicals that had to be reviewed by EPA prior to their manufacture. After a new chemical is reviewed by EPA and manufacturing begins, the chemical substance is to be added to the inventory and reclassified as an existing chemical. The existing TSCA chemicals inventory currently contains approximately 60,000 existing chemical substances.

The authorities that TSCA provides to the EPA Administrator for regulating new chemicals and existing chemicals differ. The Senate Environment and Public Works Committee's Subcommittee on Toxic Substances and Environmental Oversight and the House Energy and Commerce Committee's Subcommittee on Commerce, Transportation, and Tourism asked GAO to review and report on EPA's regulation of new chemical substances under TSCA.

We are also issuing a companion report on EPA's regulation of existing chemicals under TSCA--EPA's Efforts to Identify and Control Harmful Chemicals In Use (GAO/RCED-84-100).

The premanufacture notification program did not begin until late fiscal year 1979, and EPA did not receive many notifications until fiscal year 1980 when 281 were submitted. Since that time the number of notifications submitted annually has increased each year, reaching 1,301 in fiscal year 1983. Through September 1983, EPA had received premanufacture notification on 3,012 new chemical substances.

REGULATORY ACTIONS AVAILABLE TO EPA

If the Administrator determines that the new substance presents an unreasonable risk, then he/she is required under section 5(f) to take control actions to protect against that risk. If it is determined that there is insufficient data to assess the substance's effect on health and environment and that an unreasonable risk may be present, the Administrator is authorized under section 5(e) to control human and environmental exposure to the substance until sufficient data is developed to make a reasoned evaluation of human health and environmental effects. Under its section 5 authority alone, EPA cannot require that this data be developed. EPA can, however, impose controls on the manufacture and use of the chemical in order to protect against potential unreasonable risks until data necessary to determine the chemical's effects on health and environment are developed.

EPA's premanufacture notification review results in one of the following:

- --No control action is taken.
- --Actions are taken to control exposure because the chemical presents an unreasonable risk, with actions ranging from requiring labels to banning the product.
- --Manufacture and use are allowed as proposed by the submitter, while requiring significant new uses of the chemical to be submitted for EPA review.
- --Environmental and human exposure to the substance is limited or controlled pending development of additional data.

Once manufacturing is allowed by EPA, with or without controls placed on the proposed manufacture or use, and manufacturing begins, the chemical is reclassified as an existing chemical and added to the existing chemicals inventory. As an existing chemical, it can then be manufactured by anyone, in any quantity and for any use without any further premanufacture notification to EPA. The only exception is if EPA has issued a final significant new use rule (see pages 16-18), which as of September 30, 1983, it has not done, that identifies specific uses or circumstances of manufacture as being a significant new use requiring notification and review by EPA.

EPA NEEDS TO MONITOR NEW CHEMICALS

Since the premanufacture requirement became effective in July 1979, through the end of fiscal year 1983, EPA had received 3,012 premanufacture notifications for new chemical substances and had completed its review of about 2,900 of these. EPA's review involves an assessment of risks based on its judgments about the chemical's toxicity and the nature and extent to which there would be human or environmental exposure. As a result of its premanufacture review, EPA determined that for about 94 percent of the new chemicals reviewed, there was no reasonable basis to conclude that the expected exposure from the manufacture and use described in the premanufacture notification would present an unreasonable risk of injury to health and environment. For these chemicals, EPA allowed manufacturing to proceed without any regulatory controls being imposed. (See p. 12.)

Controls were imposed on the manufacture or use of 163 substances as a result of EPA's review. Formal regulatory controls were put on 132 chemical substances and voluntary controls were taken by manufacturers on 31 substances because of an EPA expressed concern. Controls included such actions as requiring workers to wear protective clothing during the manufacturing process and limiting the quantity of the chemical that could be produced before the results of testing being conducted by the manufacturer are submitted to EPA. In addition, the premanufacture notifications for 24 substances were withdrawn because EPA was considering regulatory controls. (See pp. 13 to 14.)

During its premanufacture review EPA assesses risk by analyzing information on a chemical substance's toxicity and the potential human and environmental exposure to the chemical. According to EPA, even highly toxic chemicals may not present an unreasonable risk if their manufacture and use do not result in significant human or environmental exposure. (See pp. 9 to 12.)

When EPA completes its assessment of the risk posed by the proposed manufacture and use of a new chemical, it makes a decision concerning

NEW CHEMICALS PROGRAM
ACTUAL AND PLANNED STAFF YEARS AND OBLIGATIONS
FISCAL YEARS 1981 THROUGH 1984

Fiscal Year	Full-time equivalent staff years	Obligations (millions) EPA salaries and expenses	Extramural support activities	TOTAL
1981 (Actual)	148.5	$5.3	$ 6.1	$11.4
1982 (Actual)	178.7	6.8	10.8	17.6
1983 (Actual)	201.2	7.7	5.8	13.5
1984 (Planned)*	207.8	8.2	5.4	13.6

*As of January 5, 1984

OBJECTIVES, SCOPE, AND METHODOLOGY

The objective of our review was to evaluate the adequacy of EPA's review of new chemicals in achieving the objectives of TSCA. As agreed with the Subcommittees this was done by examining

--EPA's process for reviewing new chemicals and deciding on potential risks presented by the new chemical substance and the need for regulatory action by EPA;

--the extent to which EPA enforces requirements for new chemical substances prior to their manufacture, including the number of on-site inspections and the type of enforcement actions taken for this purpose; and

--the level of resources committed to the review of new chemicals.

Our examination of EPA's new chemicals program involved the detailed review of EPA's policies, practices and procedures for (1) reviewing new chemicals for which premanufacture notifications were submitted, (2) assessing the risks that the new substances might present to health and environment and (3) controlling those aspects of the chemicals manufacture, distribution in commerce, use, or disposal that do or may present an unreasonable risk to health or environment. We also reviewed EPA's proposed and final rules, policy and guidance documents, process instructions and manuals, case files on a judgmentally selected sample of 42 new chemical substances which came through the premanufacture review process, and published studies and comments relevant to EPA's new chemicals program. Our review of these documents was augmented by (1) discussions with EPA personnel and officials associated with the new chemicals program and (2) reviews of the published views and/or discussion with representatives of the Chemical

which premanufacture notifications had been submitted to EPA. Because the reporting requirement is directed at significant increases in production and new uses, such reporting should not present an unreasonable burden upon industry or EPA. (See p. 21.)

Recommendation to the Administrator, EPA

To achieve the act's objective of identifying and controlling unreasonable risks before they occur or become widespread, GAO is recommending that EPA establish monitoring procedures and reporting requirements for new chemicals that have undergone EPA's premanufacture notification review and have been added to the inventory of existing chemicals. Such action is necessary so that changes that occur in the manufacture and use of chemical substances after EPA completes its premanufacture review can be evaluated for their potential risks to health and the environment. (See pp. 23.)

Matters For Consideration By the Congress

The act distinguishes between new and existing chemicals in terms of EPA's authority to regulate them. Once a new chemical clears EPA's premanufacture review and manufacturing has begun, it is then considered an existing chemical. The basic difference is that EPA is authorized to impose regulatory controls on the manufacture and use of a new chemical while data necessary to determine the chemical's health and environmental effects is being developed. With an existing chemical, EPA must obtain the data necessary for determining that the chemical's effect on health and environment presents an unreasonable risk before it can impose regulatory controls on the chemical's manufacture and use.

To better enable EPA to achieve the act's objective of protecting against unreasonable risks from new chemicals before they occur or become widespread, the Congress may wish to provide EPA with additional authority to control changes in manufacture and use of new chemicals that have undergone EPA's premanufacture review while data necessary for determining the chemical's health and environmental effects is being developed.

Industries Association in France and the United Kingdom; and the European Council of Chemical Manufacturers' Federations. We also reviewed published studies and comments regarding the U.S. and EEC programs and the differences between them.

We were assisted in our work by two consultants, George S. Dominguez of Springborn Regulatory Services Inc. of Enfield, Connecticut and Steven D. Jellinek of SCJ Incorporated of Washington, D.C. They reviewed our study plans, advised us on issues, and reviewed and commented on our report draft. In addition, Mr. Dominguez compiled data for us on the chemical regulatory laws of the EEC member nations and the OECD efforts to harmonize certain activities associatd with chemical regulation among its member nations such as good laboratory practices, testing guidelines, and data requirements.

Our review was conducted from November 1982 through September 1983. A draft of this report was provided to EPA for comment. EPA expressed general agreement with the data presented and with our conclusions and recommendations. Their comments have been incorporated in the report where appropriate. Our review was performed in accordance with generally accepted government auditing standards.

were diverted to enforce other requirements of the Act for which large numbers of violations were being found, such as compliance with EPA regulations on polychlorinated biphenyls and asbestos in schools. This diversion of enforcement resources was influenced by the difficulties involved in enforcing the premanufacture notification requirement. (See pp. 28 to 30 and 32.)

Recommendations To The Administrator, EPA

GAO makes two recommendations to the Administrator, EPA that are directed at facilitating and increasing enforcement inspections. (See p. 34.)

COMPARISON WITH THE EUROPEAN NEW CHEMICALS PROGRAM REVEALS CERTAIN DIFFERENCES BUT NO SIGNIFICANT TRADE ADVANTAGES

The United States and the 10 member nations of the European Economic Community have pursued different approaches to new chemicals regulation. The U.S. program is a national regulatory system designed to protect against unreasonable new chemical risks without creating unnecessary economic barriers to technological innovation, whereas a major objective of the Community's program is to avoid non-tariff trade barriers that might result from 10 different reporting requirements. As a result, their program is a standardized multi-national notification system with risk assessment and control decision left primarily to the individual member countries in accordance with their national laws, which vary considerably. (See pp. 42-43.)

The major differences between the two programs include the following:

--The European Community's program involves a premarket notification that requires a standard set of tests to be conducted as a precondition for marketing new chemicals. The U.S. program involves premanufacture notification and does not require standardized testing as a precondition to manufacturing or marketing a new chemical. (See pp. 36-37.)

A recent study by the Office of Technology Assessment[1] reviewed the amount of information contained in premanufacture notifications and found that it varied widely. The study involved the examination of notifications submitted for 740 new chemical substances for the presence or absence of the information specified by TSCA and for other items of physical/chemical and toxicity information useful in estimating potential health and environmental effects. The examination included all notifications received by EPA in the first 2 years of program operations (through June 1981) and those submitted in June 1982.

In general, more than 90 percent of all the notifications included information about the chemical's identity, estimated production volumes, intended uses, the number of workers who may be exposed, and intended methods of disposal.

However, the study found that nearly one-half of the inspected notifications had no information about toxicity. For those notifications which had some toxicity data, most was for acute toxicity which identifies the immediate effects from short-term exposure. Test data on chronic toxicity--health effects resulting from low exposures over long periods--was not provided for about 83 percent of the new chemicals notified to EPA. Data about environmental toxicity (ecotoxicity) was reported even less frequently than data on chronic toxicity. TSCA does not require that new chemicals be tested prior to manufacture. It only requires the manufacturer to submit any information on health or environmental effects that is known to him or that is reasonably ascertainable. The fact that test data on chronic toxicity and ecotoxicity is not being submitted for most new chemicals is an indication that such testing is generally not being done on new chemicals prior to their manufacture.

