TSCA PRIORITIES AND PROGRESS

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Authorized Signature and Date

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EXECUTIVE SUMMARY

This report, prepared by the Office of Toxic Substances (OTS) of the U.S. Environmental Protection Agency (EPA), updates OTS' January 1982 report, "Priorities for OTS Operation." It describes the OTS' progress in carrying out the agenda announced in the 1982 report, the Office's current approach to implementing the Toxic Substances Control Act (TSCA), and new directions for the future. The policies and initiatives this report announces have not been formally reviewed or approved by other EPA offices or the EPA Administrator. It was developed to provide internal guidance to OTS staff on the general status of TSCA programs and on priorities for future operations. The report is now being made available to the public for the same purpose. OTS welcomes comments from members of the public and from interested groups on any aspect of this report.

I. Introduction

OTS remains committed to the broad program goals announced in the 1982 "Priorities" document: to provide better guidance for OTS implementation of its new and existing chemicals programs; to develop more cost-effective means for achieving industry compliance; and to strengthen OTS operations. Within this broad framework, OTS has considerably refined, focused, and in some cases redirected its activities. In doing so, it is working toward six broad program objectives:

- To ensure the development of adequate data on both new and existing chemicals.
- To monitor the commercial development of new chemicals more closely after they have completed premanufacture review.
- To use TSCA regulatory authorities more flexibly and effectively to ensure that existing chemical hazards are promptly reviewed and controlled.
- To refine and expand the analytical and technical tools used in support of the OTS' regulatory programs.
- To share information developed under TSCA more effectively and to promote technical exchanges with other agencies and the public.
- To integrate OTS' new and existing chemicals programs more closely.

II. New Chemicals Program

The basic framework of OTS' new chemicals program, as outlined in the 1982 "Priorities" document, is now in place. Final premanufacture notice (PMN) rules for new chemicals have been issued; OTS is more frequently taking action on new chemicals to control exposure and to ensure that adequate data are developed; broad-based exemptions from PMN requirements have been proposed for certain polymers, site-limited intermediates, and low volume chemicals; and a case-specific new chemicals followup program has been incorporated within the new chemicals review process. With this framework in place, OTS will be concentrating its efforts for the next year on the following activities:

- Premanufacture review of new chemicals, with continued use of §5(e) and other mechanisms to encourage data development and control exposure to new chemicals of concern.

- Development of a general §8(a) followup rule for new chemicals, based on production volume, to complement the current case-specific new chemicals followup program.

- Use of Advisory Circulars to communicate the rationale behind new chemical decisions and to provide guidance to new chemical notice submitters.

- Refinement and validation of technical tools used by OTS in PMN review, including the development of data bases and analytical techniques based on structure-activity relationships.

III. Existing Chemicals Program

Since publishing the January 1982 "Priorities" document, OTS has developed an integrated existing chemicals program, capable both of identifying potential problems and of bringing them to resolution. Approximately 60 substances have been or are now under review in this program. About one-fourth have been dropped from active review; two-thirds have been targeted for further analysis and preliminary decisions with 12 months; and five have moved into regulatory development.

The basic objectives of the existing chemicals program are: (1) to identify potential risks through TSCA mechanisms; (2) to ensure the development of data adequate to assess those risks; (3) to ensure that these risks are addressed under the

appropriate regulatory authority; and (4) where that authority is TSCA, to ensure that appropriate action is taken. Examples of recent activities are:

- o An Advance Notice of Proposed Rulemaking (ANPR) on MBOCA (4,4'-methylenebis(2-chlorobenzeneamine)), a curing agent used in plastics, which has been shown to be carcinogenic in several species of animals.

- o Designation of MDA (4,4'-methylenedianiline), a high-production volume chemical intermediate for high priority review under §4(f) of TSCA.

- o Establishment of an interagency Federal Asbestos Task Force to coordinate federal activities concerning asbestos; promulgation of a §6 rule requiring school inspections for asbestos and a §8(a) rule requiring industry to submit information on asbestos manufacture, processing, and disposal.

- o Promulgation of §6 rules governing certain aspects of the use of PCB's (polychlorinated biphenyls).

- o Proposal of a §8(a) reporting rule for chlorinated terphenyl and a §5(a)(2) significant new use rule for chlorinated naphthalenes.

Within the next six months, OTS anticipates three to five additional actions from its existing chemicals program.

In carrying out this program, OTS has adopted a flexible approach, making full use of TSCA regulatory and information-gathering authorities. Among the major features of this program are:

- o Identification of candidates for action primarily through basic TSCA mechanisms, such as §4 rules, §8(e) notices, §21 petitions, and PMN review.

- o When rulemaking is appropriate, earlier publication of Advance Notices of Proposed Rulemaking, before the details of the various possible regulatory approaches have been completely worked out, to allow greater public participation and more timely rule development.

- o Close coordination with other regulatory agencies where responsibilities overlap.

- When immediate regulation is not warranted or feasible, use of the §5(a)(2) "significant new use" authority to prevent existing chemicals of concern from expanding in production volume or use without prior EPA review.

- Use of nonregulatory mechanisms, such as Risk Management Advisories, either by themselves or in connection with a rulemaking, to bring problems more promptly to the public's attention.

As a complement to the existing chemicals control program, OTS' §4 test rules program is now operating effectively. The Office has successfully met a court-ordered schedule for responding to a backlog of Interagency Testing Committee (ITC) recommendations for test rules, and it is responding to current ITC recommendations within the statutory 12-month period. In total, by the end of 1983, OTS will have responded to ITC recommendations on 64 chemicals or chemical categories. As the backlog of ITC chemicals is eliminated, OTS will develop test rules on substances not designated by the ITC. The Office anticipates that it will begin its first §4 efforts on a non-ITC chemical within the next year, with proposal in fiscal year 1984.

To support these programs, OTS conducts a wide range of chemical monitoring activities. These activities include studies monitoring the level of PCB's and other chemicals in human tissue samples, monitoring asbestos in schools and public buildings, and identifying and evaluating exposure to specific chemicals under review. These monitoring activities are closely integrated with the Office's existing chemicals program, and they provide direct support to OTS' regulatory agenda. Within the next year, they will be used to identify candidates for both testing and control, and they will provide exposure information necessary for ongoing OTS reviews.

OTS is also taking steps to ensure that its new and existing chemicals programs are coordinated. It has now developed or will soon be developing in the near future a number of mechanisms to promote a more unified overall program. These include:

- Use of the PMN review process to identify chemicals for review in the existing chemicals program.

- Use of generic assessments developed in the PMN process to support existing chemicals review.

- Use of physical-chemical estimation, structure-activity-relationship, and modeling techniques developed for the PMN review process in existing chemicals review.

- Use of health and environmental effects data developed under other TSCA authorities to support the review of new chemicals.

- Use of the §5(a)(2) significant new use authority to place a limit on the growth of existing chemicals until adequate data are developed or their safety is otherwise ensured.

IV. Technical Developments

A major priority of OTS has been developing analytical tools -- such as computerized data bases, environmental fate models, SAR (structure-activity-relationship) techniques, standardized test methodologies, and quality assurance procedures -- to support its chemical risk assessments and regulatory activities. During the next year, the Office will commit significant resources to the further development of these tools and will continue to integrate them into the decisionmaking process.

Several important areas of development are:

- Data systems. OTS is developing several internal systems to provide ready access to data submitted under TSCA and to data on specific areas of OTS concern, such as genetic toxicity, aquatic toxicity, and chemical fate. These include computerized data bases such as SPHERE and systems for indexing and organizing TSCA submissions under §8(d) and §8(a).

- Models and analytical tools. OTS uses a broad range of estimation techniques to predict the physical-chemical properties of chemicals from their structure, and it has developed a number of computer models to estimate environmental fate, population exposures, and health risks. Several projects are now underway to refine and expand these tools.

- SAR development and validation. OTS is now conducting or sponsoring a series of projects to refine and validate its use of structure-activity relationships in chemical review. These activities are essential in determining the level of confidence that should be assigned to specific techniques, and they will significantly expand the Office's present capabilities.

- Priority-setting methods. Along with other groups such as the ITC, OTS has encouraged and sponsored the development of chemical scoring and priority setting systems to aid in selecting chemicals for further evaluation from among large numbers of candidates.

- Quality of data. To ensure the integrity of its data, OTS has developed health, environmental effects, and chemical fate testing guidelines; it will soon be prescribing good laboratory practices for TSCA testing; in cooperation with the Food and Drug Administration, it periodically inspects and audits laboratories conducting tests under TSCA; and it is conducting a Gene-Tox Program to evaluate the current status of genetic toxicology. OTS also has an active quality-assurance program to assure the integrity of data developed in its monitoring projects.

V. Information Sharing and Technical Exchange

TSCA gives EPA unique authority to gather or require the development of a wide range of production, exposure, and health and environmental effects data on commercial chemicals. Much of the information collected under TSCA is potentially of great value to the public, states and local governments, EPA regions and other EPA offices, other federal agencies, and other nations. From the beginning, OTS has assigned a high priority to sharing such information and promoting technical exchanges. Current initiatives in this area include:

- Developing Risk Management Advisories for selected existing chemicals and Advisory Circulars for new chemicals.

- Publishing quarterly reports identifying chemicals under evaluation in the existing chemicals program.

- Providing access to a number of OTS data bases now under development, such as SPHERE.

- Promoting technical exchanges with states, federal agencies, and foreign nations (such as the current OTS agreements with the Federal Republic of Germany and the Michigan Department of Natural Resources to share computational and modeling capabilities).

- Publishing nonconfidential aggregations of data from confidential data bases (such as reports on asbestos or ITC chemicals submitted under §8(a)), so that the public has as much access as possible to this information.

- Entering into agreements with other regulatory agencies that provide them restricted access to TSCA confidential information.

- Establishing a program to ensure better information exchange and coordination between OTS and the toxics programs of individual states.

- Exploring the possibility of using the TSCA information-gathering authority (for example, §8(a)) to support other EPA offices and other federal agencies.

Addendum

OTS is now exploring several additional initiatives that are early in their planning stages and have not yet been fully articulated. Before decisions are made to pursue these initiatives -- or how far to pursue them -- their policy, legal, and resource implications will require further review. For this reason, some of the initiatives may not be adopted while others may be phased in gradually as the Office continues to gain experience in its new and existing chemicals programs. However, these initiatives represent alternative routes that OTS is now exploring to reach its overall program goals:

- Place categories of substances that have raised concern in the PMN process on the §5(b)(4) "risk list."

- Issue §4 test rules for chemical categories that have raised concern in the PMN process.

- Develop a "me-too" SNUR automatically extending the terms of §5(e) orders to subsequent manufacturers and processors.

- Issue §8(a) followup rules together with new chemical significant new use rules.

- Develop a TSCA biotechnology program to ensure that risks from TSCA uses of genetically engineered material are appropriately controlled.

- Issue triggered §4 rules to require testing of low production volume/exposure/release chemicals for which existing data indicate a need for testing if production, exposure, or release were to increase.

- Issue significant new use rules on §4 chemicals to ensure that production does not increase or new uses develop before testing is completed.

- Update the TSCA Chemical Substance Inventory through a §8(a) rule.

- Select existing chemicals for OTS evaluation by "cluster" analysis, a priority-setting system that would assign aggregate measures of risk to categories of chemicals with similar uses or structures.

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F. Quality of Data

1. Test Data
2. Exposure and Monitoring Data

V. Information Sharing and Technical Exchange

A. General Background and Current Activities

B. International Activities

1. OECD Chemicals Program
2. United Nations Programs
3. Bilateral Activities

Addendum

PREFACE

In January 1982, the Office of Toxic Substances (OTS) issued a report, "Priorities for OTS Operation," describing the general goals and objectives of the Office in implementing the Toxic Substances Control Act (TSCA). The report focused primarily on OTS' new and existing chemicals programs, conducted under §5, §6, and §8 of the Act. It described the Office's basic strategy for identifying and controlling risks from both new and existing chemicals, and it defined priorities for future OTS activities.

In the year and a half since this report was prepared, OTS has substantially accomplished the program goals that the report announced. Furthermore, OTS' experience during this period has confirmed the basic principles stated in the 1982 document and the general framework it laid out for both the new and existing chemicals programs. In conducting its ongoing programs, however, OTS has come to identify possible refinements within the general program framework, goals toward which more attention should be focused, and new initiatives that should be explored. The present report, "TSCA Priorities and Progress," updates the 1982 "Priorities" document, by describing the Office's progress in carrying out the agenda announced in that document, OTS' current approach to implementing TSCA, and new directions for the future.

In addition to updating the 1982 document, the present report significantly broadens its scope. The 1982 "Priorities" document was for the most part limited to OTS' new chemicals review program under §5 of TSCA and its existing chemicals control program under §6 and §8. The present report describes progress, refinements, and new initiatives within these programs. However, it also adds a discussion of OTS' activities under §4, which gives EPA the authority to require health and environmental effects testing of chemicals. At the time of the earlier report, OTS §4 testing program was faced with a series of court-ordered deadlines, and therefore its priorities were clearly set. As these deadlines are met, however, OTS will have greater flexibility to implement §4 more broadly. In addition, the present report discusses OTS initiatives in two major areas central to its mission -- technical tool development and information exchange with other Federal agencies and the public. The Office devotes considerable resources to these areas, which are vital to the success of its overall program, and expects significant progress in both.

The report also includes an Addendum describing possible OTS initiatives in the future. The initiatives described in the Addendum have not been fully developed, and some may not be possible given current resource constraints, but they represent

alternative routes OTS is now exploring to reach its overall program goals.

This report has not been formally reviewed or approved by other EPA offices or the EPA Administrator. It is an OTS staff document developed to provide internal guidance to OTS staff on the general status of TSCA programs and on priorities for future operations. The report is now being made available to the public for the same purpose. OTS welcomes comments from members of the public and from interested groups on any aspect of this report.

CHAPTER I

OVERVIEW OF OTS INITIATIVES

In January 1982, OTS announced a coordinated program to identify and control chemical hazards under the Toxic Substances Control Act. At that time, OTS identified three major program goals:

- To provide better guidance for OTS implementation of its new and existing chemicals programs.
- To develop more cost-effective means for achieving industry compliance.
- To strengthen OTS operations.