EPA's RISK ASSESSMENT CONSIDERS TOXICITY AND EXPOSURE

EPA reviews the information submitted in the premanufacture notification along with other available information on the new chemical substances and reaches a decision on the need for regulatory action. The decision is based on judgments about (1) the substance's potential toxicity based on its structural similarities to existing chemicals whose toxicity is known and (2) the manner and extent to which people and the environment are likely to be exposed to the substance when manufactured and used as specified in the premanufacture notification.

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[1]Office of Technology Assessment background paper, The Information Content of Premanufacture Notices, April 1983, prepared in response to a request from the Subcommittee on Commerce, Transportation, and Tourism of the House Committee on Energy and Commerce.

has not been confirmed through testing as well as those for which there is no scientific basis for predicting toxicity. The point GAO is making is that in these cases the need to determine the chemical's toxicity may not be very great if exposure is controlled and/or limited but would increase as the nature and extent of exposure to the substance increased.

In addition, EPA commented that the report underestimated major program accomplishments but provided no data to demonstrate this other than to indicate that in fiscal year 1984 it has begun to use the act's authority to require further notification for specific new uses or changes in manufacture of previously reviewed chemicals. GAO believes that the report presents an accurate picture of the program through fiscal year 1983. The increased use of this authority in fiscal year 1984 after GAO completed its review is a step in the right direction but more needs to be done. (See pp. 25 to 26.)

The study acknowledges that it might not have had access to results of some toxicity tests, such as confidential files of industrial labs, and based on incomplete information, it may have slightly underestimated the extent of knowledge about chemical toxicity.

Assessment of exposure by EPA

In assessing exposure to a chemical, EPA reviews available data to predict how people and the environment might come into contact with the substance, the amount of the chemical that might be released into the different environmental mediums (air, soil, and water) and through them to the food chain, how the substance might be assimilated by humans and other living organisms (skin absorption, inhalation, and ingestion) and the adverse effects that such exposure may have on the environment, people, and other living organisms.

In assessing human exposure, EPA considers two human exposure pathways. The first, sometimes called direct exposure, occurs as an immediate consequence of manufacturing, processing, distribution in commerce, use, or disposal. EPA assesses two types of direct exposure: occupational exposure and consumer exposure. An example of occupational exposure occurs when a worker comes in contact with the chemical during its manufacture or processing. Consumer exposure occurs when a person comes in contact with the chemical while using a product containing the chemical. In these cases, there is a direct path of human exposure to the chemical substance which is relatively easy to trace.

The other type of human exposure occurs when the substance reaches the general population through the air, water, or soil, and through them to the food chain. This is generally called indirect exposure or general population exposure. An example of this type of exposure is when a chemical is discharged into a river and absorbed by fish. Human exposure would occur through the consumption of the contaminated fish. Because of the indirect nature of the exposure it is considerably more difficult to identify or predict.

Risk assessment

Risk is a function of both toxicity and exposure and consequently the risks presented by toxic chemicals will be highly dependent on the nature and extent of exposure. For example, when exposure is limited or controlled to the extent where it would not be considered significant, then the overall concern for risk would be reduced even if the toxicity of the chemical substance was considered significant. Even highly toxic chemicals would not present an unreasonable risk if they were manufactured and used in a manner in which there is no significant human or environmental exposure. However, chemicals of relatively low toxicity could present an unreasonable risk if the manner in which they are manufactured and used would result in substantial human or environmental exposure.

ABBREVIATIONS

EEC	European Economic Community
EPA	Environmental Protection Agency
GAO	General Accounting Office
OECD	Organization for Economic Cooperation and Development
TSCA	Toxic Substances Control Act

production of shale oil until the company's ongoing long-term toxicity tests are completed and the results reviewed. Also, voluntary actions were informally agreed to by EPA and the manufacturer on 31 substances. The basic difference between formal regulatory actions and voluntary actions is that the formal regulatory actions are legally binding on the manufacturer while the voluntary actions are not.

In addition to the formal regulatory actions and voluntary agreements, the premanufacture notification process has caused some manufacturers to cancel their plans to manufacture new substances. For instance, as of September 30, 1983, 24 new chemicals which had been submitted for premanufacture notification were withdrawn by submitters before completing the review process because EPA was considering regulatory action.

Formal regulatory control actions

TSCA provides two different authorities under which EPA can impose regulatory controls on new chemical substances. The first, section 5(f), requires EPA to regulate a new chemical when it has sufficient data to determine the chemical's effect on health and environment and it concludes that the proposed manufacture or use will present an unreasonable risk. Under this section, EPA can impose control measures to reduce exposure, restrict production or use, or prohibit manufacture or import to prevent the unreasonable risks. As of September 30, 1983, no regulatory control actions had been taken using this authority. In fiscal year 1983, EPA was considering three chemicals for section 5(f) control action until the premanufacture notification for each of the chemicals was withdrawn by the submitting company.

Under section 5(e) EPA is allowed to impose controls on the proposed manufacture or use of a new chemical if available data is insufficient to determine the chemical's effect on health and environment, but EPA believes that an unreasonable risk may be present. Before taking such action EPA must determine that the available data is insufficient to permit a reasoned evaluation of the new chemical's effects and that either (1) the new chemical may present an unreasonable risk to health or the environment or (2) exposure to the chemical is likely to be significant. The formal regulatory control actions EPA has taken have all been section 5(e) actions and all were based on a significant toxicity concern. The section 5(e) actions are of two types. The first are orders issued unilaterally by EPA, generally referred to as unilateral 5(e) orders. Unilateral orders are used when EPA's decision is to ban the manufacture pending the development of data necessary to determine the chemical's health and environmental effects. The other orders, generally referred to as consent 5(e) orders or consent agreements, represent negotiated agreements between EPA and the manufacturer wherein the manufacturer agrees to comply with EPA imposed controls in exchange for being allowed to manufacture the chemical until sufficient data is developed. When EPA imposes controls under a section 5(e) consent order, they

TSCA PROVISIONS FOR THE REVIEW OF NEW CHEMICALS

In enacting TSCA, Congress recognized that the best time to identify and protect against the adverse effects of chemical substances was before they could become widely used in commerce. In order to achieve this objective Congress established notification requirements with which manufacturers of new chemical substances must comply.

Under section 5 of the Act any person who intends to manufacture or import a new chemical substance for commercial purposes in the United States must submit a notice called a premanufacture notification to the EPA at least 90 days before beginning manufacture. This provision is considered a major and very important feature of the Act since it directs EPA to review and evaluate the potential risks of new substances and control unreasonable risks before they can cause significant harm to human health or the environment.

The Act specifies that the notification include information on substance identity, uses, and exposure. However, test data and other data related to the effects on health and the environment as a result of the manufacture, processing, distribution in commerce, use or disposal of the new chemical substance must be submitted only to the extent they are in the possession or control of the submitter. Other health and environmental effects data that is known to or reasonably ascertainable by the submitter must be described in the notification.

EPA can not require that additional information be developed on new chemicals simply because they are new. However, under section 4 of TSCA, testing to determine a chemical's health and environmental effects can be required if EPA determines that the information available is insufficient to make a reasoned evaluation of the health and environmental effects of a chemical substance and either that

--the chemical may present an unreasonable risk of injury to health or environment, or

--the substance is or will be produced in substantial quantities that may result in significant human or environmental exposure.

EPA is required to review each new chemical substance for which a notification is made and assess whether or not the new substance either presents or may present an unreasonable risk to health or environment. Once EPA receives a notification, the Agency normally has 90 days to make its review. However, the Agency for good cause may extend the review period for up to an additional 90 days.

order to address EPA concerns about the toxicity of the chemicals. While this voluntary testing was being done, EPA's premanufacture review period was suspended until the test results were made available to EPA. The testing requested by EPA involved tests for either acute or chronic toxicity or both. Also on September 30, 1983, EPA's premanufacture reviews of 79 chemicals were in a suspended status pending either the completion of EPA requested testing or a manufacturer's decision about withdrawing the substance from premanufacture review.

Scope of EPA's premanufacture review decisions

The following excerpts from (1) EPA's standardized letter to the premanufacture notification submitter advising him that he can begin manufacture of the new substance and (2) EPA's fiscal year 1984 budget justification illustrate that EPA's decisions on the risks posed by new substances are limited in scope and directed primarily at the initial manufacture and use of the substance as described in the premanufacture notification.

Excerpt From EPA Letter To Submitter

"The Environmental Protection Agency (EPA) has completed its premanufacture review of the notice cited above and has decided not to begin any action with respect to the use(s) you planned for this chemical. Therefore, manufacture of this chemical is no longer constrained by the Toxic Substances Control Act (TSCA) after the date cited above. However, because the review required by TSCA is limited in time and depth and only limited data are required from PMN [Premanufacture Notification] submitters, EPA's decision not to act should in no way be construed as an approval of this chemical or as a finding that the risks that this chemical may present are insignificant or reasonable. Please note that this review under TSCA does not affect your obligations under any other applicable laws and regulations." (underlining added)

Excerpt From EPA's FY 1984 Budget Justification

"The PMN [Premanufacture Notification] review of new chemicals address an extremely narrow segment of the risks that a new chemical may eventually pose, because it can only focus on the intended methods of manufacture, production volume, and uses described in the PMN notice. After a new chemical has cleared PMN review, however, unrestricted commercialization, including significant increases in production volume and development of new uses, is possible without further review. In some cases, these new conditions may present significant risks."

NEW CHEMICALS PROGRAM RESOURCES

New chemical program activities are carried out primarily by technical staff located at EPA headquarters augmented by technical assistance contracted for by EPA. The technical staff involved in reviewing new chemicals and assessing risks is assigned to various divisions within the Office of Toxic Substances and many are involved with EPA chemical control activities for both new and existing chemicals. For fiscal year 1983, the Office of Toxic Substances estimates that its staff scientists, including chemists, toxicologists, biologists, environmental protection specialists, and engineers, and other technical assistance, clerical and management personnel expended 204 full-time equivalent staff years on the new chemicals program. Other activities of the new chemical program besides the review of premanufacture notification are (1) follow-up on new chemicals after the premanufacture review, (2) development and implementation of premanufacture notification exemptions, (3) development of regulations, and (4) other support activities. Fiscal year 1983 obligations for salaries and expenses for the new chemicals program were approximately $7.7 million.

The Office of Toxic Substances' fiscal year 1983 obligation for related extramural support activities for the new chemicals program was approximately $5.8 million. Extramural support includes support provided through contracts with private companies and grants or agreements with other agencies, with most of the extramural support being provided through contracts with private companies. Support activities performed by contractor personnel for the new chemicals program include assisting EPA in

--reviewing individual premanufacture notification,

--developing background information in support of individual premanufacture reviews,

--assessing exposure to new and existing chemicals,

--gathering and analyzing industrial data,

--performing literature searches,

--maintaining the TSCA inventory of chemicals,

--analyzing the market for chemicals and the economic conditions of the chemical industry,

--analyzing options for controlling substances, and

--supplying computer modeling support for exposure assessments.

The following table presents actual obligations for the new chemicals program for fiscal years 1981 through 1983 and the planned obligations for fiscal year 1984 as estimated by EPA.

reporting authority provided by section 8(a) of TSCA. EPA has noted the importance of monitoring changes in the manufacture and use of new chemicals after completion of the premanufacture risk assessment but has not issued any final rules under the significant new use authority and has not required reporting on any new chemicals under the Section 8(a) authority.

In a July 1983 program plan, EPA's Office of Toxic Substances stated that it plans to more closely monitor the commercial development of new chemicals, through greater use of the section 5(a)(2) and section 8(a) authorities. GAO believes that under the present legislation, section 8(a) reporting needs to be required for most new chemical substances.

Section 5(a)(2) significant new use authority

In reviewing premanufacture notifications for new chemicals, EPA sometimes can anticipate significant new uses, other than those proposed in the notification, that might present an unreasonable risk to health or the environment. In such cases Section 5(a)(2) authorizes EPA to issue an administrative rule requiring that a new premanufacture notification be submitted for each such potential use prior to manufacture for that purpose. The Conference report on TSCA provides the following guidance about what might be considered a significant new use.

> . . . a significant increase in the projected volume of manufacture or processing for a substance, a significant change in the type or form of human or environmental exposure, or a significant increase in the magnitude or duration of human or environmental exposure could be the basis for determining that a use is a significant new use.

Through September 30, 1983, EPA had proposed three significant new use rules, one of which was withdrawn. The other two were still under consideration by EPA for issuance as final rules as of January 1, 1984. In commenting on why no final significant new use rules had yet been issued through fiscal year 1983, the Director of the Chemical Control Division in the Office of Toxic Substances cited the view that to issue a significant new use rule the following factors should be present: (1) there is reason to be concerned about the substance's toxicity, (2) there are potentially other uses that could lead to higher exposure, and (3) there is a possibility that such other uses will occur. Using these kinds of factors as a basis for issuing significant new use rules involves being able to anticipate specific situations that might occur which could present unreasonable risks of injury to health or environment.

In fiscal year 1983, EPA decided that it would issue a significant new use rule for each chemical for which it had issued a section 5(e) consent order. The significant new use rule would specify that anyone planning to manufacture or use the substance

Manufacturers Association, the Synthetic Organic Chemicals Manufacturers Association, the Chemical Specialties Manufacturers Association, the Conservation Foundation, and the Natural Resources Defense Council. We also followed 11 substances through EPA's premanufacture review process and observed the process in operation.

We did not attempt to assess the correctness of EPA's decisions on individual chemicals. Rather our efforts were directed at examining the process EPA follows in making its decisions.

Our review of EPA's enforcement efforts related to the new chemicals program involved the (1) review and analysis of inspection policy and strategy documents, inspection files, background documents and accomplishment reports at EPA headquarters, and (2) discussions with officials of the Pesticides and Toxic Substances Compliance Monitoring Staff about enforcement efforts and plans.

The information we present on resources for the new chemicals program was compiled from EPA budget and accounting documents supplemented by discussions with Office of Toxic Substances program and budget officials. We did not verify this information.

Our other area of review as requested by the Subcommittees was to identify the differences between EPA's new chemicals program for screening, assessing, and controlling risks with the new chemicals notification program adopted by the European Economic Community (EEC) and to provide our observations on (1) the potential influence of such differences on international trade, (2) the efforts of the Organization for Economic and Cooperative Development (OECD) to harmonize activities associated with chemical regulation, (3) the relative merits of each system's data requirements and (4) the relative influence of the U.S. and European programs on

--developing relevant information for assessing potential risks of chemicals to health and environment;

--protecting public health and the environment from unreasonable adverse effects; and

--diminishing chemical innovation.

Our examination into the differences between the U.S. and European programs included, in addition to the work specified above, a review of the documents that specify the establishment of the European new chemicals notification program and other related documents to include the laws of the EEC member nations related to the EEC program. This was supplemented with discussions with representatives of the European Economic Community; the Organization for Economic Cooperation and Development; the governments of Denmark, France, West Germany and the United Kingdom; the Chemical

development of information necessary to determine the health and environmental effects of the chemical substance, when EPA finds that the substance may present an unreasonable risk. When regulated as an existing chemical, control actions cannot be taken until sufficient information is available to show that the chemical substance does present an unreasonable risk of injury to health or environment. Using the significant new use authority avoids this by specifying uses that will be considered new uses requiring notification to EPA and, therefore, be subject to regulation through section 5(e) controls on exposure until adequate data is developed to determine the chemical's effects on health and environment.

As of September 30, 1983, EPA has not used the section 8(a) authority to require reporting of manufacture and use data on any of the new chemicals whose risks were assessed by EPA during the premanufacture notification process. However, EPA has expressed its intent to follow up on new chemicals using both the section 5(a)(2) and section 8(a) authorities.

Monitoring actions under consideration

In July 1983, the Office of Toxic Substances issued a report entitled "TSCA Priorities and Progress" which identifies various actions that EPA is planning for its TSCA programs. This report states that EPA plans to more closely monitor the commercial development of new chemicals after they have completed premanufacture review. The report states that they will do this by

- --implementing a case-by-case follow-up program under the "significant new use" authority of section 5(a)(2) and the section 8(a) information-gathering authority, and

- --developing a general section 8(a) follow-up rule which would require companies to notify EPA when the annual production volume of a new chemical reached a certain level.

EPA needs to monitor changes in exposure to new chemical substances

A major TSCA objective is to identify and control unreasonable risks of injury to health and the environment from new chemicals before they become widely used in commerce. In order to provide reasonable assurance that this objective is achieved, EPA needs to monitor changes in the manufacture and use of new chemical substances from what was described in the premanufacture notification. Such monitoring is needed because

- --presently, significant changes in the manufacture and use of new chemical substances are possible without any notification to EPA,

CHAPTER 2

NEW CHEMICALS SHOULD BE MONITORED AFTER THE PREMANUFACTURE REVIEW

EPA's review of new chemical substances through the premanufacture notification process involves an assessment of the risks to health and the environment that might result from the proposed manufacture and use of the substance. This risk assessment considers both its potential toxicity and the manner and extent to which people and the environment may be exposed.

EPA judges the potential toxicity of new chemicals primarily through structure activity relationships analysis (structural analysis)--judgements are made about the potential toxicity of the new chemical substance based on what is known about the toxicity of structurally similar existing chemicals. EPA relies on structural analysis because toxicity testing is not required on the new chemicals and such data is generally quite limited.

Risk is a function of both toxicity and exposure, and therefore, the extent to which exposure is limited will reduce the overall risk, even though the chemical might be highly toxic. EPA has decided that control actions were not needed for most new chemicals because it had no basis to conclude that, when manufactured and used as described in the notification, the expected exposure of people and the environment to the substance may or will present an unreasonable risk or that the substance would be produced in substantial quantities with substantial human or environmental exposure.

Exposure situations, however, can change from those considered by EPA in its risk assessment. In most cases, once a new chemical is permitted to be manufactured, it is added to the existing chemicals inventory allowing it to be manufactured by anyone, in any quantity, and for any use without further notification to EPA. It is important to monitor changes in the manufacture and use of new chemical substances that occur after EPA's premanufacture review to assure that unreasonable risks are controlled before the chemical substance becomes widely used in commerce. EPA has not been monitoring changes in the manufacture and use of new chemical substances, but it has indicated that it is considering doing so.

TOXICITY DATA PROVIDED IN PREMANUFACTURE NOTIFICATIONS IS LIMITED

TSCA identifies certain kinds of information that should be included in the premanufacture notification. The information is mandatory, however, only to the extent that it is known to or reasonably ascertainable by the submitter.

Requiring reporting of changes in manufacture and use should not be a substitute for the establishment of significant new use rules. Whenever EPA can anticipate a specific use not described in the premanufacture notification that would require a reassessment of risk, it should issue a significant new use rule which brings the chemical back through the premanufacture notification process for such a reassessment. The section 8(a) reporting requirement would be in addition to any significant new use rules.

Potential reporting burden on industry

The adoption of this type of reporting requirement for chemicals not included in the original existing chemicals inventory will impose some burden on the chemical industry and EPA, but it may not be very extensive for the following reasons.

--The information to be reported (see page 20) would be limited and involves information that should be known to the manufacturers.

--Manufacturing was begun for only 1,124 of the 3,012 (about 37 percent) substances for which EPA had received premanufacture notifications as of September 30, 1983.

--Only an estimated 44 percent of new chemicals that are manufactured ever become commercially successful (i.e. uses of the chemical are found for which there is sufficient demand to make their manufacture profitable).

--About one-half of the chemicals on the existing chemicals inventory are marketed in quantities of less than 10,000 pounds annually.

The above information indicates that for most of the new chemicals that come through the premanufacture notification process new uses will not be found and large increases in production volume will not occur. Consequently, for these chemicals there will not be any significant reporting. Because reporting will be generally limited to those that become commercially successful, the reporting requirement should not present an unreasonable burden.

EFFECT OF ADDING NEW CHEMICALS TO THE EXISTING CHEMICALS INVENTORY

Section 8(b) of TSCA directs that a new chemical substance is to be added to the existing chemicals inventory after EPA has completed a premanufacture review of the substance and its manufacture has begun. The effect of adding the substance to the inventory is that this new chemical substance becomes reclassified as an existing substance that is no longer subject to the premanufacture notification requirements. Consequently, under EPA's current procedures the chemical substance in most cases can then be manufactured by anyone, for any use, and in unlimited

quantities. This occurs, even though EPA's premanufacture review of the chemical is often made (1) without health and environmental effects test data, (2) without any direct monitoring data on which to predict the potential exposure of people or the environment, and (3) with considerable uncertainty about the eventual commercialization of the chemical.

Because of the limited nature and considerable uncertainty of EPA's premanufacture review, we believe that EPA needs to use the section 8(a) authority to require information reporting on these chemicals that will allow EPA to monitor what happens to them after they are added to the existing chemicals inventory. Such reporting is needed to alert EPA to potential unreasonable risks as they occur and provide EPA the opportunity to take actions to (1) assess the nature and extent of risk that is likely to be occasioned by changes in a substance's manufacture and use, and (2) control those risks that EPA determines to be unreasonable. However, under the current law EPA would not be able to regulate the chemical as a new chemical when new uses or changes in manufacture are reported through a section 8(a) reporting requirement. As previously indicated (see p. 18), once the premanufacture review is completed and manufacturing begins, the chemical is required to be reclassified as an existing chemical and added to the inventory.

For EPA to have the opportunity to continue to regulate these chemicals as new chemicals (i.e., pending the development of information necessary to determine the chemical's effects on health and environment), TSCA would have to be amended to preclude the addition of these substances to the inventory of existing chemicals. This could be done by amending sections 5 and 8 of TSCA to establish an interim inventory of notified new substances. Substances on this interim inventory would require subsequent premanufacture notification and review by EPA when the substance is to be manufactured by a new company or when the circumstances of manufacture and use will be significantly different from what a manufacturer had indicated in its previous premanufacture notification. This would afford EPA an opportunity to review changes in manufacture and use and regulate the substance as a new chemical. Movement of a chemical from this interim inventory to the existing inventory could occur when EPA has sufficient information to determine that the substance is not sigificantly toxic.