In the past year and a half, OTS has taken significant steps in achieving these program goals. At the same time, the Office's day-to-day experience in carrying out this agenda and in conducting its new and existing chemicals programs has allowed it to refine, focus, and in some cases redirect its activities. On the basis of this experience, OTS has identified six major program objectives for the next year, as well as a series of initiatives designed to accomplish each:

- Ensuring adequate data development on both new and existing chemicals. OTS will continue to use its §5(e) authority more frequently on new chemicals, limiting production of chemicals of concern pending the development of data, and it will encourage premanufacture notice suspensions to allow health and environmental effects testing before manufacture begins. The Office is also exploring the possibility of listing categories of new chemicals under TSCA §5(b)(4) or issuing §4 test rules on selected new chemical categories to ensure adequate data submissions under the PMN program. In addition, OTS will continue to use the §4 authority flexibly to eliminate OTS' court-ordered testing backlog and to respond promptly to future Interagency Testing Committee (ITC) designations. Finally, OTS will begin to develop test rules on chemicals identified through mechanisms other than the ITC.

- Using TSCA regulatory authorities more effectively and flexibly to ensure that existing chemical risks are promptly reviewed and controlled. The overall goal is to resolve problems identified through standard TSCA mechanisms more quickly and more effectively. Important strategies for achieving this goal are close coordination with other regulatory agencies where responsibilities overlap; earlier publication of Advance Notices of Proposed Rulemaking, before the details of the various possible regulatory approaches have been completely worked out; the use of the §5(a)(2) "significant new use" authority to prevent existing chemicals of concern from expanding in production volume or in uses without prior EPA review; and the use of nonregulatory mechanisms, such as Risk Management Advisories, to bring problems more promptly to the public's attention.

- More closely monitoring the commercial development of new chemicals after they have completed premanufacture review. OTS will continue to implement a case-by-case followup program, under the "significant new use" authority of §5(a)(2) and the §8(a) information-gathering authority. The Office also intends to develop a general §8(a) new chemical followup rule, which would require companies to notify EPA when the annual production volume of a new chemical reached a certain level. This will provide a general safety net, giving EPA the opportunity to reevaluate new chemicals after they have completed premanufacture review and have grown in the marketplace. In addition, OTS is considering a "me-too" §5(a)(2) rule that would automatically extend restrictions imposed on PMN submitters under §5(e) to other companies that might manufacture or process the new chemical.

- Further developing analytical and other technical tools to support the regulatory objectives of the Office. OTS now has several projects underway to refine and expand its use of structure-activity analyses, which in the absence of complete data help to identify potential health and environmental effects of new chemicals that will require further evaluation; to develop computerized and other data bases specifically adapted to OTS needs; to design and carry out field monitoring studies to support chemical regulation and to identify potential problems; and to implement quality assurance procedures to ensure the integrity of scientific data under review. OTS' commitment in this area includes not only the refinement and development of these tools, but also their full integration into the OTS decisionmaking process.

- More effectively sharing information developed under TSCA and promoting technical exchanges with other agencies and the public. TSCA provides OTS unique ability to collect information on commercial chemicals and chemical risks, and it imposes a corresponding responsibility on OTS to share this information with other agencies and the public. OTS is committed to expanding its mechanisms for sharing data with other groups. These include agreements with other regulatory agencies allowing them access to TSCA confidential business information, to the extent this can be done under the Act; dissemination of non-confidential data through the National Technical Information Service and other mechanisms; technical exchanges at the state, regional, national, and international levels; and the use of Risk Management Advisories and Advisory Circulars to communicate data or the results of OTS analyses more promptly. In addition, OTS is committed, where appropriate, to using TSCA information-gathering authorities (such as §8(a)) to support other EPA program offices or other regulatory agencies. For example, OTS is exploring the possibility of updating the TSCA Inventory, in part because of the support it would would provide to the EPA Office of Solid Waste, the EPA regions, and other offices.

- More closely integrating the new and existing chemical programs. This includes referral to the existing chemicals program of categories of chemicals that have repeatedly proved of concern in the PMN program, and the use of §5(a)(2) significant new use rules on existing chemicals, bringing them under §5 authority. OTS is also working to ensure the ready access of both programs to the data, analyses, and analytical tools of each.

The remainder of this report discusses the status of OTS' programs, its general progress in implementing a coordinated TSCA program, and its specific progress in the initiatives described above.

CHAPTER II

NEW CHEMICALS PROGRAM

A. Introduction

In "Priorities for OTS Operation" (January 1982), OTS announced an integrated new chemicals program based on four major elements:

- Completion of the final premanufacture notice (PMN) rule, with a mandatory form for new chemical notices, specifying minimum information requirements needed for a preliminary review of the chemical.
- Priority placed on review of PMN's, with increased use of §5(e) to induce the development of data and to control exposure.
- Development of PMN exemptions under §5(h)(4) to reduce the notice review burden for low-risk chemicals.
- Establishment of a followup program through §5(a)(2) significant new use rules and §8(a) reporting rules to monitor the development of selected new chemicals of concern.

Since the preparation of the 1982 report, OTS has taken major steps toward implementing this program. These steps include the promulgation of a final PMN rule; the continued operation of an effective PMN review program, with a more aggressive approach toward requiring data on new chemicals and controlling exposure in cases of potential risk; the proposal of limited PMN exemptions for selected site-limited intermediates, low volume chemicals, and polymers; and the development of a new chemical followup process, with several significant new use rules proposed or under development. Together these steps implement the basic framework of the new chemical program outlined in the "Priorities" document.

Equally important, in its almost four years of new chemicals review, OTS has gained invaluable experience that has led to a more effective review of new chemicals, allowed the refinement of the current program, and indicated directions for further development. Recent experience has confirmed the basic observations on new chemicals review made in the "Priorities" document, while providing a clearer focus in certain areas. With the perspective of an additional year and a half of new chemicals review, the following observations can now be made:

- The number of new chemical notices submitted for review is increasing steadily and has now reached the rate of about 1,200 a year. The large number of PMN's received has necessitated not only a carefully coordinated review process, but also a reliable institutional memory.

- The review of new chemicals must be undertaken in an atmosphere of considerable uncertainty, even when a base set of toxicity data is available. Near certainty can only be attained from a wide range of acute and chronic tests for both health and environmental effects. Such testing is not practical for most new chemicals. For this reason, it has been necessary in PMN review for OTS to rely on structure-activity analyses as a screening tool to help in estimating potential for hazard, and to assume reasonable worst cases in assessing potential exposure.

- The amount of test data received on new chemicals has remained relatively constant and has generally focused on physical-chemical properties and acute toxic effects. While this may be appropriate in some cases, in others the lack of data complicates the Office's review. Lack of data on specific PMN chemicals has led to review suspensions, requests for the voluntary submission of additional data, withdrawn notices, and in some cases regulation under §5(e).

- Because of the wide variety of new chemicals received in the program, decisions on what data are appropriate on a given new chemical, for the most part, are best made on a case-by-case basis. Given the diversity of new chemicals, generic approaches to data development are less appropriate.

- OTS experience continues to indicate that a significant number of new chemicals now subject to PMN are of relatively low concern and do not warrant extensive testing at the time of PMN submission. Many of these chemicals can be eliminated early from PMN review. The proposed exemptions for certain site-limited intermediates, low volume chemicals, and polymers would allow the earlier commercialization of many of these chemicals with no increase in risk over the current approach.

- At an early stage in their life cycle, most new chemicals are particularly vulnerable to additional costs. Testing costs imposed at such a stage will impede chemical innovation to some extent. Therefore, OTS must impose

such costs prudently and take care to avoid impeding this innovation unduly. Also, in conducting its new chemicals program, OTS should attempt to channel innovation toward safer substitutes for existing hazards.

- At the time PMN's are reviewed, it is often difficult to know which new chemicals are likely to be commercial successes, and how circumstances of exposure might change. As a result, any successful new chemicals followup program must include a relatively broad-based followup requirement, as well as chemical-specific actions targeted at specific concerns.

As the remainder of this chapter discusses, these observations are reflected in OTS' current new chemicals program, and the lessons drawn from them have shaped its future directions.

B. Premanufacture Review Program

Since the beginning of the premanufacture review program, EPA has reviewed more than 2,300 new chemicals -- approximately 1,300 since the release of the "Priorities" document in January 1982. The effective review of these chemicals remains the first priority of the overall new chemical program. Consequently, OTS has devoted significant resources to refining the PMN review process, to developing appropriate analytical tools for new chemicals review, and to reviewing and if necessary regulating new chemicals.

1. PMN Rule

In the earlier "Priorities" document, OTS stated that it was moving ahead to issue a final premanufacture notice rule, clarifying the §5 new chemical notice requirements. EPA had published proposed rules in January and October 1979 and was operating the new chemicals program under an interim policy statement.

The final rule, together with a mandatory notice form, was issued in May 1983 (48 FR 21722). The rule reflects almost four years of OTS experience in PMN review and incorporates extensive comments from public interest groups and industry. It includes the following basic requirements:

- Information requirements for premanufacture notices (e.g., chemical identity; production volume; use; information on manufacture, processing, and disposal; available test data). These requirements, which follow the statutory requirements specified in TSCA §5(d)(1), provide enough information for an initial EPA screen of new chemicals.

- Use of a mandatory form by notice submitters. (An Instructions Manual has also been developed to assist submitters in completing the form.) By standardizing notice submissions, this form simplifies OTS' review, facilitates the entry of data into automated data bases, and promotes consistency in decisionmaking; it also provides a clear standard to industry concerning data requirements.

- Confidentiality procedures, including instructions on claiming information confidential and a requirement that companies provide "sanitized" versions of confidential submissions for inclusion in the public file. The confidentiality procedures, which ensure consistency in the handling of confidential business information, are designed to achieve a balance between public access to information and the protection of legitimate trade secrets.

- Specification of notice review procedures, including definition of "incomplete submissions," which fail to meet the basic statutory requirements and therefore are not considered PMN's.

- Submission of a Notice of Commencement of Manufacture by companies when they begin production of a substance that has completed PMN review. This requirement allows EPA to add new substances to the TSCA Inventory when production begins, establishing them as existing chemicals not subject to PMN review.

In addition, OTS is working to clarify key statutory terms, such as "research and development" chemicals, which are exempt from PMN review, and to provide guidance on other requirements, such as the level of detail that must be provided on test data submitted in PMN's.

OTS is also developing a rule under §8(a) that will require companies to notify it before they make a new chemical solely for export. Because export-only new chemicals are not covered by §5 prenotice requirements, this rule will fill a gap in PMN coverage.

Through these and other provisions, the PMN rule sets the basic framework of the new chemicals program, providing industry with clear standards for compliance, simplifying EPA's review of new chemicals, and contributing to the program's consistency. With this rule in place, OTS is now able to focus more of its resources on other aspects of the new chemicals program.

2. New Chemicals Review

In addition to issuing the PMN rule, which will standardize information submissions and notification procedures, OTS has focused and refined its new chemicals review process so that it can more effectively review the large number of notices now received. Important refinements that have been instituted or are now under development include process modifications to eliminate low concern chemicals from review early; the development of data bases to allow ready access to information; the preparation of generic assessments of recurring concerns in the PMN process; and the development and use of structure-activity-relationship (SAR) techniques to identify chemicals for further evaluation.

The major modification in the new chemicals review process is the establishment of a staged approach, reflecting the fact that a large number of new substances are of low concern not requiring in-depth review. In the earlier process, most substances were subjected to a standard 45-day "initial screen," which meant that considerable resources were committed to the review of low-concern chemicals. OTS now drops these substances from review after a preliminary review of chemical identity, available test data, use, and exposure factors. To identify such substances effectively, OTS has instituted an early decision meeting attended by senior OTS decisionmakers; as a result, up to 40% of substances are dropped from review by day 16 of the process. The meeting also serves to focus the further review of substances that are not dropped. This approach has allowed the Agency to use its resources more effectively and to concentrate them on chemicals of potentially greater concern.

OTS is also taking important steps to ensure that its accumulated experience in new chemicals review is brought to bear fully on each case. Because most "new substances" seen under TSCA belong to chemical or use categories that have been subject to past review, the retrieval of information from these reviews has been particularly important in the PMN program. Similarly, access to data received under other TSCA authorities or analyses performed by other OTS programs also contribute significantly to PMN review. As more PMNs are received, and as more data are submitted under §4, §5(e), §8, and other authorities, the Office's accumulated experience will become increasingly important in the review of PMN's, and the ability to call upon this experience readily will become essential in ensuring the consistency of OTS decisions. The following initiatives begun in the past year will contribute significantly to this goal:

- o Automation of data from previous reviews. OTS has developed an automated PMN file, to allow ready access to information from previous reviews. This data base, which is discussed more fully in Chapter IV, is now being

substantially upgraded to include summaries of past OTS reviews and the key findings of those reviews.

- Development of generic analyses of recurrent issues. OTS has conducted several "generic" analyses of technical issues arising repeatedly in PMN review, including studies addressing specific industry sectors, chemical categories, and similar topics. For example, the Agency has completed a study of technical issues raised in the review of certain dyes. These studies provide OTS staff with in-depth analyses that typically could not be performed in the statutory time frame for PMN review. Also, they have served as starting points for discussions with industry. The Agency has met with industry groups to discuss issues raised by several assessments and to encourage industry to provide data that could resolve Agency concerns. For example, certain azo dyes and certain lubricant additives known as ZDDP's are now under discussion with industry groups. Cooperation with industry and other groups on these broader issues may in some cases encourage data development more effectively than case-by-case requirements on PMN's.

- Development of data systems allowing ready access to data obtained in other OTS activities. OTS is developing various data bases allowing quick access to information submitted under TSCA or used in OTS analyses. These include SPHERE, which will allow on-line access to a wide range of physical-chemical properties, health and environmental effects, and other data; and a Global Indexing system for §8(d) submissions and other OTS documents.

- Development of a nonconfidential tracking system for the PMN program. OTS has developed a tracking system that provides the status of PMN's under review and the schedule for the reviews.

In addition, OTS is now refining its use of SAR techniques in evaluating the adequacy of data submitted in PMN's. These techniques (which involve the analysis of chemical structure for insight into physical-chemical properties and toxicity) are particularly important because of the variety and number of chemical substances received in the PMN program, as well as the limited amount of data generally received on new substances. At one extreme of the new chemicals seen in the program are substances that belong to chemical classes, or have structural features, that make them highly suspect toxicologically. At the other extreme are chemicals belonging to classes that are generally recognized as low in toxicity. No one level of testing would be appropriate for all of the chemicals falling within

these extremes. Determining the appropriate level of testing for a given chemical, and the nature of that testing, therefore, depends in part on an evaluation of chemical structure and analog data -- that is, on SAR analysis. This analysis is not a general replacement for testing; rather, SAR considerations, along with such exposure factors as manufacturing process, use, and production volume, is used to determine whether a new chemical has been adequately tested and, if not, what further tests would be appropriate.