CONCLUSION

Risk assessment involves an analysis of the degree of harm that might result to health and the environment from the combination of a chemical substance's toxicity and its exposure to people and the environment. The toxicity of most new chemical substances has not been tested; instead, EPA has had to make judgments about their potential toxicity based on structural analysis, but EPA's judgments, in many cases, cannot be verified without considerable testing. The manner, frequency, and extent

to which people and the environment would be exposed to a substance are major determinants of whether or not the chemical substance will present an unreasonable risk to health or the environment.

In deciding on the need for regulatory controls, EPA's assessment of exposure is primarily directed at the manufacture and use of the substance as specified in the premanufacture notification. However, after EPA completes its premanufacture review of a new chemical and manufacturing begins, the substance is added to the inventory of existing chemicals. Once put on the inventory, the chemical can be manufactured by anyone, for any use, and in unlimited quantities without any notification to EPA.

Because the toxicity of most new substances has not been tested and the exposure situation is subject to change, there is a need to monitor new chemicals after EPA has completed its premanufacture notification review. EPA needs to take action to ensure that it is notified when changes occur in a new chemical substance's manufacture and use that can significantly affect the way and extent to which people and the environment may be exposed. Such notification will alert EPA to potentially unreasonable risks and enable EPA to take corrective measures where warranted. We believe that this can be accomplished under section 8(a) of TSCA by establishing a general reporting requirement for new chemicals that have undergone EPA's premanufacture notification review. However, if the Congress wants these substances to continue to be regulated as a new chemical, TSCA would have to be amended.

RECOMMENDATION TO THE ADMINISTRATOR, EPA

To enable EPA to achieve TSCA's objective of identifying and controlling unreasonable risks to health and the environment from new chemical substances before they occur or become widespread, we recommend that the Administrator, EPA establish monitoring procedures and reporting requirements for new chemicals that have undergone EPA's premanufacture notification review and have been added to the inventory of existing chemicals.

Specifically, we recommend that EPA use the section 8(a) authority of TSCA to require

--premanufacture notification submitters to notify EPA of any significant changes in the manufacture and use of the substance described in their notification submission, and

--subsequent manufacturers to notify EPA when they begin to manufacture the new substance and provide information on production volume and uses of the substance.

Exclusions from the reporting requirement should be limited to those new chemicals demonstrated through testing or scientific consensus as not being chronically toxic.

MATTERS FOR CONSIDERATION BY THE CONGRESS

The act distinguishes between new and existing chemicals in terms of EPA's authority to regulate them. Once a new chemical clears EPA's premanufacture review and manufacture begins, it is then considered an existing chemical. The basic difference is that EPA is authorized to impose regulatory controls on the manufacture and use of a new chemical while data necessary to determine the chemical's health and environmental effects is being developed. With an existing chemical, EPA must obtain the data necessary for determing that the chemical's effect on health and environment presents an unreasonble risk before it can impose regulatory controls on the chemical's manufacture and use.

When EPA receives section 8(a) reports, as recommended, of significant changes in manufacture and use of chemical substances that have gone through the premanufacture review process, EPA cannot regulate them as a new chemical pending the development of information necessary to determine the chemical's effects on health and environment.

To better enable EPA to achieve the act's objective of protecting against unreasonable risks from new chemicals before they occur or become widespread, the Congress may wish to provide EPA with additional authority to control changes in manufacture and use of new chemicals that have undergone EPA's premanufacture review while data necessary for determining the chemical's health and environmental effects is being developed.

In order for EPA to retain the authority to continue to regulate such chemicals as new chemicals, it would be necessary to amend TSCA to preclude the addition of these substances to the existing inventory. This could be accomplished by amending sections 5 and 8 of TSCA to establish an interim inventory of notified new substances and to subject these substances to additional premanufacture notification review when the circumstances of manufacture and use will be significantly different from those indicated in the previous premanufacture notification. Movement of a chemical from this interim inventory to the existing inventory could occur when EPA has sufficient information to determine that the substance is not significantly toxic.

The approach could place an additional burden on industry and EPA. However, because of the lack of information on changes in manufacture and use of new chemicals after the premanufacture review, it is difficult to predict what the increased burden will be. Implementation of GAO's reporting recommendation should generate data that would enable EPA to assess what the increased burden would be. Congress may wish to require EPA, after it implements GAO's reporting requirement, to assess how the use of an interim inventory of chemicals will change the burden on itself and industry. This would provide the Congress an improved

information base for considering the magnitude of the regulatory burden that would be associated with this type of legislative change.

AGENCY COMMENTS AND OUR EVALUATION

In commenting on a draft of this report, EPA stated:

> "Overall, the GAO report shows a commendable understanding of the basic tenets of the Toxic Substances Control Act (TSCA) program. The report has fairly dealt with a complicated set of issues and accurately points out the problems the EPA is committed to resolving. The recommendations to the EPA Administrator in the report concerning section 8 reporting and clarification of the research and development (R&D) definition are among the options being examined in the Office of Toxic Substances (OTS)."

However, the EPA comments also state that (1) the major accomplishments of its new chemicals program have been underestimated in the report and (2) that information presented in the report regarding toxicity consideration in premanufacture notification review and the status of new chemical follow-up needs to be clarified and it provided additional explanation to do so.

New chemical program accomplishments are underestimated

EPA comments state that major accomplishments of its new chemicals program are underestimated in our report but provides no data to demonstrate this point other than its identification of the increased incidence of its use of significant new use authority during fiscal year 1984. We believe that the information presented in this chapter presents an accurate picture of the premanufacture review of new chemicals through fiscal year 1983 and the regulatory actions taken by EPA as a result of its premanufacture review.

Toxicity consideration in premanufacture notification review

In its comments on our draft report EPA states that the report overstates EPA's reliance on exposure during the premanufacture review and, as a result, gives the impression that there are a large number of chemical substances that EPA believes may be highly toxic, but which it did not regulate under section 5(e) and 5(f) because exposure is low. To clarify its basis for controlling exposure as a result of its premanufacture review, EPA stated that it

- --issues section 5(e) orders to make sure exposure remains low whenever it believes a chemical's potential toxicity is such that increased exposure may present an unreasonable risk, and

--does not need a positive basis for toxicity concern to take a section 5(e) action for a substantial production volume substance, if it finds that there will be significant or substantial exposure or release.

It was not our intent to imply nor do we believe that the report either states or implies that EPA has chosen not to regulate a large number of chemicals it believed to be highly toxic because of low exposure. In citing the relationship between exposure and toxicity, our focus was on those chemicals for which the chemical's toxicity has not been confirmed through testing as well as those for which there is no scientific basis for predicting toxicity. The point we are making is that in these cases, the need to determine the chemical's toxicity may not be very great if exposure is controlled and/or limited but would increase as the nature and extent of exposure to the substance increased.

New chemical follow-up

In its comments on our draft report EPA states that the report gives the impression that EPA is not pursuing a strong program to monitor new chemical substances of concern after they have completed the premanufacture review. EPA said that fiscal year 1983 was the first year in which EPA fully implemented the follow-up program. EPA identified a number of significant new use rules that have been proposed during fiscal year 1984 to illustrate its progress in implementing the use of significant new use rules and developing a strong, viable follow-up program. EPA stated that through April 16, 1984, it had proposed significant new use rules for 17 substances and that proposed rules for 13 other substances were undergoing agency review.

The principal message of our report is that unless EPA monitors new chemicals after they complete the premanufacture review process it will not achieve the act's objective of identifying and controlling unreasonable risks from new chemicals before they occur or become widespread. The accomplishments cited by EPA are a step in the right direction but more needs to be done.

CHAPTER 3

ENFORCEMENT INSPECTIONS HAVE BEEN LIMITED FOR THE NEW CHEMICALS PROGRAM

Enforcement inspections are important to the achievement of the TSCA objective of protecting health and the environment against unreasonable risks from new chemical substances. Inspections are EPA's primary means to determine that

- --premanufacture notifications on new chemical substances are being submitted to EPA as required by TSCA,
- --control actions specified by EPA for individual new chemical substances are being carried out by the manufacturer, and
- --data submitted in the premanufacture notification is reliable.

Although EPA has set goals for making enforcement inspections to ensure compliance in these areas, few inspections have been performed. Enforcement resources allocated for the new chemicals program have been diverted to enforcing other TSCA requirements for which EPA was finding high violation rates. For example, EPA accomplished only about 10 percent (33 of 318) of its fiscal year 1982 goal and only about 48 percent (126 of 265) of its fiscal year 1983 goal. The diversion of enforcement resources from the new chemicals program was influenced by difficulties associated with enforcing the new chemicals program requirements. Factors contributing to these enforcement difficulties included (1) the absence of final regulations, (2) the magnitude and complexity of the enforcement task, and (3) vague exemption criteria. The issuance of final rules for the premanufacture notification process should enhance EPA's ability to enforce the new chemicals program requirements.

LIMITED EFFORTS TO ENSURE REQUIRED NOTIFICATIONS ARE SUBMITTED

Notifying EPA prior to manufacturing, processing, or importing a new chemical substance is a basic requirement of the new chemicals program. EPA, however, through fiscal year 1983, has performed only 11 inspections to determine if notifications are being submitted as required. Assuring compliance with this requirement is a difficult task because of (1) the absence of final regulations, (2) the large number of firms to be covered, and (3) vague criteria as to which chemicals are exempt from the requirement.

Absence of final regulations

Through fiscal year 1983, the premanufacture notification process was conducted under interim proposed regulations and the

absence of final regulations during this period made it difficult to enforce the program requirements because certain aspects of the requirements remained unresolved. These included (1) the form and content of the data that was to be submitted, and (2) company recordkeeping requirements which are of particular importance to the enforcement effort. Final rules for the premanufacture notification process became effective in October 1983, and should contribute significantly to EPA's ability to enforce premanufacture notification requirements and inspect for compliance.

Size of chemcial industry dwarfs inspection efforts

The chief of the Compliance Unit of the Pesticide and Toxic Substances Compliance Monitoring Staff told us that a major reason for the limited inspection effort can be attributed to the fact that TSCA's premanufacture notification requirement is extremely difficult to enforce. The following are reasons for the enforcement difficulty.

--There are approximately 10,000 chemical manufacturers, 100,000 chemical processors, and 35,000 chemical importers in the United States that could potentially be involved with a new chemical substance for which notification to EPA would be required under TSCA.

--Random inspections to determine if a company is manufacturing, processing, or importing a new chemical without notifying EPA as required by TSCA are difficult and resource-intensive because they require that all chemicals identified through random searches of a company's records be checked against the inventory of approximately 60,000 existing chemicals.

According to this official, these factors contributed to the limited number of inspections because the enforcement office experienced difficulty in (1) identifying, out of this large universe of companies, those that are most likely to be manufacturing or processing new chemicals, and (2) devising an effective inspection approach for identifying new substances being manufactured by a company.

Up through fiscal year 1982, EPA limited its inspections for compliance with the premanufacture notification requirement to some companies which either (1) submitted incomplete notifications which were rejected by EPA and never resubmitted them or (2) withdrew their notification during the course of EPA's review process. Following this strategy, EPA conducted inspections of four substances whose notifications were rejected or withdrawn. No violations were found.

In fiscal year 1983 EPA revised its strategy for making inspections to ensure that required notifications were being

submitted. As part of its revised strategy EPA initiated a pilot program of inspections of a sample of companies that had reported a large number of chemicals for inclusion in the initial existing chemicals inventory but have never submitted a premanufacture notification to EPA. Three companies were inspected as part of the pilot program. The inspections disclosed that some chemicals had been reported to and included in the existing chemical inventory that did not qualify as existing chemicals because they had not been manufactured, processed, or imported during the three year period specified for classification as an existing chemical. EPA plans to expand the number of such inspections in fiscal year 1984. Additionally, EPA performed four inspections in response to tips or complaints but no violations were found.

Vague exemption criteria

Another factor that contributes to the difficulty of enforcing the premanufacture notification requirement is the fact that EPA has not established clear criteria as to which new chemicals are exempt from notification. Section 5(h) of TSCA exempts from the notification requirement those chemical substances that were manufactured or processed

--for test marketing purposes upon application to EPA showing that the manufacture, processing, distribution in commerce, use, and disposal will not present any unreasonable risk of injury to health and the environment; and

--in small quantities (as defined by the Administrator by rule) for scientific experimentation or analysis, or chemical research, including such research for the development of a product.

The difference between the test marketing exemption and the research and development exemption is that a company must apply for the test marketing exemption. Research and development activities do not require a company to notify EPA.

In its final regulations EPA defines small quantities solely for research and development as "quantities that are not greater than reasonably necessary for scientific experimentation, research, or analysis (including activities associated with product development)." EPA's TSCA enforcement office has determined that this definition is not precise enough for enforcement purposes and that it will be difficult to demonstrate that a particular use is not within the definition of research and development. Furthermore, the manner in which EPA defines test marketing does not provide an operative definition of what test marketing is and how it is distinguished from research and development activities and commericial use. The enforcement office has advised the Office of Toxic Substances that more specific criteria is needed for enforcement but the problem has not been resolved.

The lack of more definitive criteria for distinguishing between research and development, test marketing, and commercial uses adds to the difficulty of enforcing the premanufacture notification requirement. For instance, if enforcement officials discover that a company is manufacturing a new chemical without notifying EPA or applying for a test marketing exemption, the company could claim it is for research and development and EPA would have difficulty proving otherwise. A situation similar to this has already occurred. In 1983 EPA planned to prosecute and heavily fine several companies which used a new chemical without notifying EPA. The companies claimed, however, that much of their use of the substance was for research and development, and EPA subsequently negotiated a settlement which resulted in a reduction in the fine from $1 million to $139,000. EPA's enforcement officials told us that the settlement was made with the companies because they lacked clear criteria for what constitutes research and development.

A company may test market a new substance without submitting the substance for EPA's premanufacture review. However, the company must submit a test market exemption request to EPA with sufficient information to allow EPA to determine whether the substance might pose an unreasonable risk during test marketing. In granting the exemption, EPA may impose restrictions on the test marketing of the substance. These could include restrictions on the production, distribution, disposal or use of the substance during the test marketing or they could involve requiring specific recordkeeping. Through fiscal year 1982, EPA conducted a total of 43 inspections related to the new chemicals program, and 39 were directed at determining compliance with test marketing exemptions to the premanufacture notification requirement.

COMPLIANCE WITH EPA-IMPOSED CONTROL ACTIONS

When EPA assesses the risks posed by a new chemical substance and finds that the substance may present an unreasonable risk to health or environment but information is not sufficient to reasonably determine its effect on health and environment, it can, under section 5(e), issue orders to limit or control the manufacture, processing, distribution in commerce, use, or disposal of the substance pending the development of sufficient information. These orders may be issued unilaterally by EPA (referred to as unilateral 5(e) orders) or negotiated with the submitter (referred to as consent 5(e) orders). These orders impose requirements on the manufacturer that are legally enforceable by EPA. Through September 30, 1983, EPA has issued 14 section 5(e) orders, 5 unilateral 5(e) orders covering 13 substances, and 9 consent 5(e) orders covering 14 substances.

Short of issuing either unilateral or consent 5(e) orders, EPA has on occasion asked manufacturers to voluntarily take specific actions to control or reduce exposure (control actions)--such as consumer labeling, engineering controls, informing workers of

potential risks, and providing protective equipment to workers--to mitigate EPA concerns about potential risk. However, unlike the section 5(e) orders, such voluntary agreements are not legally enforceable. Through September 30, 1983, EPA has negotiated 31 such voluntary control actions with premanufacture notification submitters.

If EPA uses voluntary control actions to mitigate its concerns about possible risks, it needs to know if the manufacturers are in fact carrying out the actions specified by EPA. Prior to fiscal year 1983, no inspections were made to determine compliance with voluntary control actions because compliance is not legally enforceable.

Because EPA uses voluntary agreements as a means of mitigating their concerns about risks, it is important that EPA check the manufacturers' performance to determine if they are in fact complying. Not doing so because the agreements are not enforceable may indicate to the manufacturers that EPA does not care if companies carry out the actions that were specified in the agreement and raises questions as to what purpose is served by such voluntary agreements.

In fiscal year 1983, EPA identified inspections to determine compliance with EPA-specified control actions, whether by regulatory order or through voluntary agreement, as an enforcement inspection objective, and some inspections were performed. However, EPA does not know how many inspections of voluntary controls were performed because regional offices perform the inspections and only send inspection reports to EPA headquarters if violations are found. No violations of voluntary controls have been reported to EPA headquarters. As indicated on page 14, EPA decided to discontinue the use of voluntary control agreements and to use section 5(e) consent agreements for any controls it determines to be needed.

EPA VERIFICATION OF DATA SUBMITTED

In assessing risks to health and the environment, EPA relies on information provided by the manufacturer submitting the notification as to how a chemical is to be manufactured and used and the amounts that are expected to be manufactured for each use. This information becomes the basis for EPA's exposure assessment, which is a major determinant of the risks that are likely to be presented by the substance. Significant changes in the exposure situation could involve significant changes in the risks that might be posed. However, there is no requirement that the manufacturer limit his activities to what he had stated in his notification. The premanufacture notification regulations prohibit the manufacturer from submitting false or misleading data, and enforcing this prohibition has been an enforcement objective since 1980. However, EPA did not perform any inspections to determine data validity until fiscal year 1983.

EPA enforcement officials said they did not perform these types of inspections prior to fiscal year 1983 because (1) the new chemicals program received little management attention and (2) data reliability inspections were unlikely to result in an enforcement action since companies do not have to do what they claimed in their notification. If they wish to change their manufacturing process, increase production volume, or find other uses, they are free to do so without notifying EPA. According to these officials, in order for EPA to take an enforcement action they would have to prove that the company intended to deceive.

During fiscal year 1983, they performed inspections at 119 manufacturing sites to determine the validity of data submitted with 238 premanufacture notifications. The notifications covered by these inspections date back to the beginning of the program and represent about 8 percent of the approximately 3012 notifications submitted through fiscal year 1983. Two violations were found.

Our recommendation in chapter 2, that EPA establish a section 8 reporting requirement for manufacturers to notify EPA of any significant changes in the manufacture and use of the substances from what was reported in their premanufacture notification, would facilitate EPA enforcement efforts in this area. If our recommendation is adopted, the Enforcement Office could be alerted to those substances for which changes in exposure would be of greatest concern.

INSPECTION AND ENFORCEMENT RESOURCES

Although resources have been allocated for inspections related to the new chemicals program every fiscal year since 1980, most of these resources were eventually used to carry out inspections relevant to other TSCA programs. For instance, in fiscal year 1982, a goal of 318 inspections was established for the new chemicals program but only 10 percent (33) of the inspections were performed. However, inspections for compliance with TSCA section 6 regulations governing polychlorinated biphenyls, chlorofloro-carbons, dioxin, and asbestos in schools totalled 2,164 in fiscal year 1982, almost double the fiscal year goal of 1,095 for such inspections. These 2,164 inspections represent 98 percent of all TSCA-related inspections performed that year. This occurred because EPA placed a higher priority on section 6 enforcement. EPA decided that because they were finding a 70 percent violation rate in the section 6 area, their enforcement resources would be better spent in the section 6 program rather than in the new chemicals program where the likelihood of uncovering violations was small because of the absence of final regulations and the difficulty in identifying violations. The number of inspections performed in fiscal year 1983 increased to 126. However, the 126 inspections that were performed represented about 48 percent of EPA's goal of 265 inspections for fiscal year 1983.

In addition to the diversion of TSCA enforcement resources from the new chemicals' program to conduct section 6 inspections,

the following additional changes occurred that reduced the total level of resources available for all TSCA enforcement activities in fiscal year 1983.

--Actual work years spent on TSCA enforcement in fiscal year 1983 were 2.6 workyears less than what was spent in fiscal year 1982 (78.3 versus 80.6).

--Funding for contractor support in fiscal year 1983, was reduced by 87 percent from approximately $1.5 million in fiscal year 1982 to about $200,000. Although contractor support was never used for Section 5 enforcement activities, the loss of contractor support for other TSCA enforcement efforts increases the demand on EPA's TSCA enforcement staff and could further limit their availability to perform Section 5 inspections.

--EPA has dedicated 10 enforcement workyears at the regional level to assist manufacturers in complying with TSCA requirements.

The following table shows the level of actual workyears used by EPA for TSCA enforcement for fiscal years 1980 through 1984.

ACTUAL WORKYEARS USED BY EPA FOR TSCA ENFORCEMENT FOR FISCAL YEARS 1980 - 1984

Fiscal Year	Actual Workyears
1980	81.0
1981	81.6
1982	80.6
1983	78.3
1984	95.3[1]

[1]Estimated.

CONCLUSION

Although EPA has set enforcement inspection goals for the new chemicals program, it has not achieved them. For example, EPA planned 318 new chemical inspections for fiscal year 1982, but only 33 were performed because inspection resources were diverted to other TSCA requirements with high violation rates. Without an effective inspection program there is little assurance that EPA's program for reviewing new chemicals is satisfying TSCA's objective of protecting people and the environment against unreasonable risks.

We believe that more inspections are needed to provide reasonable assurance of compliance with the new chemical program requirements. At present, EPA has little assurance that

--Premanufacture notifications are being submitted to EPA on new chemical substances as required by TSCA, and

--exposure control actions specified by EPA for individual substances are being carried out by the manufacturer.

In addition, to better insure that required premanufacture notifications are submitted, EPA needs to establish clear criteria as to which new chemicals are exempt from the notification process.