SAR analysis occurs at several different levels during PMN review. First, OTS has organized and developed techniques to estimate certain physical-chemical properties critical to exposure assessment (e.g., vapor pressure, octanol-water partition coefficient, water solubility) from a chemical's structure. These techniques, which are discussed in Chapter IV, are routinely used in PMN review to supplement test data on the new chemical. Second, OTS relies primarily on the professional judgment of senior scientists to identify chemicals of possible health or environmental concern. These judgments are based on available test data, the chemical's structure, analog data, and similar factors. Examples of the kind of structural factors that might indicate a concern with a chemical are:

- The substance is structually analogous to a chemical of known concern or a member of a class of substances some members of which are known to exhibit toxic properties.
- The molecule has substituent groups that are often associated with a toxicological response of concern.
- The substance is likely to be transformed to metabolites that are structurally related to substances that have demonstrated effects of concern.
- The molecule has characteristics that may indicate potential toxicity, based on known mechanisms of action.

The review of such factors in the case of any given chemical requires considerable expertise and the knowledge of a wide range of toxicological data. The development of systems that allow OTS scientists ready access to a wide range of data will greatly enhance their ability to perform these reviews.

In the final analysis, the use of SAR in the review of new chemicals reflects the recognition that existing literature and past experience with chemical substances are powerful sources of insight into the potential toxicity of chemical substances and that such insight should be used to focus evaluation of new chemicals.

OTS has several projects underway to refine, expand, and validate its use of SAR in PMN reviews. These projects are discussed in Chapter IV.

3. Regulatory and Other Actions

In the earlier "Priorities" document, OTS indicated that it would rely increasingly on its §5 regulatory authorities and other mechanisms in conducting new chemicals review. The recent record of the PMN program demonstrates the Office's commitment to this policy. From the beginning of the PMN program in 1979 through June 1983, the Agency has issued nine §5(e) orders banning or controlling exposure to 20 chemicals, pending the development of additional data; four of these orders have been issued this year. In addition, eight to ten more orders are now being pursued and may be issued in the next two months, indicating a sharp increase in activity. Also, the notice review periods for 30 substances are currently under suspension to allow further OTS review or to give the submitter an opportunity to develop additional data. Further testing has been or is being performed for 29 substances.

This increased activity reflects in part the fact that the PMN review process, after several years of operation, is working smoothly and efficiently. With its experience in new chemicals review and regulation, OTS can now act more quickly to identify potential problems or gaps in data. More important, perhaps, the increased activity reflects several operating assumptions derived from the Office's recent experience in reviewing PMN's:

- Section 5(e) orders banning or limiting production are appropriate when the toxicity of a new chemical substance is not well characterized and exposure is likely to be relatively high, or when the potential adverse effects are likely to be serious, even if exposure is likely to be relatively low.

- The Office originally focused most of its attention on carcinogenicity, mutagenicity, and teratogenicity. Without reducing its attention to these effects, it now considers action under §5(e) because of other potential effects. One recent §5(e) order, for example, prohibited the use of two new chemicals in consumer products until it was tested for eye irritation at likely concentrations in consumer products. In PMN review, OTS is also placing increased emphasis on neurotoxicity, reproductive toxicity, and other effects.

- OTS now issues §5(e) orders to ensure that submitters maintain exposure controls that they adopted voluntarily, either on their own initiative or as a result of negotiation with OTS during the PMN review period. Unless a §5(e) order is issued in these circumstances or other regulatory action is taken, the manufacturer would not be required to maintain these controls. Because these controls are part of a §5(e) order, they are monitored by EPA's enforcement office.

- OTS increasingly empnasizes "significant or substantial exposure" and "significant release" in deciding to take §5(e) action. Where these standards are met, and where health and environmental effects data are insufficient for a reasoned evaluation, EPA can act to control a new chemical, pending the development of data, even in the absence of affirmative evidence of potential risk. EPA recently issued a §5(e) order controlling the manufacture of new shale oil products under this standard.

To put these principles into practice, OTS has adopted a more flexible approach to §5 regulation. Two developments -- voluntary notice suspensions pending the development of data and the negotiation of consent orders under §5(e) -- have proved particularly fruitful.

First, OTS frequently encourages companies to suspend notice review periods voluntarily when it has identified data gaps, so that the companies can develop additional data to meet its concerns. OTS has found that companies are often willing to suspend the review period in these cases if data gaps are identified early in PMN review. This is especially true in the case of data that can be developed promptly -- such as data from acute health effects tests, in vitro carcinogenicity screens, and aquatic toxicity tests. If the company is informed of data gaps early, it can complete the tests and submit the results for OTS review without major delays in commercialization (assuming the tests confirm the chemical's safety). Consequently, OTS has taken procedural steps to ensure that senior decisionmakers confirm data needs early in PMN review and that these needs are promptly communicated to notice submitters.

In one case, for example, OTS was concerned that an imported, fiber-reactive dye for cotton fabrics was potentially carcinogenic. Concern focused on exposure to workers involved in dyeing operations in textile mills and releases to drinking water during the dyeing. Because of the nature of the new chemical and data on existing analogs, OTS concluded that short-term screening tests would provide a reasonable indication of carcinogenic potential. At OTS' request, the manufacturer suspended the

review period and conducted carcinogenicity screening tests on the dye molecule and a hydrolysis product, to which the PMN substance might be converted in drinking water. In both cases, the tests proved negative. The notice review period has now recommenced; after its expiration the submitter will be free to import the dye.

Second, OTS has found that negotiated §5(e) orders are the most appropriate mechanisms for developing limited §5(e) orders, which allow controlled production of the new chemical. OTS' first §5(e) orders were unilateral actions, banning the manufacture of the new chemical pending the development of data. In each of these cases, the manufacturer chose to forgo production of the chemical rather than to conduct the tests necessary for EPA to lift or modify the order. While OTS remains committed to taking such actions when necessary, it also recognizes that restricted production of a new chemical may be appropriate, pending the development of data necessary to evaluate uncontrolled uses. In these cases, §5(e) orders are often best developed through negotiation with the submitter, leading to a binding consent order. In many cases, the notice review period is suspended, allowing for a more reasoned pace in developing the order.

An example of this approach is the §5(e) consent order OTS recently negotiated with a major shale oil developer, who will soon be producing this country's first commercial shale-derived petroleum substitutes. This order, which was based on an extensive OTS review of analytical and health and environmental effects data provided by the developer, requires worker exposure and waste disposal controls during production of the synthetic crude oil. It also requires the developer to provide OTS the results of ongoing environmental and chronic health effects tests, and it reserves for OTS the right to regulate the production or use of the synthetic crude oil further under its §5 authorities if the results of the tests raise concerns. In addition, to add ess potential problems identified during PMN review, the shale oil developer, the state of Colorado, EPA's regional office, and EPA's Office of Research and Development reached an agreement that ensures EPA participation in Colorado's review of the developer's research and environmental monitoring plans. This negotiated consent order illustrates the flexibility of §5 in addressing complex technical and regulatory issues, its unique authority for ensuring the development of data on new chemicals (and in this case, new industries), and OTS' commitment -- discussed more fully in Chapters III and V of this report -- to coordinate its work with other offices and regulatory agencies.

At the same time, OTS is exploring ways in which it can more effectively communicate the technical rationale for its decisions on new chemicals. To the extent that OTS can articulate its decisions and concerns, it can provide the chemical industry with important insight into how the Agency has dealt with specific issues, and it can promote greater public oversight of its new chemical reviews.

Toward this end, OTS is developing a new chemicals Advisory Circular system. The Office will periodically publish circulars summarizing actions on specific categories of new chemicals or describing specific decisions. For example, for certain categories of new chemicals, OTS has generally imposed controls pending completion of short-term carcinogenicity screens, if such tests had not already been conducted. By stating this fact in an Advisory Circular, the Agency will provide greater certainty on its standards for action; this would be particularly useful for companies submitting notices on chemicals within these categories.

OTS will also use Advisory Circulars to announce decisions or legal interpretations related to new chemicals review. In response to specific requests, OTS frequently reaches decisions on such questions as the applicability of PMN requirements to certain substances, the line between research and development (R&D) and non-R&D commercial activities, and the kind of data appropriate for a test-marketing exemption application. These decisions, however, are generally communicated only to the company making the inquiry. By announcing such decisions in Advisory Circulars and explaining their implications, OTS will provide important guidance to the public, and it will contribute significantly to more consistent §5 submissions and a broader awareness of the new chemicals program.

C. PMN Exemptions

As explained earlier, OTS' PMN experience indicates that many new chemicals are of relatively low concern, either because of low exposure or low toxicity. Review of these substances is often completed before the 90-day PMN period has ended. As a result, OTS believes it is appropriate to exempt certain categories of low risk chemicals from full 90-day PMN review, reducing the reporting burden and allowing earlier commercialization. Such relief should significantly promote new chemical innovation without increasing risks to health and the environment.

EPA took a major step toward a broad exemption policy in August 1982, when it proposed limited PMN exemptions for certain

site-limited intermediates, low volume chemicals, and polymers -- categories of chemicals that have generally been of low concern in the PMN process. The proposals would establish the basic framework of OTS' exemptions program, as outlined in the January 1982 "Priorities" document. Exempt chemicals would generally undergo a shortened review and would be subject to reduced information requirements. Because of the diversity of chemicals that could be produced under the exemption, however, EPA included a series of safeguards in the rules. For example, certain types of polymers would be automatically excluded from the polymer exemption, and low volume chemicals and site-limited intermediates (produced at more than 1,000 kg/yr) would undergo review by an industry "qualified expert" and would be automatically excluded from the exemption if they were possible carcinogens or teratogens.

EPA is now developing final rules based on these proposals In developing these rules, the Agency is considering technical and policy comments from industry and public interest groups, as well as it own impact analyses and risk assessments. OTS estimates that 36-49% of new chemicals would be potentially eligible for at least one of these exemptions, assuming the final rules follow the basic framework of the proposal. Because of the restrictions built into the exemptions, however, many manufacturers of potentially exempt chemicals may choose to submit PMNs instead.

By reducing notice requirements for certain low volume chemicals, site-limited intermediates, and polymers, these exemptions would provide important relief for a broad range of new chemicals. In the future, OTS expects exemption requests for chemicals that would not be eligible for the proposed exemptions, or for which the exemption applicant is requesting greater relief. The Office anticipates that these exemption requests will be for narrowly focused categories of chemicals -- defined either in terms of exposure or chemical class. Depending on the category, the exemption might be from all PMN requirements, from certain information requirements, from the full 90-day review period, or from other PMN requirements. Because the applicants would be requesting greater relief than that provided in the basic exemption framework proposed by EPA, OTS will place the primary burden of defining and justifying the exemption on the applicant. It will be up to the applicant to:

- Specifically define the exemption category.
- Provide the necessary supporting data on toxicity, exposure, and other factors.

- Make the case, based on a risk assessment, that the exempt chemicals will not present an unreasonable risk.

OTS, of course, has the final responsibility for identifying the category, defining the terms of the exemption, and making the finding of no unreasonable risk. However, it must be the responsibility of the exemption applicant to perform the basic work necessary to support an exemption.

In addition to issuing PMN exemptions under §5(h)(4), OTS grants test-marketing exemptions under §5(h)(1). To grant a test-marketing exemption, OTS must find that the substance will not present an unreasonable risk to human health or the environment under test-marketing conditions. Exemptions must be granted or denied in 45 days. OTS now places the burden on the exemption applicant to provide sufficient information for the Office to make the "no unreasonable risk" finding. Where the information is insufficient, OTS will deny the exemption. In a forthcoming Advisory Circular, OTS will specify the kinds of information that are necessary. OTS also carefully scrutinizes test-marketing exemption applications submitted at the same time as PMN's on the same chemical. Unless the applicant company can clearly demonstrate that its test-marketing activities are legitimately distinguished from subsequent commercialization and that it is not simply shortening the PMN review period by 45 days, these applications will be denied.

D. New Chemicals Followup

In the January 1982 "Priorities" document, OTS announced its commitment to developing an effective new chemicals followup program. The rationale for the program remains valid: OTS' review of new chemicals at the premanufacture stage generally focuses on intended methods of manufacture and use described in the PMN, and it is based on toxicity and exposure data that the manufacturer has developed before commercialization. After a chemical has been entered on the TSCA Inventory, however, unrestricted commercialization is possible without further data development or EPA review. For this reason, a credible followup program is an essential element of OTS' new chemicals program.

Since the 1982 "Priorities" document, OTS has begun to implement its followup program. New chemicals review now includes a process for identifying followup candidates; a new chemical SNUR has been proposed; and several other case-specific followup rules are undergoing internal EPA review. OTS anticipates that six new chemical SNUR's and one followup §8(a) rule will be proposed by the end of FY83 and that in the future approximately 10 followup rules will be issued a year.

In conducting this program, OTS has developed several general principles, which are now guiding its followup activities:

- The major advantage of SNUR's is that OTS has the full range of §5 authorities to regulate or require data on a substance when a SNUR notice is received. They are an appropriate followup mechanism where concerns are focused on specific health effects and OTS has been able to identify possible new uses or growth in the marketplace likely to increase risk.

- SNUR's are frequently necessary in connection with §5(e) orders, because the order applies only to the notice submitter. The order can in effect be extended through a SNUR to other manufacturers and to processors, who otherwise could make or process the chemical without any restrictions. As a result, OTS has adopted a policy of issuing SNUR's together with §5(e) orders. The triggers for reporting under the SNUR generally follow the terms of the §5(e) order.*

- Where concerns are not focused, or where it is less clear what the next step should be when followup data are received, §8(a) rules are generally more appropriate for followup than are SNUR's.

OTS identifies candidates for followup action on the basis of toxicity concerns and possible changes in exposure that could lead to increased risk. Such changes in exposure include a wide range of situations. Several examples are:

- Change from industrial to consumer use. For example, one proposed SNUR would require notification of EPA before two PMN chemicals, which are intended for use in industrial cleaners, are manufactured or processed for consumer use. The chemicals are known to be eye irritants, and they have a clear potential for use in consumer products. However, they have not been tested for eye irritation in consumer strength formulations.

*OTS is also exploring the possibility of a "me-too" SNUR that would automatically subject all §5(e) chemicals to SNUR requirements. This possible approach is discussed in the Addendum.

- o Change in circumstances of use. A SNUR now under internal EPA review would require notice before a specific PMN chemical was used in metalworking fluids. OTS is concerned about possible nitrosamine formation (and therefore carcinogenicity) if the PMN chemical is used in metalworking fluids together with nitrosating agents.