RECOMMENDATIONS TO THE ADMINISTRATOR, EPA

To improve the enforceability of the new chemicals program, we recommend that the Administrator, EPA revise the premanufacture notification regulations on what constitutes an exemption from the notification requirement by developing more specific criteria for distinguishing between research and development, test marketing, and commercial uses.

With the current emphasis on reducing government spending, we recognize that it may be difficult to obtain the additional staff and funds for the new chemicals program needs. We believe, however, that because of the importance of achieving TSCA objectives, EPA should provide adequate inspection resources to achieve its inspection goals in the new chemicals program. If these resources are not available because of higher priority requirements, we recommend that EPA establish the additional needs of the program and provide such information to the appropriate congressional committees for their consideration.

AGENCY COMMENTS AND OUR EVALUATION

In commenting on our recommendation concerning the development of more specific criteria for distinguishing between research and development, test marketing and commercial uses, EPA states that it is extremely difficult to define research and development in a way that is highly specific yet at the same time covers such activities across the entire chemical industry. Therefore, the Agency is considering approaches to recordkeeping and notification procedures that would more clearly distinguish among R&D activities, test marketing, and commercial uses. In addition, EPA believes that this distinction will be further clarified as it responds to specific questions about permissible practices and disseminates such responses industrywide. EPA stated that this approach should address the concerns raised by our report and still allow industry a reasonable amount of flexibility in conducting R&D activities.

We agree with the agency comments and believe that the kinds of actions they cited are consistent with our recommendation.

CHAPTER 4

COMPARISON OF U.S. AND EUROPEAN NEW CHEMICAL NOTIFICATION PROGRAMS

The United States and the European Economic Community (EEC)[1] have pursued different approaches concerning the notification and testing of chemicals before they are placed on the market. The major differences between the two approaches are in the chemicals covered, data required for notification, and tracking of new chemicals after initial notification.

It is too early to tell how international trade might be affected by the differences between the two systems. However, we did identify several potential situations where international trade could be affected. The Organization for Economic Cooperation and Development (OECD) is working with its 24 member nations to harmonize, where possible, various aspects of chemical regulation on the international level.

MAJOR DIFFERENCES IN U.S. AND EEC PROGRAMS

Among the differences between the U.S. and EEC new chemicals programs are the chemicals covered, data required for notification, and tracking of new chemicals after initial notification. These programs are in different stages of development. The requirement for notification under the U.S. program was established in 1979 and EPA has had considerable experience in reviewing new chemicals under this program. Through September 30, 1983, EPA has received 3012 premanufacture notifications. Although the EEC program was to become effective in September 1981, the notification of new substances did not go into force until January 1, 1983, and according to EEC officials, only a few new chemical notifications had been received as of July 29, 1983.

Chemicals covered

The two programs differ in terms of (1) chemicals to be considered as new chemicals, (2) chemicals exempted from notification, and (3) the status of a new chemical after initial notification and clearance.

Both programs define new chemicals as those which do not appear on an inventory of existing chemicals. The beginning U.S. inventory was established in 1980 and contained about 55,000 existing chemicals; subsequent adjustments to the inventory raised that number to more than 60,000. The EEC has not yet finalized

[1]The EEC consists of 10 member nations--Belgium, Denmark, France, West Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, United Kingdom

its existing chemicals inventory but expects to publish one sometime in 1985. However, it has prepared a "core inventory" containing 34,000 chemicals which serves as a basis for classifying new chemicals until a final inventory is prepared.

The EEC program requires premarket notification as contrasted to the U.S. program which requires premanufacture notification. As such, under the EEC program site-limited intermediates--those chemicals produced and used only during the manufacture of another chemical--are exempt from notification. In addition, the EEC does not require notification of polymers--chemical substances consisting essentially of repeating structural units--and allows the marketing of any substances in quantities of less than one metric ton without having to submit the required base set data. Another distinction between premanufacture and premarket notification is that under the U.S. program risks to workers during the manufacturing process can be considered before they occur.

Under the U.S. program as it has operated through fiscal year 1983, site-limited intermediates and polymers were not exempt from notification nor was there any small volume exemption except for research and development and test marketing uses. Therefore, those categories of chemicals that were exempt from notification under the EEC program required notification under the U.S. program. According to EPA, about 10 percent of the new chemical substances reviewed under the PMN process were site-limited intermediates and 49 percent were polymers. EPA is considering exempting most polymers, site-limited intermediates, and low-volume chemicals from some of the premanufacture notification requirements. Although EPA has not finalized its exemption program, our review of the proposed exemption rule, EPA's draft of the final exemption rule, and discussion with the EPA officials responsible for developing the final exemption rule indicate that it is unlikely that EPA will totally exempt these catagories of chemicals from notification as is done in the EEC program. Instead, it is more likely that EPA will perform a more limited review of these new chemicals. (See appendix I for a description of EPA's proposed exemption program.)

Another major difference betwen the two programs is related to the question of who is required to notify. Under the EEC program the initial marketer and all subsequent marketers must notify because the substance is not added to the existing inventory and will always be considered a new chemical. However, under the U.S. program, after the initial manufacturer notifies and begins to manufacture the substance, it is added to the inventory of existing chemicals. Once the substance is added to the inventory, any one is free to manufacture the substance without having to submit a premanufacture notification. Consequently, subsequent manufacturers are exempt from the notification requirement.

Data requirements

The EEC program requires that a standard set of data be developed and submitted by the manufacturers before they can

market a new chemical substance. The data required by the EEC program is for the most part also required to be submitted as part of TSCA's premanufacture notification if it is known to the submitter or is reasonably ascertainable. The major difference is that under the U.S. program the manufacturer is not required to develop the data, and experience to date indicates that the full range of testing required by the EEC program is not generally being done under the U.S. program. In the absence of the test data, EPA generally relies on structural analysis to estimate physical-chemical properties and toxicity potential of new chemical substances. However, EPA can request and has on occasion requested that certain tests be conducted on specific chemical substances when it determined that such testing was needed for assessing risks. (See p. 14.)

EEC data requirements

As discussed earlier, the EEC program requires that a standard set of data (called the base set) be submitted as part of the manufacturer's premarket notification. The required data includes

--information on the identity of the substance,

--information on use, production, and handling of the substance,

--physical-chemical properties of the substance,

--toxicological studies,

--ecotoxicological studies, and

--information on the possibility of rendering the substance harmless.

All of the base set data must be developed and submitted. The only exception is if the notifier can substantiate that it is technically impossible to develop the data or that the data is not needed. The costs of developing the base set data are not well defined because of the lack of actual experience. However, the EEC cost estimate for the base set is $38,000. The OECD has estimated that the cost of completing these tests ranges between $25,000 and $50,000. Estimates provided by the European chemical industry and government officials we interviewed as to the approximate cost of developing the base set data were generally within the OECD's estimated cost range. It must be noted that these estimates refer to the total costs of developing all the required data. To the extent that some of the base set data is routinely developed by manufacturers, the incremental costs would be less.

The EEC's Directorate-General for Environment, Consumer Protection and Nuclear Safety stated the following reasons for adopting these base set data:

"A minimum standard notification requirement was necessary as the foundation of a system in which each Member State would, in effect, act as the agent of the other Member States in receiving new chemical substances on the EC [European Community] market. Furthermore, it represented the state of the international consensus in the OECD countries on the minimum information necessary for an initial hazard assessment of a chemical substance. Lastly, it was felt important that the Community should endeavor to adopt a notification system that would be internationally compatible with the approaches being considered in other countries. TSCA's case-by-case approach contained too much looseness for the interdependencies of the Member States of the EC."

U.S. data requirements

The U.S. program does not require that data be developed specifically for the premanufacture notification. Instead, it identifies data that should be submitted as part of the notification to the extent it is known to the submitter or is reasonably ascertainable. As discussed on page 9, the study of the information content of premanufacture notifications by the Office of Technology Assessment indicates that test data is not routinely provided.

As discussed on pages 8-9, EPA uses structural analysis to estimate physical chemical properties and toxicity when such data are not provided by the notification submitter. Structural analysis is relied on by EPA because (1) standardized testing like the base set is not authorized by TSCA and (2) EPA believes that its approach is generally adequate for assessing risks posed by the manufacture and uses of new chemical substances specified in premanufacture notifications and, therefore, a mandatory data requirement like the EEC base set is not necessary. EPA maintains that on those occasions where it believes specific test data is needed it has obtained the necessary test data through either section 5(e) orders or voluntary agreements with the notification submitter.

Benefits of base set testing and structural analysis

The primary benefit of the EEC approach is that it provides data on physical-chemical properties and toxicity potential that are generally recognized as scientifically more valid than are estimates based on structural analysis. The primary disadvantage is that the cost of developing the EEC-required base set data puts an additional cost burden on the development of new chemicals.

The primary benefit of the U.S. approach is that it minimizes the cost burden on the development of new chemicals. The primary

disadvantage is that EPA's assessments are often based on estimates of physical-chemical properties and toxicity potential developed using structural analysis, which is generally recognized as being a scientifically less acceptable basis for assessing physical-chemical properties and toxicity potential than is testing.

Consequently, the trade-off involved between the EEC and U.S. approaches is a choice between (1) the cost burden on a new chemical and the possible impact that it might have on chemical innovation and (2) scientifically more reliable data on physical-chemical properties and toxicity potential. Underlying such a choice is the consideration of whether or not the less scientifically reliable data is reliable enough for the purpose it is being used. EPA believes that it is, but there is some debate over whether it is. Unfortunately, until the substances undergo toxicity testing the accuracy of EPA's toxicity judgments based on structural analysis cannot be assessed.

Base Set Testing - The basic argument for base set testing is that it is reasonable and useful to have certain basic information about chemical properties--and that in many cases industry is already developing this type of data. Therefore, the base set only represents a formalization of what some companies are already doing for their own purposes or to meet other legal requirements. The primary argument against mandating that a standardized set of data be developed for all new chemicals is that it is scientifically unsound and unnecessary, because some of the standardized tests are often inappropriate for a given substance. It is further argued that such mandatory testing will result in unnecessary and costly testing and that it is far more appropriate to employ a case-by-case approach to testing based on expert scientific judgment.

The U.S. Chemical Manufacturers Association offers the following arguments as to why the "mandatory base set" approach is not appropriate for EPA's new chemicals program.

--Many chemicals are manufactured in small quantities and will have minimal releases into the workplace or the environment. Because such chemicals have an extremely limited potential for exposure, reasonable assurance of safety may exist even if little or no testing is performed.

--No single set of tests is appropriate for every chemical, and testing decisions require the exercise of professional judgment in light of the unique properties of each particular chemical. Three principal factors must be taken into account in determining the need for and scope of testing: (1) physical/chemical properties, (2) structure activity relationships, and (3) exposure and use conditions. EPA's review process allows EPA to consider these three factors for each chemical substance in order to determine whether any testing is needed and, if so, what

specific kinds of tests are appropriate for assessing risks to health or the environment.

--New chemicals are unproven in the marketplace and have unproven commercial prospects. Performing a mandatory set of tests as required by the EEC could be costly. It is extremely unlikely that most new chemicals manufactured in limited quantities and having limited revenue-generating potential could absorb the expense of all these tests and remain economically viable. A U.S. requirement for a similar mandatory set of tests could result in the elimination of numerous new chemicals, with a corresponding reduction in technological innovation in the chemical industry.