- o Change in formulation, such as change from liquid to powder form. Another SNUR under development would require notice before a specific PMN chemical was manufactured or processed for use in powder form. OTS is concerned that the chemical, which is a dye intermediate intended for use as a wet solid, might have carcinogenic potential if inhaled or ingested. Manufacture or processing of the intermediate as a powder would significantly increase the possibility of inhalation exposure.

OTS' case-by-case approach to followup -- which is driven by identifiable toxicity concerns and is generally focused on specific new uses -- allows the Office to concentrate on circumstances of legitimate concern without imposing broad or burdensome reporting requirements on a wide range of chemicals. The considerable resources needed to implement case-by-case new chemical followup makes it difficult to develop more than a relatively few followup rules a year (compared to the total number of PMN's). However, because new chemicals tend to be specialized and have limited potential for new uses, OTS believes that its current projection of 10 case-by-case followup actions a year (primarily significant new use rules) represents an appropriate level of effort. At the same time, given the inevitable uncertainties built into new chemicals review, OTS may miss possible concerns that could develop as a result of the commercialization of specific new chemicals. As a result, OTS intends to supplement its current case-by-case followup program with a broader approach.

To establish this broad-based program, OTS intends to issue a general §8(a) rule requiring companies to submit followup reports on new chemicals when the chemicals reach a given annual production volume. The report would contain limited information on production, exposure, and potential risk, such as estimated future production volume, uses, and available health and environmental effects data. Under one approach -- suggested originally by the Chemical Manufacturers Association* --

*CMA suggested this approach in its comments on the proposed PMN rules and its 1981 report First Four Years of the Toxic Substances Control Act. An alternative approach would be to require automatic followup reporting only on selected categories of new chemicals.

reporting would be required for all new chemicals at the same production volume (e.g., 50,000 kilograms a year), regardless of the category of chemical. Alternatively, OTS is considering an approach in which the production volume trigger would vary depending on the chemical category. For example, the volume trigger might be lower for typically low volume chemicals, such as photographic chemicals or fragrances, and higher for typically high volume chemicals, such as lubricant additives and surfactants. This approach would provide greater flexibility, and it takes more direct advantage of OTS' experience in the PMN program.

Under either alternative, the §8(a) followup rule would provide an important supplement to the current new chemicals followup program. OTS would be able to track new chemicals as they developed commercially, and, in cases of concern, it would be able to take steps to require data development or to regulate specific chemicals before they were well established in the marketplace. This would provide a general safety net, allowing OTS to address potential new chemical concerns that were not anticipated during PMN review. At the same time, OTS would set the production volume triggers at a level at which the new chemicals could support the costs of notification. Therefore, the rule would impose little burden on industry. The impact of the rule would be further limited because many new chemicals fail commercially and relatively few would reach the production volume trigger.*

The general §8(a) followup rule would also allow OTS to evaluate submitter estimates in PMN's and OTS' own conclusions during PMN review concerning likely production volume, future uses, health and environmental effects, and similar questions. The ability to conduct such an evaluation will lead directly to a more effective new chemicals program.

*OTS now receives Commencement of Manufacture Notices on approximately 55% of new chemicals within 2-3 years of PMN submission. As a result, OTS believes that a significant proportion of new chemicals do not enter commerce.

CHAPTER III -- EXISTING CHEMICALS PROGRAM

A. Introduction

Since publishing the January 1982 "Priorities" document, OTS has developed an integrated existing chemicals program, capable both of identifying potential problems and of bringing them to resolution. This program is now firmly established, with several initiatives underway and a clear direction for the future.

In developing this program, OTS has faced the same practical and technical difficulties that have hindered existing chemicals regulation under TSCA in the past. The most important of these are described below.

- Over 60,000 commercial chemical substances are potentially subject to TSCA regulation. Many are known to be hazards, potentially warranting some degree of control, while the risks of others are poorly characterized. At the same time, new health and environmental effects data are continually being developed on commercial chemicals by government, industry, and universities. The task of identifying priority candidates for data development and regulation from this great number of chemicals could be never-ending.

- Technical issues raised during existing chemical regulation can be extraordinarily complex. These issues include the assessment of risk, the identification and evaluation of appropriate control options, the identification of substitutes, and the analysis of the economic impact of possible controls (or of failure to control). Consequently, rulemakings on existing chemicals are often extremely complex and must be supported by extensive technical analysis.

- Because society frequently has a stake in the production and use of existing chemicals -- expressed in profits to industry, jobs for workers, and benefits to customers -- regulatory controls on existing chemicals often have considerable economic and social impact. Frequently, the more serious the problem (e.g., because of widespread use and exposure), the greater the impact of regulation.

- There is considerable overlap between OTS' authority to regulate existing chemicals under TSCA and the authorities of other federal and state agencies. Most identifiable chemical hazards potentially addressed under TSCA fall at least partially under other authorities as well. As a result, it is often difficult to identify the proper role for TSCA.

Despite these difficulties, TSCA nevertheless gives EPA the responsibility to address a broad spectrum of chemical risks, both to humans and the environment, and it provides EPA with an opportunity to take the initiative in existing chemicals control.

- o TSCA gives EPA authority, unique among regulatory agencies, to gather existing data on chemical risks and to require the chemical industry to test substances of concern. No other regulatory agency, for example, can require manufacturers to test general commercial chemicals for a full range of human health and environmental effects.

- o TSCA gives EPA unique flexibility in addressing chemical risks. Not only does the Act provide a wide variety of regulatory mechanisms; it gives EPA the authority to address all phases of a chemical's lifecycle (e.g., manufacture, processing, distribution, use, and disposal). Other authorities typically address specific categories of chemicals, specific media (such as air or water), or specific circumstances of exposure (such as occupational risks).

- o The authorities listed above, the coordination provisions of §9, and the data-sharing provisions of §10 give EPA a central role among federal agencies in coordinating approaches to the assessment and control of commercial chemicals.

OTS' current chemical control program aims at a reasoned and flexible exercise of these authorities, adjusted to the realities of existing chemicals. The major principles underlying this program flow directly from the points listed above, as well as from several years of experience in existing chemicals review.

- o Broad-based priority-setting exercises, designed to identify the "best" candidates for regulation out of the universe of existing chemicals, can be counterproductive if they divert resources away from clearly identified problems.* Candidates for OTS action should be identified primarily through basic TSCA mechanisms, such as §4 rules, §8(e) notices, §21 petitions, and PMN review. In

*Priority setting exercises have an important role in identifying substances for testing and in assigning resources to existing chemical problems identified through TSCA mechanisms. This activity is discussed in Chapter IV.

addition, monitoring data are important in identifying high-exposure chemicals as potential candidates for regulation.

- Any effective existing chemicals program must be committed to resolving problems, not simply to identifying and evaluating them. An appropriate response to a problem might not always mean regulation; it could involve nonregulatory approaches to risk reduction, referral to another authority, or dropping from review. However, a credible existing chemicals program cannot allow chemicals to remain under active review indefinitely.

- In considering action under TSCA, OTS must be flexible and creative. Because the level of OTS concerns, the nature of the evidence, and the impact of controls will vary, actions will vary as well. They could range from immediate control of imminent hazards under §7 or regulatory action under §6 to circulars advising industry and the public of potential risks. They might also include joint action with other authorities.

- The program should address manageable risks; apparently intractable problems should be addressed in smaller segments. Rather than attempting to develop comprehensive analyses of all the possible risks from a specific chemical, OTS first should focus more narrowly on particular effects and exposures of concern.

- Because of the coordinating role assigned to EPA by TSCA and because of OTS' responsibility to seek resolution of problems identified through TSCA mechanisms, OTS should promote cooperation with other regulatory agencies and other parts of EPA. Where appropriate, OTS and other agencies should take joint action to characterize or control particular hazards.

Together, these principles define the basic objectives of the current existing chemicals program: (1) to identify potential risks through TSCA mechanisms; (2) to ensure the development of data adequate to assess those risks; (3) to ensure that these risks are addressed under the appropriate regulatory authority; and (4) where that authority is TSCA, to ensure that appropriate action is taken. OTS' approach to achieving these objectives, both now and in the near future, is discussed in the sections below.

B. Existing Chemicals Regulation

1. Identification of Regulatory Candidates

One of the major problems with the existing chemicals program in the early years of TSCA was the absence of a coordinated process for identifying and characterizing potential risks, selecting those that warranted OTS control, and bringing specific issues to resolution. There was no Office-wide system for selecting candidates for review, and specific chemicals often underwent long-term assessment with no regulatory (or nonregulatory) outcome in sight.

OTS addressed these issues in an October 1982 report supplementing the 1982 "Priorities" document. In this report, OTS laid out principles for selecting regulatory candidates: attention goes to chemicals or categories of chemicals (1) on which test data have been received under §4; (2) which are the subject of §8(e) substantial risk notices; (3) on which test data have been received from such sources as the National Toxicology Program or §21 petitions; or (4) which have consistently raised concerns during PMN review. The report also recommended the establishment of a task force to implement a process not only for selecting chemicals for action, but also for initiating action.

In response to these recommendations, OTS established an Existing Chemicals Task Force in the fall of 1982. The Task Force to date has conducted (or is now conducting) reviews of 60 substances, identified through the mechanisms above. About one-fourth of these substances have been dropped from active review (e.g., because data needed for a full assessment are currently under development, because other authorities are addressing the risks, or because risks do not warrant control); at the same time, about two-thirds are targeted for further analysis and preliminary decisions within twelve months. Five have already moved into regulatory development. Recent regulatory actions emerging from this process include an Advance Notice of Proposed Rulemaking (ANPR) for MBOCA (4,4'-methylenebis (2-chlorobenzeneamine)) and a §4(f) "significant risk" designation for MDA (4,4'-methylene dianiline). Within the next six months, OTS anticipates three to five additional actions.

2. Existing Chemical Control

The scope of OTS's chemical control program and the nature of control options now under consideration are best illustrated by examples of current activities:

- OTS has recently issued an ANPR on MBOCA, a curing agent used in plastics which has been shown to be carcinogenic in several species of animals. Although the chemical is not now manufactured in the United States, two firms are considering domestic manufacture, and it is imported at 1-3.5 million pounds per year. The primary risks from MBOCA appear to be to plastics formulators, generally working in small establishments exempt from Occupational Safety and Health Administration (OSHA) inspections. There is no OSHA standard for this chemical, and no other federal authority is directly addressing these risks. As a result, after consulting with OSHA, EPA has issued an ANPR suggesting a range of regulatory options, including a ban of certain uses of MBOCA. The ANPR also asks the public to provide information and recommend alternative approaches. The reason for OTS action on this chemical, which is primarily a workplace concern, is TSCA's unique authority and the absence of current OSHA activities.

- OTS has designated MDA for priority review under §4(f) and is considering the possibility of joint regulatory action with OSHA. MDA, a high-production volume chemical used primarily as an intermediate, was designated for §4 testing consideration by the Interagency Testing Committee (ITC).* The ITC expressed concern for a range of potential effects. However, a recent test conducted by the National Toxicology Program already indicates serious carcinogenic potential; therefore, OTS has initiated priority review of the chemical under §4(f).** Because MDA risks are primarily a workplace issue, OTS is coordinating its action with OSHA. Depending on the nature of subsequent activity (for example, if the best alternative is to set workplace exposure levels), it may be appropriate for OSHA to take the lead. In any case, the §4(f) mechanism has been critical in ensuring prompt regulatory attention to this potential hazard.

*The role of the TSCA Interagency Testing Committee in designating candidates for §4 testing consideration is discussed in the next section of this report.

**Section 4(f) requires that, upon receipt of data indicating that there may be a reasonable basis to conclude that a chemical substance presents or will present a significant risk of serious or widespread harm to humans from cancer, gene mutations, or both defects, the Administrator shall within 180 days, initiate appropriate aciton under §§5, 6 or 7 to prevent or reduce the risk, or publish a finding in the Federal Register that the risk is not unreasonable.

- Asbestos has been the subject of OTS activities since the early years of the program. Recently, however, OTS has taken important steps toward consolidating its efforts toward asbestos and ensuring a coordinated approach by the various regulatory authorities concerned with this material. These steps include:

  - Issuing a final §6 rule (in May 1982) requiring inspection of public and private elementary and secondary schools for friable asbestos-containing materials. The compliance date for this rule was June 1983. EPA Regional Offices are providing technical assistance to school districts in conducting inspections. In July 1983, OTS will begin a survey of local education agencies responsible for compliance to determine the rule's effectiveness.

  - Publication, together with the Consumer Product Safety Commission (CPSC), of an Asbestos in Homes Booklet, providing guidance for detecting and dealing with asbestos in homes. This and similar efforts at public outreach are discussed in Chapter V of this report.

  - The establishment of an interagency Federal Asbestos Task Force to coordinate federal efforts concerning asbestos. The Task Force, which was established last year, is chaired by OTS, and includes representatives from OSHA and CPSC. During the next year, OTS will be working with the Task Force to coordinate asbestos control.

  - To support the Federal Asbestos Task Force, OTS issued in July 1982 a §8(a) reporting rule requiring information on major aspects of asbestos manufacturing, processing, and disposal. This information is now coming into the Agency; both CPSC and OSHA have received TSCA confidential business information clearance and have access to information appropriate to their authority. In addition, summaries of the information will be available to the public.*

  In connection with these activities, OTS is now developing an overall regulatory strategy for asbestos, which will identify specific asbestos uses for possible regulatory action or other controls. This strategy will be completed by the summer of 1983.

*Information-sharing and the problems of confidential business information are discussed in Chapter V.

- In 1979, OTS issued rules implementing the TSCA §6 provision banning polychlorinated biphenyls (PCB's). In October 1980, the U.S. Court of Appeals for the District of Columbia ordered EPA to revise two aspects of these rules: one defined electrical uses of PCB's as "totally enclosed," excluding them from the ban; the other excluded from regulation PCB's incidentally generated at 50 ppm or less. In response to the court decision, OTS has issued during the past year a rule governing the use of PCB's in electrical equipment and a rule addressing one aspect of the 50 ppm issue -- under this rule, processes that can be characterized as closed and controlled waste manufacturing processes have been excluded from the 1979 ban. OTS is now developing a rule addressing the remaining issues raised by the 50 ppm regulatory cutoff. The Agency recently received a proposed approach for dealing with these issues, prepared jointly by the Chemical Manufacturers Association, the Natural Resources Defense Council, and the Environmental Defense Fund. A proposed rule is scheduled for December 1983.