We discussed the EEC's base set testing requirement with the Director General and other officials of the European Council of Chemical Manufacturers' Federations and the Executive Secretary of the European Chemical Industry Ecology and Toxicology Center. We asked for their views about the appropriateness and reasonableness of the EEC base set requirement. These officials stated that the European chemical industry does not necessarily agree that new chemical notification is necessary but, given the fact that new chemicals notification is required, they expressed the following views about the base set data requirement.

--The EEC base set data requirements are not unreasonable provided that a manufacturer is exempted on a case-by-case basis from specific testing requirements where it can be scientifically demonstrated that such testing would be unnecessary or inappropriate as is provided for in the EEC notification system's "escape clause."

--There is some concern in the European chemical industry about whether the individual EEC governments will allow specific tests to be exempted on individual chemicals where it is appropriate to do so. However, it is too soon to know whether this will happen.

--The EEC base set was developed as a result of negotiation between the European chemical industry and the EEC and represents industry's acceptance of the base set requirements in exchange for the "escape clause" provision, the outright exemptions from notification for polymers, site-limited intermediates, and the exemption for chemicals produced in amounts less than one metric ton. The industry viewed a standard data requirement like the base set for gaining access to the European market as preferable to individual European governments adopting different notification and data requirements.

Structural Analysis - The principal arguments for using structural analysis to estimate physical-chemical properties and toxicity potential are that (1) it minimizes the cost burden on

new chemical development and (2) allows decisions to be made on a chemical-by-chemical basis as to the specific information needed to estimate the risk posed to health and the environment. EPA maintains that it is reasonable to rely on structural analysis to assess new chemical risks when the exposure from the planned manufacture and use of new chemicals is sufficiently limited or adequately controlled. The major criticism of structural analysis is that it is not a reliable method for predicting the toxicity of a chemical substance and is incapable of giving a chemical a clean bill of health. For example, the EEC has stated the following regarding structural analysis.

> "It [the EEC] is convinced that structure-activity relationship analysis in no way is an equivalent substitute for test data about the effects of chemical substances. A general principal of toxicology is that small changes in the structure of a chemical may greatly influence the biological activity of the chemical. That is to say, that many biologically active substances differ only slightly in structure but greatly in effects."

> "There is no comprehensive, reliable system of predicting the environmental behavior and effects of even simple molecules on the basis of their structure. Only in limited areas (pharmaceuticals, pesticides) have certain correlations been observed--these are the exception, not the rule."

EPA and representatives of the U.S. Chemical Manufacturers Association have indicated agreement that structural analysis by itself is not a reliable basis for definitive conclusions that a chemical is safe. However, these industry representatives have stated that structural analysis "is an increasingly computerized and powerful, however empirical, discipline to make maximum use of the ever increasing body of existing toxicological information." They further stated that although structural analysis does not predict toxicity it does provide a judgmental basis for determining if testing is needed. When EPA decides that no control action is necessary on a notified substance, the decision is not that the substance is safe (i.e. not significantly toxic) but rather that, when manufactured and used as proposed, it will not present an unreasonable risk of injury to health or the environment.

Tracking New Chemicals After Initial Notification

The EEC program requires that, after the initial notification, the manufacturer report to the notified government when the volume it markets within the EEC reaches certain specified levels. As these levels are reached by the manufacturer, additional testing can and may be required by the notified government if it believes additional testing is needed. These specific levels are

--10 tonnes[2] per year or 50 tonnes cumulative,

--100 tonnes per year or 500 tonnes cumulative, and

--1,000 tonnes per year or 5,000 tonnes cumulative.

Therefore, under the EEC program, the new chemical substances subject to notification will be automatically tracked, and the need for additional testing will be considered at specific points in their commercialization.

In contrast, the U.S. program does not require automatic tracking of new chemical substances. EPA has the authority to follow the commercialization of new chemicals under the provision of section 8 of TSCA, but as of January 1, 1984, it has not used this authority to do so, although it has indicated its intent to do so (see pp. 17-19).

POTENTIAL OF U.S. AND EEC PROGRAMS FOR ASSESSING RISK AND PROTECTING AGAINST UNREASONABLE RISK

The objectives of the U.S. program as specified by TSCA are to identify the risks to health and the environment from new chemicals and to take regulatory actions necessary to protect against those risks determined to be unreasonable. In terms of the scope of the U.S. program and the authority provided to the EPA administrator, the U.S. program has the potential for and is directed at the protection of health and the environment against unreasonable risks from new chemicals. How well it does this is a function of EPA's (1) ability to identify the risks that are posed, (2) judgments about what risks are unreasonable and what actions are adequate to protect against them, and (3) willingness and ability to use various authorities to identify and control unreasonable risks.

In contrast, the stated purpose of the EEC program is

"to approximate the laws, regulations and administrative provisions of the Member States on:

a) the notification of substances, and

b) the classification, packaging, and labeling of substances dangerous to man and the environment,

which are placed on the market in the Member States."

Consequently, under the EEC program risk assessment and control of chemicals are generally limited to classifying the hazards associated with the chemical (i.e. explosive, highly flammable,

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[2]Metric ton equal to 1.1 U.S. ton.

toxic, carcinogenic etc.) for the purpose of specifying the packaging and labeling requirements that must be met when the substance is marketed in the EEC. Controlling chemical risks beyond the imposition of the standardized EEC packaging and labeling requirements is generally left to the discretion of the individual EEC member countries and the requirements of their respective laws, which vary considerably. Therefore, the EEC program is much more limited in its objectives than is the U.S. program under TSCA. In effect, the EEC program represents an agreement among its member nations as to (1) what new chemicals will require notification to the EEC Community before they can be marketed in any of the member countries, (2) what data will be required to be submitted as part of this notification, and (3) how hazardous substances are to be packaged and labeled.

The development of the EEC program was influenced by a growing interest in chemical regulation by individual member states and a shared interest in minimizing the extent to which notification and data requirements for new chemicals would become artificial barriers to trade among the EEC members countries. The EEC program was intended to preclude the situation where a manufacturer in attempting to market his product throughout the European Community might be subject to 10 different notification systems with perhaps very different data requirements. As adopted, the EEC provides that, when a manufacturer satisfies the premarket notification requirements in one EEC member country, he is in fact satisfying the notification requirement in all 10 member countries. Each member state has thereby agreed to include the EEC notification program as an integral part of its national chemical control program and laws. However, the chemical control programs of member states can and in some cases do go beyond the EEC program.

POTENTIAL IMPACT OF PROGRAM DIFFERENCES ON INTERNATIONAL TRADE

New chemicals marketed in an EEC country must satisfy the EEC notification requirements, and new chemicals marketed in the United States must satisfy the U.S. notification requirements. There is no reciprocity between the U.S. and the EEC notification programs, and therefore a new chemical can not gain access to both the U.S. and the EEC markets by only meeting either the U.S. or the EEC requirement. Consequently, when competing in either the U.S. or the European markets, neither U.S. nor European manufacturers will gain a significant competitive advantage because of the differences between the two systems.

It is too early to tell how international trade might be affected by the differences between the U.S. and EEC programs for notifying new chemicals. However, some ways in which international trade might be affected are described below.

--A U.S. manufactured product that is not marketed within the EEC community may have a price advantage over a competing substance that is manufactured and marketed in an EEC member country when they are competing in a third (non-EEC) country's market because it may not have to incur any or all of the base set testing costs that the EEC substance will incur.

--An EEC manufacturer could choose to introduce a new chemical into the U.S. market to determine its commercial potential before introducing it into the EEC market. By so doing, the cost of base set testing can be delayed until the chemical has generated enough sales to offset the costs of testing required by the EEC. However, according to several European chemical industry officials, this option is only likely to occur when the EEC manufacturer has a subsidiary in the U.S. Furthermore, they feel that in most cases the manufacturer is unlikely to delay marketing the substance in the EEC market because the manufacturer that is first to market a new substance usually acquires the predominant market share. The opposite could be true for a U.S. manufacturer with respect to a new polymer substance because of the outright exemption given to polymers in the EEC program. For instance, a U.S. manufacturer might first market new polymers in an EEC country because polymers are completely exempted from notification in the EEC program.

--The U.S. Chemical Manufacturers Association has stated that because of EEC notification system requirements, U.S. manufacturers may choose not to market some new substance that they would otherwise consider marketing in Europe. They advised us that this could have a substantial negative effect on the U.S. export of new chemicals to the EEC.

OECD HARMONIZATION EFFORTS

The OECD was established in 1961 to provide intergovernmental cooperation among 24 industrialized countries on matters relevant to economic and social policy (appendix II lists the OECD member countries). Based on the OECD work, member nations have adopted uniform testing guidelines, principles of good laboratory practices, and agreement on the mutual acceptance of data. Although OECD considered mandatory minimum test data for new chemicals, similar to the EEC base set, this recommendation was not adopted.

In 1970, OECD established an Environment Committee to address a variety of environmental problems and policies. One of the first official acts of the Environment Committee was to establish a "Chemicals Group" with responsibility for work in the field of control of chemical substances to protect the environment and health while avoiding negative effects on the economy and trade.

The first activities of the Chemicals Group tended to concentrate on specific chemicals (or families) that were of immediate concern to various OECD member states. Among these were polychlorinated biphenyls, mercury and cadmium. However, as general concern with new chemical introduction began taking on increasing importance in the early to mid-1970's, and as more member states were enacting various national laws dealing with this subject, the Chemical Group began to review the necessity for a more unified approach--harmonization. The result was that in 1974 the OECD issued a recommendation on "The Assessment of the Potential Environmental Effect of Chemicals."

The objective of this original recommendation was to examine the question of "harmonization" of new laws in the areas of new chemicals, and an international study was conducted in 1975. This study summarized the various laws and their requirements and considered future trends and directions in such legislation. This report in turn resulted in another OECD recommendation in 1977 to establish guidelines for procedures and requirements to be employed in predicting or anticipating chemical effects. In November 1977 the Chemicals Group initiated its "Chemical Testing Programme". Under this program Expert Groups were established to pursue specific areas of study.

The work of the Expert Groups has resulted in the adoption by the OECD membership of

--Mutually Acceptable Testing Protocols. A mutual agreed upon set of toxicology testing guidelines - these have been developed for a number of toxicology tests and widely distributed. All OECD members have agreed that they will accept toxicology tests conducted by these protocols provided that they meet with mutually accepted good laboratory practices.

--Mutually Accepted Good Laboratory Practices. This second major accomplishment establishes a detailed system of Good Laboratory Practices which in turn provide a basis for quality assurance in toxicity testing.

--Mutual Acceptance of Test Data. In its third major accomplishment OECD has established the principle of mutual acceptance of test data from one OECD member country by another provided that the OECD testing protocols (or their equivalent) have been followed and that good laboratory practices were employed.