- Chlorinated naphthalenes and chlorinated terphenyl, organic chemicals with a wide range of potential uses, were designated for §4 testing consideration by the ITC because of possible carcinogenicity and other concerns. However, the use of chlorinated naphthalenes has declined to low levels, while chlorinated terphenyl is no longer used in the United states. As a result, OTS concluded that test rules were not justified at this point. But, to ensure against renewed production or expansion of use without adequate data, the Office is proposing to monitor these chemicals through followup rules. Chlorinated napthalenes, which are now imported and used in relatively small amounts, are the subject of a proposed SNUR; chlorinated terphenyl, which is not now produced or imported, is the subject of a proposed §8(a) reporting rule.

These examples of ongoing activities illustrate the flexibility TSCA provides OTS in choosing among regulatory options. The full range of options now considered by OTS and the advantages of each are summarized more directly below:

- Section 6 regulatory action. As illustrated by OTS asbestos activities, this authority provides the Agency considerable flexibility. In the future, OTS will use §6 more effectively by moving promptly to publish ANPR's, as it did in the case of MBOCA. The Office will issue ANPR's when data indicate that regulation may be needed to reduce

a potential unreasonable risk, but before the details of the regulatory approach have been worked out. Earlier publication of ANPR's will alert the public to a potential concern, encourage public participation, and speed up the rulemaking process.

- o Section 4(f). Section §4(f) is designed to compel EPA's priority attention to situations of significant risk of "serious or wide spread harm." For this reason, OTS believes that the threshold for action under this section is higher than simply a potential for "unreasonable risk." A §4(f) situation should be one that is an especially serious one, because of either the number of persons potentially at risk or the likelihood of injury. MDA was designated for priority review under §4(f) in major part because of its carcinogenic potential and the lack of any workplace regulations.

- o Information gathering under §8 or control under §5(a)(2). Section 8(a) reporting requirements and §5(a)(2) significant new use rules are generally most appropriate for existing chemicals when they are used to complement broader regulatory activities, such as OTS' test rules program and its investigations of asbestos, or to monitor the development of potential risks -- such as chlorinated naphthalenes or chlorinated terphenyl -- that do not warrant immediate action. These sections provide OTS flexible information-gathering and regulatory authorities that are an important complement to its other authorities. Section 8(a) is useful for more general information gathering or to provide data in support of specific regulatory actions, while §5(a)(2) allows EPA to prevent increases in exposure to chemicals of concern before necessary data can be developed.

- o Referral to other agencies. Many potential risks identified through TSCA may be more effectively controlled by other agencies. OTS will defer to these agencies and offices when their statutory authority is sufficient to control the risks adequately and when they are actively addressing the risks. (However, as explained above, OTS intends to act jointly with other agencies when TSCA's regulatory authority uniquely protects against risks).

- o Voluntary approaches. The 1982 "Priorities" document gave high priority to voluntary approaches to existing chemical control. While OTS continues to believe that voluntary actions are useful in specific circumstances, it has not yet found it appropriate to negotiate "voluntary controls" with a specific company or trade organization.

- Risk Management Advisories. In one area, OTS sees considerable promise in a "voluntary" approach: the Office will be publishing Risk Management Advisories focused on specific problems associated with specific substances. These Advisories will describe toxic effects of concern, routes of exposure, and alternative methods of reducing risks; they will be published after consultation with interested parties, which could include industry, public interest groups, or other agencies. Risk Management Advisories, OTS anticipates, will be an important nonregulatory endpoint of the existing chemicals process; they will be particularly useful where an increased awareness of risk is likely to lead to meaningful precautions. Risk Management Advisories will not be a substitute for rulemaking; in fact, they may in certain cases be issued in connection with rulemaking activities -- for example, together with an ANPR -- in order to alert industry and the public as soon as possible to potential risks.

In the coming year, OTS will assign high priority to reviewing chemicals identified by TSCA mechanisms under the existing chemicals process and, where appropriate, will promptly initiate action under the regulatory options discussed above. As noted earlier, one of the most important triggers for action will be data received under §4 test rules. Within the next few years, significant amounts of these data will become available.

C. Section 4 Testing Program

Section 4(a) of TSCA authorizes EPA to issue rules requiring chemical manufacturers or processors to test specific chemicals, categories of chemicals, or mixtures for potential health and environmental effects. To require testing, EPA must find that (1) the substance may present an unreasonable risk of injury to health or the environment, or it is or will be produced in substantial quantities and there is or may be substantial environmental release or significant or substantial human exposure; (2) data and experience are insufficient to determine the potential effects of the manufacture, processing, distribution, use, or disposal of the substance; and (3) testing is necessary to develop data concerning these potential effects.

TSCA also establishes a priority-setting mechanism to ensure that potential hazards are addressed expeditiously under this authority. Section 4(e) sets up an Interagency Testing Committee (ITC), composed of representatives from the major federal agencies concerned with health and the environment. This committee recommends substances to EPA for priority consideration

for testing under §4(a). The ITC may also "designate" priority chemicals -- not to exceed 50 at any one time. EPA must respond within 12 months to a chemical's designation, either by initiating rulemaking under §4 or by publishing in the Federal Register its reasons for not initiating a rulemaking.

Through its twelfth report, issued in May 1983, the ITC has designated 69 individual chemicals or categories of chemicals for testing consideration.* Two additional categories have been recommended without designation for response within 12 months. EPA's testing program initially got off to a slow start, as the Agency failed to meet three statutory deadlines with responses that the court considered to be legally sufficient. This lack of action led to a lawsuit in 1979, which resulted in a court schedule for Agency responses to the 37 backlogged ITC designations.

Since imposition of the court-ordered schedule in 1981, the main priority of OTS' testing program has been to eliminate the backlog within the court-ordered time periods and to respond to additional ITC designations within the one-year statutory deadline. As a result, OTS has complied with the statutory deadline for all new ITC designations, and has responded to the required number of backlogged designations in 1981 and 1982. The Office anticipates eliminating the backlog by December 31, 1983, as required by the court. In total, by the end of 1983, OTS will have responded to recommendations on 63 designated chemicals or chemical categories and one nondesignated category.

In responding to ITC designations, OTS places considerable importance on developing needed test data rapidly, so that potential risks can be identified as soon as possible. As a result, where appropriate, the Office will accept negotiated testing programs submitted by manufacturers or industrial consortia, rather than proposing test rules to obtain these data. This is often in industry's interest as well as EPA's because, according to industry, ITC designations can place chemicals at a competitive disadvantage. Therefore, industry has an incentive to complete testing and to clear up any uncertainties as soon as possible. EPA believes that negotiated testing programs are in the public interest and are preferable to rulemaking where they will provide the needed test data substantially sooner than could be accomplished through rulemaking.

*One category, alkyltin compounds, was withdrawn by the ITC.

Generally, as much information is produced under negotiated agreements as would be required in a test rule. Furthermore, negotiated agreements provide greater flexibility than test rules, particularly in facilitating tiered testing. In a rule, tiered testing is feasible only where automatic triggers for followup testing can be defined ahead of time -- as in the case of mutagenicity testing. Tiered schemes that rely on judgment often do not lend themselves to test rules, because criteria for further testing cannot be readily written into the rule language. Consequently, it is necessary in these circumstances to require the full range of testing in the initial rule. Negotiated agreements, however, are flexible enough to allow tiered schemes that depend on judgment by providing for interim review of data and staged decision points.

Negotiated test agreements with industry have been criticized by some public interest groups as unenforceable and as excluding outside parties from EPA's decisionmaking process. While OTS agrees that negotiated agreements are legally unenforceable, the Office believes these agreements are generally entered into in good faith. Furthermore, the threat of rulemaking under §4 will ensure that the chemical industry adheres to its agreements. OTS will learn of departures from the agreements, because tests conducted under negotiated agreements, as well as tests conducted under §4 rules, will be monitored through OTS' laboratory audits, and because periodic reports are required in the negotiated agreements.* If the Office has reason to believe that industry has not acted in good faith, it will promptly initiate §4 rulemaking.

OTS also takes steps to ensure an adequate opportunity for public participation in negotiated testing agreements. There is an opportunity for written comment, and two public meetings are held on each ITC chemical before OTS develops a response to the ITC recommendation. Furthermore, if a negotiated approach is chosen, public interest groups are given an opportunity for updates and discussions on the status of negotiations. As a result of these procedures, outside groups actually have a greater opportunity to participate in the Agency's decisionmaking in negotiated agreements then they do in rulemaking.

Overall, negotiated test agreements have achieved their major purpose -- to speed up the development of data on ITC chemicals. OTS estimated earlier that on average 1 to 1.5 years may be saved through negotiation. This is proving to be the

*The laboratory audit program is discussed in Chapter IV.

case. In 1982, the Office received 95 testing studies from negotiated agreements; under test rules, these studies probably would not have been completed until 1984. OTS anticipates that another 195 studies will be received by the end of 1983 and 250 in 1984, all from negotiated agreements. Where they indicate adverse effects, these data will be used by the existing chemicals program to determine the need for additional data or regulatory action.

OTS, however, has also found that certain chemicals are not appropriate for negotiation. For example, where there are numerous manufacturers of a chemical, testing needs are extensive, or complex issues prevent agreement, rulemaking is often necessary. In responding to the original court schedule for addressing the backlog, OTS first picked those chemicals that could be most rapidly addressed. Many of these lent themselves to negotiation; however, many of the remaining chemicals do not. Therefore, the percentage of chemicals on the backlog list that go into rulemaking is likely to increase significantly. In 1982, OTS proposed one test rule, negotiated ten testing agreements, and decided that testing was not required on eight chemicals or chemical categories. In the first half of 1983, OTS has negotiated testing agreements for one ITC chemical, proposed test rules for six chemicals or chemical categories, and decided that further testing is not required on one chemical.

As the backlog of ITC chemicals is eliminated, OTS will develop test rules on substances not designated by the ITC. For example, these might include substances shown to have significant human exposure by OTS' monitoring activities or classes of substances identified as potential concerns in the PMN review process. OTS anticipates that it will begin its first §4 efforts on a non-ITC chemical within the next year, with proposal in FY85.

D. Monitoring Chemical Exposure

To complement the §4 testing program and to support its overall existing chemicals program, OTS conducts a wide range of chemical monitoring activities. These activities are particularly important because accurate data on chemical exposure are needed to support regulatory decisionmaking, and because information on exposure to existing chemicals, where available, is often unreliable or difficult to interpret. OTS' general monitoring activities are designed to address these problems by providing actual levels of human and environmental exposure to specific compounds. The major goals of these activities are:

- To support the assessment and possible regulation of specific chemicals by providing human and environmental exposure data, which are necessary to estimate the magnitude of risk and evaluate the effectiveness of different control measures.

- To identify potential candidates for testing under §4, control under §6, or other regulatory action (for example, chemicals may be appropriate for §4 or §6 action if they are found in high concentrations or are widespread in the environment or in human body fluids or tissue).

- To establish baseline levels of human exposure to chemicals of concern, so that OTS can measure trends over time and identify populations, geographic areas, or other groupings for which exposure is higher than the baseline level.

One of the most important direct contributions of these activities is to provide ongoing support to long-term OTS projects, such as the Office's work on asbestos and PCB's. Examples of this support are described below.

- OTS recently conducted an asbestos monitoring study in one school district. This study was designed to indicate the levels of asbestos in school buildings and to evaluate a formula that had been developed for determining when asbestos-containing materials should be removed from schools. This effort has led to the identification of an important factor to be considered in removal decisions, and it has served as a basis for OTS technical guidance to schools in monitoring for asbestos and in removing asbestos-containing materials.

- OTS will be conducting a similar survey in "habitable" public buildings, such as hospitals, libraries, and housing projects. This one-year project will provide information critical to assessing risks associated with the presence of asbestos-containing materials in public buildings. As a result, this work may directly support future OTS activities.

- OTS will evaluate permit applications, submitted in accordance with TSCA §6 PCB regulations, to dispose of PCB's by incineration or other means. OTS' review of these applications will address the adequacy of the applicants' monitoring plans for determining that the PCB's are in fact destroyed and that they are converted to harmless materials.

Monitoring activities and exposure analyses have also been thoroughly integrated into other aspects of OTS' existing chemicals program -- particularly the review of regulatory candidates and the identification of control options. As part of the existing chemicals program, OTS has developed mechanisms that allow prompt, focused monitoring support for existing chemicals review. These mechanisms ensure the development of exposure data needed to support regulatory decisionmaking. Two examples illustrate this support:

- OTS is now reviewing the risks posed by a specific class of paint additives. Monitoring activities in connection with this review involve (1) the identification of paints on the market that contain these additives, and (2) experimental work to determine the levels of exposure that can be expected to result from commercial or consumer use of these paints. This information is essential in estimating the magnitude of risk and the feasibility of different control options.

- OTS is also reviewing risks that may be associated with the use of reclaimed industrial solvents in general commercial and consumer products. At present, no regulatory authority is addressing possible risks to consumers and commercial users from these solvents, although the solvents may be hazardous themselves and they may contain toxic impurities. To get a clearer picture of the risks, OTS is now conducting a pilot study to determine the nature of the recycled solvents market, collect samples of products containing selected high-production-volume solvents, and analyze these samples for impurities. The information will be necessary to define the extent of the problem, identify possible control strategies, and support regulatory decisions.

In addition to these ad hoc projects, which support specific existing chemical assessments, OTS is conducting more broad-based studies to identify potential regulatory candidates and to define a baseline of exposure to specific chemicals of concern. The most important of these projects are described below:

- As part of the National Human Adipose Tissue Survey, OTS is monitoring the level of PCB's in human fatty tissue. This survey, which has been underway since 1967, has provided a direct measure of the human body burden of PCB's since 1972. Results recently published by OTS indicate that the percentage of the U.S. population having higher levels of PCB's has decreased since a high point was reached in 1977. This trend reflects the banning of PCB's under TSCA in 1976.

- OTS is beginning a one-year monitoring project in which human tissue samples will be analyzed for a broad spectrum of chemical substances. The project, which involves a representative sampling of the U.S. population, stratified geographically and demographically, will allow OTS to identify chemicals with high or widespread body burdens in humans. This information will be used in defining future TSCA ambient monitoring programs and in identifying candidates for testing under §4 or regulatory controls under other authorities.