In addition to these three actions, the OECD's Chemical Group recommended that the Concept of a Minimum Pre-Marketing Set of Data be adopted by the OECD. This is a mandatory minimum set of data that, as proposed for OECD adoption, would have to be developed and submitted to member governments on new chemicals and is essentially the same as the base set of data required by the EEC's new chemical notification program. The OECD's Chemical

Group had recommended that OECD members adopt the Minimum Pre-Marketing Set of Data as a uniform system of premarket testing of new chemicals. However, as a result of U.S. objections, this recommendation was not adopted. Instead, the OECD approved an agreement that commits all member states to provide information on the toxic effects of new chemicals in a meaningful form before they are marketed. The agreement identifies the Minimum Pre-Marketing Data as one way this can be done, but it does not prescribe it as the way it must be done.

OBSERVATIONS

Our analysis of the U.S. and EEC programs for the notification of new chemicals and the differences between them indicates the following.

--More categories of chemicals are required to be notified under the U.S. program.

--The EEC program system makes the conduct of certain specified tests a precondition for marketing certain types of new chemicals whereas the U.S. program does not require testing as a precondition, although it has the authority to require testing on a case-by-case basis.

--Under the EEC program, all notified chemicals automatically require further reporting and may require further testing when production volumes reach pre-established levels whereas the U.S. program does not call for any automatic additional reporting on new chemicals after initial notification.

--The U.S. program is a national chemical regulatory program for protecting against unreasonable risks from new chemical substances while the EEC program is basically a standarized notification, classification, and reporting system adopted by the EEC member governments to serve as the notification, classification and reporting elements of their 10 disparate chemical regulatory programs.

--A major emphasis of the EEC program is to provide for the development of data on new chemicals to support the existing and future chemical regulatory programs of 10 different nations in such a way as to avoid non-tariff trade barriers that might result from 10 different notification schemes. In contrast, a major emphasis of the U.S. program is to protect against unreasonable risks to health and the environment from new chemical substances without creating unnecessary economic barriers to technological innovation.

It is too early to tell how international trade might be affected by the differences between the two systems. However, there are several ways in which international trade might be affected.

EXEMPTIONS TO PREMANUFACTURE NOTIFICATION UNDER CONSIDERATION BY EPA

In response to petitions from the U.S. Chemical Manufacturers Association, EPA is considering some exemptions from premanufacture notifications. Presented below is a description of what the exemptions are expected to be based on, a draft Final Premanufacture Notification Exemption Rule, and discussions with EPA officials involved in developing the exemption program. However, because a final decision has not been made, the exemption program as described is subject to change.

Exemptions are being considered for the following categories of chemicals:

--Polymers (chemical substances that are predominantly composed of molecules that contain at least two structural units derived from functioning monomers. A monomer is a chemical substance that has the capacity to form links between two or more other molecules).

--Chemical substances manufactured or imported at 1,000 kilograms or less per year.

--Chemical substances manufactured or imported at between 1,000 and 10,000 kilograms per year.

--Site-limited intermediates (any chemical substance which is (a) used as a reactant in the intentional manufacture of another chemical substance and (b) is consumed in whole or in part in that reaction).

Although referred to as an exemption program, none of the chemicals in these categories would be totally exempt from notification. Instead, the chemicals in each of these categories would require some form of a notification to EPA, but this notification would differ from the present premanufacture notification. EPA would then review the exemption notification and decide if the standard premanufacture notification would be required. Three different forms of exemption notification are planned to be used--one for site-limited intermediates and chemical substances manufactured at between 1,000 and 10,000 kilograms per year, a second for polymers, and a third for chemical substances manufactured or imported at 1,000 kilograms per year or less.

Exemption of site-limited intermediates and chemicals produced at between 1,000 and 10,000 kilograms per year

Manufacturers seeking exemptions from the premanufacture notification requirement for chemicals in either of these two

categories would have to submit an exemption notice to EPA 21 days before the planned start of manufacture. This exemption notice is to contain

--the chemical's identity,

--available test data,

--planned production volume (for site-limited intermediates),

--site of manufacture,

--data on by-products and impurities, and

--a description of use (for low volume chemicals) by function and application.

In addition, the manufacturer must submit a report by a qualified expert that addresses the chemical's potential risks to health and the environment. EPA will review the data submitted as part of the exemption notice and before the end of the 21 day period decide if the chemical will be exempt from the standard premanufacture notification. If EPA decides that the chemical will be exempt, the manufacturer can begin to manufacture the chemical at the end of the 21 day notice period. Once manufacturing of an exempt chemical begins, the manufacturer is required to notify EPA if there is a change in volume or site of manufacture for exempted site-limited intermediates and use or site of manufacture for exempted chemicals produced at between 1,000 and 10,000 kilograms per year. An exempt chemical in either of these categories will not be added to the inventory of existing chemicals.

Exemption of Polymers

No polymers will be totally exempt from premanufacture notification and review. Instead, certain categories of polymers wil be declared ineligible for any form of exemption. Manufacturers of these categories of polymers will have to submit the full premanufacture notification and these substances will be subjected to the full 90 day premanufacture review. Polymers not in these ineligible categories will be potentially eligible for a more limited 21 day premanufacture review.

Manufacturers of polymers that are potentially eligible for the 21 day review will be required to submit a limited premanufacture notification to EPA. This limited notification must include such information as manufacturer's identity, type of exemption, site of manufacture, chemical identity, number-average molecular weight, levels of residual monomers and other reactants and low molecular weight species contained in the polymer, identity of impurities, production volume, uses, and any test data and other data concerning the polymer's health and environmental

effects that are in the possession or control of the submitter. EPA will assess the limited notification and decide if the polymer will be allowed to undergo the 21 day review. Those determined to be ineligible for this more limited review will undergo the full 90 day premanufacture review.

Polymers that undergo either the limited 21 day review or the full 90 day review will be added to the inventory of existing chemicals once manufacturing begins.

Exemption of chemicals produced at 1,000 kilograms per year or less

Manufacturers of chemical substances in this category will be required to submit a brief exemption notice to EPA 21 days before manufacture. This exemption notice is to include information on chemical identity, use, and site of manufacture. EPA will review the notice to determine if there is any reason why the substance should be declared ineligible. If at the end of the 21 day period EPA does not declare the substance ineligible for the exemption, manufacture can begin. Manufacturers must submit another exemption notice before use or site of manufacture changes. Exempt chemicals will not be added to the inventory of existing chemicals.

OECD MEMBER COUNTRIES

Australia	Japan
Austria	Luxembourg
Belgium	Netherlands
Canada	New Zealand
Denmark	Norway
Finland	Portugal
France	Spain
Germany	Sweden
Greece	Switzerland
Iceland	Turkey
Ireland	United Kingdom
Italy	United States

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 16 1984

OFFICE OF
POLICY, PLANNING AND EVALUATION

Mr. J. Dexter Peach
Director
Resources, Community and
Economic Development Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Peach:

The Environmental Protection Agency (EPA) has reviewed the General Accounting Office (GAO) draft report entitled, "Assessment of New Chemical Regulation Under the Toxic Substances Control Act" (RCED-84-84). As you requested in your March 14, 1984 letter, I am providing EPA's comments on the draft report.

Overall, the GAO report shows a commendable understanding of the basic tenets of the Toxic Substances Control Act (TSCA) program. The report has fairly dealt with a complicated set of issues and accurately points out the problems the EPA is committed to resolving. The recommendations to the EPA Administrator in the report concerning section 8 reporting and clarification of the research and development (R&D) definition are among the options being examined in the Office of Toxic Substances (OTS). Our main concern with the GAO report, however, is that the major accomplishments of our new chemicals program, which we feel are significant, have been underestimated. We also believe that three areas covered, toxicity considerations in premanufacturing notification (PMN) review, the status of follow-up program, and R&D definitions need further clarification. We have attempted below to provide additional explanation of our program's activities on these issues.

The report's discussion of the program's review considerations and new chemical substance follow-up program in our opinion overstates EPA's reliance on exposure during PMN review. Toxicity is always a critical factor in EPA's review and usually determines the extent of our exposure analysis. The report in stating that exposure determines the importance of toxicity gives the impression that there are a large number of chemical substances OTS believes may be highly toxic, but that it did not regulate under sections 5(e) and 5(f) because exposure is low. In fact, OTS issues section 5(e) orders to make sure exposures

remain low whenever it believes that increased exposure may present an unreasonable risk. The twenty section 5(e) orders (covering 37 substances) issued as of March 31, 1984, have been toxicity-driven. The one section 5(e) order on synfuel substances (covering 105 substances) was both toxicity- and exposure-driven.

Those cases where there is no scientific ability to predict toxicity have not been explicitly covered in GAO's draft report. The report does not reflect that EPA's reviews are driven by production volume or use considerations only in such cases as these. We do not need a positive basis for toxicity concern to take a section 5(e) action for a substantial production volume substance, if we find significant or substantial exposure or release.

I would like to correct the impression left by the report that EPA is not pursuing a strong program to monitor new chemical substances of concern after they have completed the PMN review. TSCA gives EPA two major follow-up tools to ensure re-evaluation of any PMN substance that has the potential to present an unreasonable risk under new conditions of use. These are the section 5(a) significant new use rule (SNUR) provisions and the section 8(a) information gathering authority.

Fiscal Year 1983 was the first year in which EPA fully implemented the follow-up program, thus accounting for the lack of information available for GAO to study before ending their investigation in late 1983. Since PMN reviews began in 1979, over 275 chemical substances have been identified and reviewed as possible follow-up candidates. These generally were identified in the early 1980s as the number of PMNs increased dramatically and experience was gained in establishing criteria.

EPA has issued 9 SNUR proposals covering 17 PMN substances, and there are 13 additional SNUR substances in Agency review. Many of these are proposals on PMN substances subject to section 5(e) orders, a practice adopted in FY 83. Five substances are covered by final SNURs now completing Agency review. I believe this recent progress illustrates that EPA is effectively implementing the use of SNURs and developing a strong, viable follow-up program.

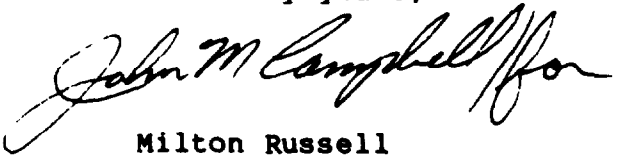
Another issue is the scope of the definition of R&D as it pertains to chemical substances subject to PMN review. It is

extremely difficult to define R&D in a way that is highly specific yet at the same time covers such activities across the entire chemical industry. Therefore, the Agency is considering approaches to recordkeeping and notification procedures that would more clearly distinguish among R&D activities, test marketing, and commercial uses. In addition, the Agency believes that this distinction will be further clarified as the Agency responds to specific questions about permissible practices and disseminates such responses industrywide. This approach should address the concerns raised by GAO and still allow industry a reasonable amount of flexibility in conducting R&D activities.

Hopefully these comments will be useful in clarifying several misunderstandings, particularly in the new chemical substance follow-up program. As I mentioned earlier, the GAO report has tackled a complex set of issues and should be useful in further discussions of program directions.

We appreciate the opportunity to review this draft report prior to its publication.

Sincerely yours,



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