The major significance of the monitoring activities illustrated above is that they are closely integrated with the Office's existing chemicals program and that they provide direct support to OTS' regulatory agenda. Monitoring by EPA traditionally has been aimed at measuring the degree of compliance with specific regulations -- for example, determining whether certain process emissions meet specific standards. OTS' monitoring program, however, is designed more to assist in identifying risks and developing control measures than it is to determine compliance or noncompliance. This focus is reflected in the direct impact of OTS monitoring activities on the existing chemicals program. Within the next year, these activities will contribute information important in the identification of candidates both for data development and for control, and they will provide exposure information necessary in ongoing OTS reviews.

E. Coordination of New and Existing Chemicals Programs

One of the major operating assumptions of TSCA is that new and existing chemicals warrant separate treatment. The difficulties and controversies associated with controlling existing chemicals should not stand in the way of a strong Agency commitment to preventing new hazards from occurring -- regardless of whether they appear to be less serious than some existing hazards. At the same time, however, OTS is taking steps to ensure that its new and existing chemical programs are well coordinated and that together they contribute to an integrated program of chemical hazard identification and control.

Chapters II and III of this report have discussed several places where OTS' new and existing chemical programs intersect. OTS is committed to strengthening these points of intersection, and it has now developed or will be developing in the near future a number of mechanisms to promote a more unified overall program. The most important of these mechanisms are described below:

- Use of the PMN review process to identify chemicals for review by the existing chemicals program. Certain categories of chemicals have repeatedly raised some level of concern in the PMN process, suggesting that there may well be hazards associated with existing chemicals in those categories. In several of these cases, the categories have been referred to the existing chemicals program for evaluation. In other cases, new chemicals have not been regulated under §5 because their introduction into commerce would be likely to lead to a net reduction of risk, since they would be used as substitutes for potentially more hazardous existing chemicals. In such cases, the existing substances may be appropriate subjects for evaluation.

- Use of generic assessments developed in the PMN process to support existing chemicals review. As discussed in Chapter II, OTS has developed generic assessment of certain industries, classes of substances, routes of exposure, and other factors that have repeatedly raised some level of concern in the PMN program. These assessments have in turn proved useful in existing chemicals review.

- Use of physical-chemical estimation, SAR, and modeling techniques developed for the PMN review process in existing chemicals review. For example, these techniques are useful in the initial evaluation of existing substances identified as potential hazards through TSCA mechanisms such as §8(e). Conversely, monitoring and exposure data developed in connection with the existing chemicals program are useful in estimating likely exposure to new chemicals.

- Use of health and environmental effects data developed under other TSCA authorities to support the review of PMN's. OTS' evaluation of new chemicals depends in part on a review of data on analogous chemicals. Data on existing chemicals submitted to OTS in accordance with §4, §8(d), and §8(e) among other authorities, are often useful as analog data in new chemicals review. With the development of SPHERE and other OTS data retrieval systems, these data will become more readily available for PMN review. (The development of these data systems is discussed in Chapter IV.)

- Use of the §5(a)(2) significant new use authority to place a limit on the growth of existing chemicals until adequate data are developed or their safety is otherwise ensured. One example of this approach is the proposed SNUR on chlorinated naphthalenes. Under the SNUR, any production in the U.S. and any importation above 100,000 lb/yr would be subject to EPA review under the full authorities of §5. Therefore, the SNUR would in effect change the status of chlorinated naphthalenes from existing to new chemicals. OTS will explore similar uses of the SNUR authority in the future.

Through these mechanisms, OTS has taken significant steps within the last year toward coordinating its new and existing chemicals programs. In the future, OTS will continue to emphasize the use of these and similar mechanisms to ensure an integrated program.

CHAPTER IV -- TECHNICAL DEVELOPMENTS

A. Introduction

The effective implementation of TSCA depends, ultimately, on the quality of the science that supports regulatory decisions. Recognizing this fact, Congress provided EPA with specific responsibility under TSCA §10 to develop methodologies, collect and disseminate data, and conduct research to support its activities; the purposes of the Act, the House Report stated in describing §10, would be "ennanced by allowing the development of proper tools" (TSCA Legislative History, pp. 699-700). Developing these tools, including computerized data bases, environmental fate models, SAR techniques, standardized test methodologies, and quality assurance procedures, has been a priority of OTS. The Office will commit major resources toward these activities during the next year and will continue to integrate them into the decisionmaking process.

B. Data System Development

In assessing risks of both new and existing chemicals, OTS depends on the ready availability of a wide range of data, including data on physical-chemical properties, health and environmental effects, and chemical exposure. The standard bibliographical and scientific data bases are an invaluable source of references, abstracts, and data concerning chemical risks; in its day-to-day operations, however, OTS has found that existing systems have important limitations for some of its purposes. As a result, OTS is taking steps to supplement these systems with its own data bases, which are designed to (1) provide enhanced access to data previously submitted to OTS under TSCA or obtained in the course of an OTS analysis, and (2) provide access to critical scientific and technical data.

Ready access to data extracted from the literature, as opposed to literature references or abstracts, is particularly important for OTS, given the nature of its programs. In the PMN program, for example, OTS must make rapid decisions (usually within two weeks) concerning which of the approximately 100 new chemicals reported every month warrant more detailed review, and which can be dropped from further consideration. To make these judgments, OTS looks not only at the data submitted on the chemical itself, but also at available data on analogous chemicals. It is essential that data on analogs be readily retrievable and, to the extent possible, that enough information be provided for the reviewer to understand the validity of these data. Standard bibliographical data bases often do not allow this, because of the time required to obtain the references, to

extract the data, and in some cases to determine their relevance to the review. Similarly, OTS benefits greatly from ready access to data in its existing chemicals program, both in conducting preliminary assessments of data submissions -- for example, under §8(e) -- and in selecting potential candidates for testing or regulation from among the large number of existing chemicals. Finally, access on computerized data bases to a wide variety of data facilitates the development and validation of SAR.

For these reasons, OTS has made a major commitment to developing computerized and other data systems that are designed to support its own regulatory programs. The Office's focus has been primarily on data submitted under TSCA or obtained in the course of OTS reviews -- in other words, the goal has been to develop an institutional memory -- although OTS has also devoted significant resources to developing data bases on specific areas of OTS concern, such as genetic toxicity, aquatic toxicity, and chemical fate, particularly where available data are difficult to obtain or are not well validated. Several representative data bases under development by OTS are discussed below:

- TDIS (Technical Data Indexing System) is an automated PMN file, containing data from PMN's such as chemical identity, production volume estimates, use categories, and kinds of test data submitted. The system, which contains almost entirely confidential information, is designed to allow quick access to previous PMN reviews and a ready overview of the PMN program. It is now in use within OTS and is constantly being updated. OTS has also instituted a project to upgrade TDIS by including key findings and summaries of past reviews.

- GENE-TOX contains results of short-term mutagenic and related assays on about 2,700 chemicals reported in the scientific literature. The major significance of this system is that the data it contains have been validated by national experts as part of OTS' Gene-Tox Program, described more fully in Section F below.

- AQUIRE covers world literature on the toxicity of chemicals to freshwater and marine organisms. This data base, which has been under development since 1981, currently contains over 30,000 studies on 2,700 chemicals and 1,800 organisms. The project, which is a joint effort of OTS and the EPA Environmental Research Laboratory in Duluth, Minnesota, represents an OTS initiative in an area poorly covered by existing data bases, but of critical importance to OTS analyses.

- The SPHERE system, which is currently under development by OTS, integrates a diverse range of OTS and other scientific data bases, including GENE-TOX and AQUIRE. It will contain data on physical-chemical properties, health effects, environmental effects, and environmental fate, derived either from submissions to OTS or from the literature. In addition to final test results, the system will include information on test protocols and other details, so that the applicability and usefulness of the results can be quickly assessed. At the moment, SPHERE is being developed as an in-house tool to assist in PMN and other reviews. However, because of its breadth and its inclusion of data not readily available elsewhere, it will be an invaluable tool to outside users. Several SPHERE subfiles will soon be available through the NIH/EPA Chemical Information System.

- A Global Indexing System has been developed by OTS to allow quick access to various OTS document collections. The system now covers the OTS public file records (17,000 documents); other collections, such as unpublished health and safety studies on ITC chemicals submitted under §8(d), will soon be added. While individual collections differ in content and physical state, they do have common traits and information that can be categorized at a level above their primary use. The data elements in the Global Indexing System were developed to capture this common information. The data elements, which are primarily bibliographic, include document title, author, date, publication title, chemical name, CAS number, document ID number, and microfiche number.

- An Asbestos Information System has been established for information submitted to EPA under the §8(a) asbestos reporting rule, discussed in Chapter III. This data base allows EPA to analyze the volume of asbestos processed, the use of the materials produced, the companies that are producing asbestos-containing materials, and similar questions. The data base is confidential, but nonconfidential aggregations of data will be developed. (For a discussion of confidentiality, see Chapter V.)

- OTS has also developed a data base of information received under its §8(a) preliminary assessment information rule. Information can be retrieved through a number of data elements, such as production volume, manufacturer, customer uses and products, and worker exposure. Like the Asbestos Information System, this data base is confidential, but aggegrates will be made available to the

public. This data base will be expanded in the future to include processor reports as well as data collected on chemicals added in the future to the §8(a) rule.

These systems generally illustrate the nature of the data bases now under development at OTS, and they indicate several general principles now guiding OTS' work: (1) the Office's first priority, at this point, is to enter TSCA data into its own systems, in order to develop an institutional memory; (2) as a second priority, OTS will enter data on areas of specific concern that are inadequately represented in existing data bases; (3) it is important to have rapid and direct access to data, as well as references and abstracts; and (4) it is important for sufficient information to be provided so that data can be interpreted and used appropriately. These principles will continue to guide OTS activities in the future.

C. Models and Analytical Tools

To complement these data bases and to provide guidance where data are missing, OTS is using a broad range of techniques, based on chemical structure, to estimate physical-chemical properties and computer models to evaluate potential environmental fate and exposure, environmental effects, and health risks.

OTS estimation techniques for calculating basic physical-chemical properties were developed during the last few years under a contract jointly funded by OTS and the Department of the Army. Within the last year, OTS has developed or made internally available two programs, CHEMEST and CLOGP, which computerize techniques for predicting water solubility, boiling point, vapor pressure, soil absorption coefficient, bioconcentration factor, octanol/water partition coefficient, and other properties. These properties are critical in estimating potential human and environmental exposure, as well as in some aspects of health and ecological effects analysis. As discussed in Chapter II, the estimation techniques are not a complete substitute for actual data; however, they are useful in pointing to areas of potential concern requiring further assessment.

The techniques are now being upgraded to include additional properties, and an extensive investigation of the accuracy of the predictions and limits of applicability is being conducted. In addition, because the use of these techniques is limited to classes of compounds for which structure-activity data are available, several projects are now underway to expand these techniques to include additional chemical classes. These activities are discussed briefly in Section D below.

In addition to estimation techniques, OTS has developed a number of computer models to estimate environmental fate and population exposures. These models can be used to evaluate air, land, surface water, or groundwater releases. They are applicable to both new and existing chemical reviews, both as screening tools to focus further assessment and as evaluation tools to provide exposure data for quantitative risk assessments. The environmental fate and exposure models have been integrated in a computer system, the Graphical Exposure Modeling System (GEMS), making them more accessible to OTS users. GEMS is a set of interrelated computer programs (including CHEMEST and CLOGP) allowing OTS to estimate physical-chemical properties based on chemical structure; to predict environmental fate and exposure through environmental simulation models applicable to air, water, and land release; and to develop quantitative or qualitative exposure estimates through a population data retrieval program. The system includes statistical analysis as well as mapping and graphics display capabilities to allow the presentation of modeling results in the most useful form possible.

For use in conjunction with derived or observed exposures and observed effects data, primarily in the health arena, OTS has acquired or developed a variety of computerized health risk assessment tools. These tools have been used to date primarily with cancer data, but expansion and use with other adverse health effects data are anticipated. Capabilities encompass models designed for use with dichotomous or prevalence data (MULTI80G, GLOBAL 83, MANTELAN, ONE HIT MD) and with incidence or so-called "time-to-occurrence" data (RANK TIME, MRS.T). These models permit OTS to make educated projections about the potential health risks of substances at exposures below those that have been studied.

D. SAR Development and Validation

As discussed in the section above and in Chapter II, SAR techniques play an important role in OTS' implementation of TSCA -- particularly in new chemicals review, where SAR has proved to be a useful tool in identifying potential areas of concern. The systematic use of SAR in estimating physical-chemical properties and health and environmental effects, however, is a relatively new technique still under development, and it has raised significant controversy. OTS is now conducting or sponsoring a series of projects to refine and validate its use of SAR; these activities are essential in determining the level of confidence that should be assigned to specific techniques and will lead to significant expansion of the Office's present capabilities. OTS' general activities in this area include:

- Projects to expand and validate the techniques for estimating physical-chemical properties based on chemical structure. These efforts include (1) refining current capabilities through validation studies, (2) developing techniques for estimating additional physical-chemical properties, and (3) extending the techniques to categories of chemicals not now covered. One of the most important efforts is a joint project with the Umweltbundesamt of the Federal Republic of Germany, which will be funding several major refinements of the CHEMEST program in return for access to that program and any future improvements to it.

- Projects to develop or refine SAR techniques for aquatic and mammalian toxicity. For example, the Office of Research and Development (ORD) laboratory in Duluth is conducting several studies to support the development of quantitative techniques to predict aquatic toxicity from chemical structure. In addition, several OTS or ORD projects are aimed at strengthening SAR capabilities for selected classes of chemicals or selected classes of chemicals or for selected effects.

- Reviews of available literature to refine SAR-based judgments in specific areas. These reviews generally focus on specific categories of concern (for example, categories that repeatedly raise concern during PMN review); routes of exposure of concern, such as dermal absorption, to allow better predictions of likely doses; and effects of concern, such as the comprehensive review of literature on mutagenicity conducted under the OTS Gene-Tox program.

- Projects to validate the use of SAR within OTS regulatory programs. For example, OTS is designing an experimental program to evaluate its use of SAR during new chemical review. The basic approach would be to test a sample of PMN chemicals for specific physical-chemical properties and health and environmental effects and to compare these test results with OTS estimations. This project, if the design proves feasible, would provide important information on the use of SAR as part of PMN review.

To support this general activity, OTS technical staff with program responsibility have been meeting with ORD researchers to direct further research on SAR development and validation. Both OTS and ORD will commit significant resources to defining and carrying out this research over the next year; the results will be directly applicable to OTS' review of new chemicals, and will provide important guidelines for selecting testing or regulatory candidates from existing chemicals.

E. Priority Setting Methods

OTS has, along with other groups such as the ITC, encouraged and sponsored the development of chemical scoring and priority setting systems to aid in selecting chemicals for further evaluation from among large numbers of candidates. One such tool is being evaluated for use with existing chemicals at preliminary stages of assessment. The system depends on experts to assign scores to chemicals based on known or suspect health or environmental effects and exposure potential. The scores are intended to assist in deciding which chemicals in a set of identified possible chemical problems present the greatest concern regarding potential risk. If shown to be consistent and valid, this approach may be used in assigning resources to existing chemical problems brought to OTS' attention through §8(e) notices of substantial risk, §4 test data, and other current testing data.

F. Quality of Data

Regardless of the strength of OTS' analytical tools and the scope of its data bases, the quality of its decisionmaking will rest finally on the integrity of the data being analyzed or retrieved. OTS, as a result, has committed considerable resources since the passage of TSCA to ensuring the quality of data developed or reviewed under the Act.

1. Test data

Frequently, available toxicity and environmental effects data can be difficult to evaluate or compare with other data, because of differences in test methods, inadequate statistics, poor characterization of test substances, poor control of test conditions, or similar problems. While data from such tests can often provide important insights into the potential toxicity of a substance, they may form a weak basis for making regulatory decisions. To address this problem, OTS at a minimum promotes the inclusion of test method documentation in its data bases, such as SPHERE, to allow users to evaluate the validity of test results for their particular purposes. In addition, OTS is also working with other national and international organizations to ensure, to the greatest extent possible, the use of standardized test procedures, leading to acceptable, reproducible data.

Several OTS activities illustrate the Office's continued commitment in this area:

- Testing guidelines. For several years, OTS has been engaged in a major effort to develop testing guidance "protocols" for a wide variety of health and environmental effects. In August 1982, OTS published 96 standardized guidelines for conducting basic health effects, environmental effects, and chemical fate tests. The publication of these guidelines (available through the National Technical Information Service) will promote consistent data submissions under TSCA. The guidelines, which will be referenced in §4 test rules, were developed in close coordination with other federal agencies and the International Organization for Economic Cooperation and Development (OECD). They are consistent with the testing guidelines recently published by the OECD. OTS is now developing additional guidelines for other tests, such as short-term screening tests where no widely accepted methodologies exist. OTS will perform an annual update of published guidelines, based on public comment, to ensure that they reflect the most current testing practices.

- Good Laboratory Practices (GLP's). OTS will be publishing in the fall of 1983 a rule specifying "good laboratory practices" that must be observed in developing health and environmental effects data under TSCA §4 test rules. This rule will specify recordkeeping and data handling procedures, animal care, personnel qualifications, and similar practices that laboratories conducting tests in compliance with TSCA will be required to observe. The rules will ensure acceptable practices by testing laboratories and will serve as a basis for audits under OTS' laboratory audit program. These GLP requirements will also be incorporated into negotiated testing programs and used in evaluating testing performed to respond to §5(e) orders.

- Laboratory Audit Program. In cooperation with the Food and Drug Administration, OTS performs periodic inspections and audits testing programs conducted under TSCA. Such inspections are now being performed on tests carried out under negotiated testing agreements; they will also apply to §4 test rules and will be extended to include testing performed under §5(e) orders. Inspections and audits will be conducted both through a program of periodic review of test facilities performing TSCA tests and as targeted reviews of specific studies and test facilities, based on the importance of the test or indications of test problems.

- Gene-Tox Program. This program, sponsored by OTS, is designed to evaluate the current status of genetic toxicology and its applications in testing chemicals for potential mutagenicity and carcinogenicity. OTS personnel and outside experts have evaluated available literature on selected mutagenicity and related assay systems to document their performance in testing different chemical classes and their ability to differentiate carcinogens and noncarcinogens. From this work, an Assessment Panel will prepare position papers recommending test batteries for generalized screening; for testing specific classes of chemicals; for estimating risk; and for identifying potential carcinogens. The papers are scheduled for publication in 1984. The program as a whole will provide valuable information in interpreting existing genetic toxicity data and will provide guidance in selecting appropriate tests in the future.

2. Exposure and monitoring data

Like health effects data, available monitoring and exposure data can often be difficult to evaluate, for example, because of questionable experimental design, improper handling of materials, or inappropriate chemical analysis. Reliable exposure data, however, are essential in identifying potential problems, in estimating the magnitude of risk, in choosing among control options, and in measuring the effectiveness of regulation or other controls. For this reason, OTS has instituted a quality assurance program designed to ensure that monitoring data sponsored by EPA are reliable.

This program, which is conducted under an EPA-wide quality assurance program administered by the Office of Research and Development (ORD), involves close OTS scrutiny of quality assurance plans developed for each monitoring project under its sponsorship. These plans typically address experimental design; sampling procedures; handling, packaging, and shipping of samples; laboratory quality assurance; data processing procedures; and similar elements. As a result of its care in the review of these plans, and in the design and conduct of its monitoring projects, OTS can rely on the integrity of its data, and be confident in their use as a basis for regulatory decisionmaking. The success of this program was recently acknowledged by ORD and the Administrator, which identified OTS as a leader within EPA in several areas of quality assurance.*

*The EPA Administrator's First Quarter FY83 Accountability Results singled out the OTS quality assurance program as a leader in statistical and experimental design and data processing.

CHAPTER V -- INFORMATION SHARING AND TECHNICAL EXCHANGE

A. General Background and Current Activities

In developing TSCA, Congress clearly recognized the need for broad public access to data on commercial chemicals and chemical hazards, and it charged EPA with specific responsibility for sharing data obtained under the Act with interested parties -- in particular, other federal agencies responsible for the protection of health and the environment.* EPA's information-sharing responsibilities are especially important because of its unique authority under TSCA to gather or require the development of data on commercial chemicals. In the course of its operations, OTS has accumulated a significant body of health and environmental effects data potentially of great value to other government bodies and the public. Much of this information is not readily available elsewhere. In addition, the information gathering and data-development authorities EPA possesses in §4 and §6 of TSCA could potentially be of great value in supporting regulatory programs other than OTS. Similarly, the assessment methods and technical tools described in Chapter IV may be useful to local, state, and federal authorities responsible for public health and environmental quality.

Examples of information and technical capabilities OTS now has available, or will soon be developing, include:

- Data submitted under §8(a). Section 8(a) of TSCA authorizes EPA to require chemical manufacturers and processors to submit certain available information on a

*The Interagency Toxic Substances Data Committee (ITSDC), jointly chaired by the Office of Pesticides and Toxic Substances and the Council on Environmental Quality, is responsible for implementing §10(b) of TSCA, which requires the development of (1) "an efficient and effective system" for collecting, disseminating, and using data developed under TSCA, and (2) "an efficient and effective system" allowing EPA and other agencies to retrieve toxicological and other scientific data. The major accomplishment of the ITSDC to date has been the establishment of the Chemical Substances Information Network (CSIN), which allows access through bibliographic data bases to more 200 data bases providing chemical information.

chemical substance or mixture's identity, human and environmental exposure, and health and environmental effects. Within the last year, OTS has issued a §8(a) asbestos rule, described in Chapter III, and a §8(a) preliminary assessment information rule, which has been used to obtain data on ITC chemicals and selected §8(e) chemicals.* Data bases containing information submitted under these rules are discussed in Chapter IV.

- Data submitted under §8(e). Section 8(e) requires chemical manufacturers, processors, and distributors to submit to EPA information that reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment. Since this requirement went into effect in 1977, OTS has received almost 500 submissions. In addition, OTS often receives test reports submitted for its information rather than as formal §8(e) submissions. Like §8(d) health and safety studies, these submissions are a valuable source of recent data on chemical risks, most of which are unavailable elsewhere.

- Data submitted under §8(d). Under §8(d), EPA can require persons to submit to the Agency health and safety studies on specific chemical substances or mixtures. Under this authority, OTS has obtained over 4,000 reports on health and safety studies, collected primarily to support OTS' evaluation of asbestos and chemicals recommended by the ITC for testing consideration under §4(a). These reports are generally unpublished, but for the most part are not confidential.

- Analytical capabilities developed by OTS for estimating exposure and physical-chemical properties and modeling exposure. These capabilities, which include OTS' CHEMEST and GEMS systems, are discussed in Chapter IV of this report.

In addition, OTS is considering several initiatives under §8(a) and other authorities, which would provide important new information on commercial chemicals. These include a general

*In June 1982, OTS issued a preliminary assessment information rule under §8(a) requiring information on approximately 250 chemicals. Future ITC designations and recommendations will be automatically added to this list; other chemicals may also be added in the future through notice-and-comment rulemaking.

§8(a) followup rule for new chemicals, described in Chapter II, and an Inventory updating project. The Inventory update project, which is described in the Addendum to this report, would update production volume and manufacturing site information for a subset of chemical substances on the TSCA Chemical Substance Inventory. This information would be invaluable not only to OTS, but also to the other EPA offices and regions that use the TSCA Inventory.

From the beginning, OTS has assigned a high priority to sharing these types of information and promoting technical exchanges, both with government agencies and the public. Examples of current activities in this area include:

- Direct transmission of information obtained under TSCA to appropriate organizations, e.g., routine forwarding of copies of preliminary OTS evaluations of §8(e) submissions to other federal agencies.

- Publication of technical material through the National Technical Information Service, e.g., the TSCA test guidelines for health and environmental effects and OTS' chemical fate and preliminary evaluations of §8(e) submissions.

- Encouragement of public participation in OTS' evaluation of testing candidates recommended by the ITC.

- Publication of technical guidance documents, such as the Asbestos in Homes Booklet and asbestos risk abatement guidelines.

- Technical assistance to states and local organizations, e.g., in monitoring and sampling techniques.

In several important respects, OTS will be expanding its information-sharing activities in the near future:

- As discussed in Chapters II and III, OTS will be developing Risk Management Advisories for selected existing chemicals and Advisory Circulars for new chemicals. These documents will provide the public and industry information on risks identified in OTS reviews and will describe control measures.

- OTS will publish quarterly reports identifying chemicals under evaluation in its existing chemicals program, and it will seek greater public participation in its preliminary evaluations of existing chemicals.

- OTS will be making a number of its data bases now under development available to public users. The TSCA Inventory data base is already available now through the NIH/EPA Chemical Information System (CIS); as SPHERE, described in Chapter IV, becomes operational, it will also be available through this system.

- EPA will promote technical exchanges with states, federal agencies, and foreign nations. OTS has already arranged to share computational and modeling capabilities with the Federal Republic of Germany and the Michigan Department of Natural Resources. The EPA Office of Research and Development, Office of Water, Office of Solid Waste, and Office of Policy and Resource Management have also expressed interest in using OTS modeling capabilities in their own work.

The major barrier to broader public and governmental access to data obtained under TSCA is the need to protect confidential business information. Much of the information received by EPA under TSCA -- particularly information related to chemical identity, production volume, manufacturing processes, and use -- is claimed as confidential by the submitter. For example, approximately 94% of PMN's have at least some information claimed confidential.* Section 14 of the Act contains strict provisions for protecting confidential business information.

In conducting its operations, therefore, OTS must constantly balance the need of other organizations and the public for access to TSCA data with industry's need, reflected in §14, for the protection of commercial secrets. In practice, this has meant strict safeguards to prevent inadvertent disclosure of confidential business information together with an affirmative commitment to share as much information as possible on commercial chemicals and potential hazards. OTS is pursuing this commitment primarily in two areas: (1) agreements with other government agencies to give them access to confidential information relevant to their authority, and (2) publication of confidential business information in an aggregated or otherwise masked form that will not divulge commercial secrets.

*Generally, claims of confidentiality are made for only some of the information in a notice. Claims are made most frequently on chemical identity (74% of PMN's), process information (67%), manufacturer's identity (64%), site of manufacture (55%), and use (49%).

In the past, OTS has developed clearance procedures allowing employees of other federal agencies access to confidential business information -- for example, in individual PMN's -- particularly when their expertise has been needed in OTS' own reviews and regulatory decisions. In the future, OTS will be gathering an increasing amount of information directly relevant to the regulatory efforts of other agencies. The Office believes, as a result, that it will become necessary to develop agreements with these agencies, giving them access to confidential data and governing their use of the data. These agreements, which will be announced in the Federal Register, will ensure that confidential information is appropriately protected by the agencies with which it is shared. Two current examples illustrate the nature of these agreements:

- o OTS has formally agreed to provide CPSC with limited access to confidential PMN information and to certain information reported under the §8(a) Preliminary Assessment Information Rule. In both cases, CPSC is interested in information on consumer uses of chemical substances. These agreements were announced last year in the Federal Register (47 FR 17860, 48 FR 504).

- o OTS has also agreed to provide OSHA limited access to confidential business information concerning occupational exposure to asbestos obtained under the §8(a) asbestos reporting rule. This agreement was announced in the Federal Register in February 1983. OTS is also in the process of negotiating an interagency agreement with OSHA for sharing other TSCA confidential business information.

As further data appropriate for sharing are developed, OTS will explore the possibility of additional information-sharing agreements, both with these and other government agencies.

In addition, OTS is committed to providing relevant information to the public in summary or masked form so that it is no longer confidential. Toward this end, for example, the Office routinely publishes summaries or descriptions of confidential business information contained in premanufacture notices and other TSCA submissions -- these descriptions include "generic names" describing the chemical type, descriptions of use, production volume ranges, and similar masked descriptions, which provide the public with information on the nature of the confidential data. OTS also routinely publishes aggregated data, such as the number of new chemicals that fall into a specific use category or production volume range. The Office is now committed to refining and expanding its aggregation techniques, so that it can increase the public availability of data that otherwise would

be confidential. Two current activities illustrate this commitment:

- The Agency has recently announced in the Federal Register a methodology for aggregating production volume information reported for the TSCA Inventory. Persons or organizations without access to confidential business information may now ask EPA to provide aggregated Inventory production volumes for specific chemicals. In the past, published production data for Inventory chemicals have reflected only nonconfidential reports; therefore, they may considerably underrepresent the total production volume of a given chemical. The published methodology allows far more accurate figures, generally reflecting confidential as well as nonconfidential reports.

- OTS is also developing aggregation methodologies for data submitted under the §8(a) preliminary assessment rule and the §8(a) asbestos rule. OTS' procedures for aggregating data from these rules were published in the Federal Register in June 1983.

These examples illustrate the general nature of OTS' information-sharing activities. More broadly, the Office is beginning a comprehensive review of information sharing and technical exchanges under TSCA, and it will form an OTS workgroup to explore how it can more effectively promote these goals. In particular, the group will investigate:

- The further development of agreements with other EPA offices and federal agencies allowing access to confidential data. (The initial goal will be to identify what data OTS has to offer other agencies, and what data they can share with OTS.)

- The feasibility of joint data development with other agencies in addition to information sharing.

- The feasibility of using TSCA information-gathering or development authorities (e.g., §§4 or 8) for other EPA programs or other agencies.

- The sharing of information and technical capabilities with industry, labor unions, public interest groups, and states. (Again, the initial goal will be to identify appropriate recipients of TSCA data, and to identify data held by other organizations that might be of importance to OTS.)

In connection with these activities, the Office will be setting up a program to ensure better information exchange and coordination between OTS and individual states. Many states have developed or are now developing their own toxic substances programs under which they are collecting chemical monitoring and epidemiological data, conducting chemical risk assessments, and in some cases making TSCA-type control decisions. These programs may benefit significantly from general toxicity and exposure data gathered under TSCA, chemical risk assessments conducted by OTS, site-specific TSCA Inventory data or other site-specific data gathered under §8(a), §8(e) reports by plant sites, OTS modeling and monitoring expertise, and similar OTS capabilities and information. At the same time, individual states may have data or analyses of importance to OTS -- for example, data on workplace practices and exposure, monitoring data, epidemiological data, and chemical risk assessments. In the next year, OTS will be working to ensure more effective coordination with state toxics programs and to promote more effective information sharing and technical exchanges.

B. International Activities

Since the passage of TSCA, OTS has actively participated in a range of international programs concerning toxic substances control. OTS' participation in these programs is important because toxic substance issues often transcend national boundaries, international chemical regulation affects trade in chemicals and national chemical industries, and nations can benefit significantly from the exchange of data and assessment techniques. Not only does OTS contribute significantly to the success of these programs through its technical expertise and its experience in chemical review and control, but OTS participation also contributes significantly to the effectiveness of its own operations and to chemical control in the United States.

The goals of OTS participation in international programs include:

- Exchanging data and assessment methodologies and sharing expertise gained in national toxic substances programs.
- Protecting health and the environment in the United States and contributing to international environmental quality through cooperation with other governments on environmental problems of an international or global nature.
- Developing testing and assessment methodologies that are recognized internationally.

- o Conserving scarce testing resources by avoiding duplicative testing.

- o Eliminating or preventing the development of obstacles to trade.

Representative examples of OTS' work with international programs and organizations are discussed briefly below.

1. OECD Chemicals Program

Perhaps the most visible and successful of OTS' international efforts has been its participation in the Chemicals Program of the Organization for Economic Cooperation and Development (OECD), an international group composed of the major industrial trading partners. Because national laws regulating hazardous chemicals can create barriers to international trade in chemicals, the OECD began a program in 1977 to harmonize its member countries' approaches to toxic substances control. The OECD Chemicals Program focuses primarily on the elimination or reduction of barriers to international trade in chemicals and the sharing of technical expertise.

A major accomplishment of the OECD program has been the adoption in May 1981 of the Decision on Mutual Acceptance of Data. This decision commits member states to accept data developed in other member countries according to the OECD Test Guidelines and Principles of Good Laboratory Practices.

More recently, OTS has participated actively in the new OECD initiative on existing chemicals. As part of this activity, the Office chairs the Switchboard Project, a referral system which will improve access by member countries to unpublished information held in other member countries. In addition, OTS experts made significant contributions to the development of a common format for chemical reviews, which will facilitate the exchange of information, and to the development of methods for setting priorities in the selection of testing candidates.

2. United Nations Programs

OTS participates in several United Nations programs, such as the International Register of Potentially Toxic Chemicals (IRPTC) of the U.N. Environmental Program (UNEP). The basic objective of this register is to promote more efficient use of national and international resources in the evaluation and control of chemical risks. Toward this end, the IRPTC provides access to existing data and distributes information on national and international

regional policies, regulatory measures, and standards. OTS supports the Register by notifying the program of chemical incidents and proposed regulatory actions and by responding to foreign inquiries relayed through the IRPTC.

OTS is also participating in a UNEP project to develop a Global Ozone Protection Convention. Once adopted, this convention will provide for better coordination and greater cooperation among nations in research, monitoring, and information exchange concerning stratospheric pollution and potential modification of the ozone layer. OTS has played an important role in the development of the U.S. positions at international deliberating and drafting sessions and has been part of the U.S. delegation to these sessions.

In connection with these activities, OTS is playing a central role in international efforts to improve global monitoring of the earth's ozone layer. OTS currently chairs a working group composed of representatives from other U.S. agencies and international research organizations, including the U.N. World Meteorological Organization and the Chemical Manufacturers Association (CMA) Fluorocarbon Program Panel. OTS and the CMA Fluorocarbon Program Panel have jointly funded a project to establish seven automatic ozone monitoring stations around the world. Scheduled to be completed in 1984, this global network will collect important data on the vertical distribution of stratospheric ozone that can be used to assess the status of the ozone layer and to detect any abnormal changes that may be taking place. Ultimately, such information should play an important role in future decisions by the U.S. and other nations on actions to protect stratospheric ozone.

3. Bilateral Activities

Many of OTS' international activities involve direct relations with other nations or regional organizations, such as the European Economic Community (EEC). Since 1978, OTS has been regularly discussing toxic substances issues with the EEC Commission. Initially discussions focused on OTS' implementation of TSCA -- particularly in the area of new chemicals -- while the EEC was still making plans for its Directive, commonly known as the Sixth Amendment. More recently, as experience has been gained on both sides, discussions have focused on problems arising from differing approaches to chemicals management under TSCA and the Sixth Amendment.

In addition, as mentioned in Chapter IV, OTS has developed an agreement to exchange technical information with the Umweltbundesamt (UBA) of the Federal Republic of Germany. The

UBA has been particularly interested in OTS' progress in developing capabilities for exposure modeling through its GEMS program and in compiling, characterizing, and computerizing methods for predicting the physical-chemical properties of chemicals.

As part of the OECD Hazard Assessment Project, OTS has provided the UBA with a computer model developed by OTS to predict the environmental partitioning of a chemical. The UBA plans to use this model, as does OTS, in its new chemical assessments. In return, the UBA has provided OTS with information on the practicability and limitations of OECD test guidelines developed through interlaboratory comparisons. The UBA has also shared with OTS preliminary reports describing the formulation of its approach to hazard assessment. Most recently, the UBA has proposed a cost-sharing program with OTS to enhance OTS' CHEMEST computer program for estimating various physical-chemical properties. These are similar programs will significantly improve the ability of OTS and of foreign governments to evaluate and control chemical hazards.

ADDENDUM

Possible OTS Initiatives

The main text of this report describes the present status of OTS' programs, the major program objectives for the near future, and initiatives to which the Office is now committed. This Addendum briefly discusses several additional initiatives that OTS is now exploring, but that the Office has not yet adopted. These initiatives are earlier in their planning stages than those discussed in the main report, and generally they have not been as completely articulated. Before decisions are made to pursue them -- or how far to pursue them -- they will require more review, both in terms of both policy and legal implications and in terms of more practical procedural details. Furthermore, some of these initiatives may not be possible given current resource constraints. For these reasons, certain initiatives may not be adopted, while others may be phased in gradually as the Office continues to gain experience in its new and existing chemicals programs. In any case, however, these initiatives represent alternative routes that OTS is now exploring to reach its program goals.

I. New Chemicals

A. Data Development

Lack of health and environmental effects data in PMN's in many cases complicates OTS review of new chemicals. In a few cases, it has led to suspensions of the review period pending the development of data, withdrawal of notices, and §5(e) actions. Many of the problems leading to such actions would have been avoided if more data had been provided on the chemicals in question in the first place. For this reason, the Office is considering several alternatives that would more directly encourage the development of data on categories of new chemicals identified as a concern.

Initiative 1. Place categories of substances that have raised concern in the PMN process on the §5(b)(4) "risk list."

Discussion. Section 5(b)(4) of the Toxic Substances Control Act (TSCA) states that the Environmental Protection Agency (EPA) may, by rule, compile a list of substances with respect to which it finds that the manufacture, processing, distribution in commerce, use, or disposal presents or may present an unreasonable risk to human health or the environment. If a PMN (or a SNUR notice) is submitted on a chemical listed under §5(b)(4), the submitter must provide data that he believes show that the substance (or the new use) will not present an unreasonable risk. As a result, under

§5(b)(4) the burden is shifted to the manufacturer to show that his product will not present such a risk; in a typical PMN, the submitter is not required to provide data demonstrating the safety or reasonableness of his product.

Under this initiative, OTS would place categories of chemicals that had consistently raised concern during PMN review on the §5(b)(4) list. These categories might be defined in terms of chemical structure, exposure factors (such as use), or both. The rule would specify the nature of the EPA concerns, and the kinds of data that might address them. As a result, it would provide guidance to notice submitters on the data that EPA believes would be appropriate.

Although this approach would not require companies to develop additional data on new chemicals belonging to listed categories, it would provide a strong incentive to do so. Furthermore, it would require notice submitters directly to address the potential risks of these substances as they developed their PMN's. At the same time, the approach is consistent with a case-by-case review of new chemicals. The specific amount of data appropriate for any given member of a listed category will depend on its exact identity, toxicity potential, production volume, uses, and similar factors. Both the manufacturer before notice submission and EPA during PMN review would address these factors on a case-by-case basis in determining the proper level of testing.

To implement this approach, OTS will have to, first, identify appropriate categories for listing, and, second, establish in the context of a rulemaking that they met the standards for listing under §5(b)(4).* This effort could require considerable resources. However, previous PMN detailed reviews will provide significant portions of the supporting analysis.

*In listing a substance under §5(b)(4), EPA must find that its manufacture, processing, distribution in commerce, use, or disposal presents or may present an unreasonable risk of injury to human health or the environment. To make this finding, EPA must consider all relevant factors, including (1) the effects of the substances on health and the magnitude of human exposure, and (2) the effects of the substances on the environment and the magnitude of environmental exposure.

Initiative 2. Issue §4 test rules for chemical categories that have raised concern in the PMN process.

Discussion: Under this initiative, OTS would develop §4 test rules on categories of new chemicals identified as concerns in the PMN process rather than (or in addition to) listing the categories under §5(b)(4). The rules would require companies to develop specific health or environmental effects data on new chemicals in these categories of concern before submitting a PMN.

This initiative would be a considerably stronger action than initiative 1, because notice submitters would have to provide data specified by OTS in the rulemaking, whereas under initiative 1 the submitter would only be required to provide data that he believed showed that the material would not present an unreasonable risk. It might also save OTS review resources. Under initiative 1, if EPA found the data were insufficient, it would take action under §5(e). Because the data requirements would be specified by rule, initiative 1 would reduce the need for individual §5(e) orders. The disadvantage of this approach is its inflexibility. It would be difficult to specify the exact level of testing appropriate for all members of the category, and, if a tiered approach were developed, to define objective criteria for moving to the second tier of testing.

B. New Chemical Follow-up

Initiative 1. Develop a "me-too" SNUR automatically extending the conditions of §5(e) orders to subsequent manufacturers and processors.

Discussion. The terms of a §5(e) order restricting the manufacture, processing, use, or disposal of a new chemical substance apply only to the PMN submitter. Once the submitter begins commercial manufacture, the substance is entered on the TSCA Inventory and can be manufactured or processed by other companies without restriction. For this reason, when OTS issues a limited §5(e) order, it also routinely develops SNUR's requiring companies to notify EPA before they manufacture or process the substance outside the terms of the §5(e) order.

Although this approach generally protects against unreviewed use of the PMN substance outside the terms of the order, there are two difficulties with it. First, because of the time needed to develop a rule, there is inevitably a gap between expiration of the PMN review period and proposal of the SNUR. This leads to at least the possibility that new uses of concern may occur before proposal of a SNUR. Second, it requires considerable resources to develop SNUR's on a case-by-case basis as §5(e) orders are issued.

To address these difficulties, OTS is considering the possibility of developing a "me-too" significant new use rule, which would automatically impose SNUR notice requirements on all importers, manufacturers, or processors of chemical substances subject to limited §5(e) orders. As a result of this rule, the restrictions of §5(e) orders would apply industry-wide.

Initiative 2. Issue §8(a) follow up rules together with SNUR's.

Discussion. New chemical SNUR's focus on specific uses or exposure scenarios that have been identified as a concern. SNUR's would generally prevent these uses from occurring without prior EPA notice.

There is always the possibility, however, that uses of concern might not be reported. For example, manufacturers or processors might in good faith misinterpret the trigger -- for example, if it were something like "manufacture for consumer use," they might misunderstand the meaning of consumer use -- or they might fail to recognize the exact nature of their own activities or those of their customers. Furthermore, it is also possible that uses of concern might occur that had not been anticipated during PMN review, and therefore would not be subject to SNUR notice requirements.

To address these problems, OTS is exploring the possibility of developing §8(a) rules in conjunction with SNUR's. The rules might, for example, require companies manufacturing or processing a chemical subject to a SNUR to provide EPA certain limited information on that chemical every few years. This would allow OTS to ensure that significant new uses, as defined by the rule, did not inadvertently occur, and in addition, that no unanticipated new uses of concern developed.

These rules would require few OTS resources to develop beyond those already needed to develop the SNUR's they accompany. However, they would increase the reporting burden on industry. If EPA develops a general §8(a) follow-up rule, the need for issuing §8(a) rules together with SNUR's would be somewhat reduced.

C. Other Initiatives

Initiative 1. Develop a TSCA biotechnology program to ensure that risks from TSCA uses of genetically engineered material are appropriately controlled.

Discussion. Biotechnology has until very recently been a laboratory-scale phenomenon; however, commercial uses potentially subject to TSCA regulation are now under development. (Examples include microorganisms used in pollution control, mining and petroleum drilling, controlling oil spills, etc.) Significant risks may be associated with some of these uses of biotechnical substances, particularly as a result of their release into the environment. OTS is now reviewing the applicability of TSCA to these products and is considering the possibility of a broader effort to ensure that health and environmental risks they may pose as a result of TSCA uses are appropriately characterized and controlled.

Preliminary analysis indicates that OTS has jurisdiction over biotechnology under TSCA and that new genetically engineered substances may be new chemical substances subject to PMN requirements. However, any review of biotechnical material by OTS under TSCA authority -- in particular the new chemical authority -- will raise a series of technical and policy issues, which the Office is now addressing:

- Assuming OTS jurisdiction, should OTS address all of biotechnology or only genetic engineering?
- How well adapted are TSCA regulatory mechanisms and the current TSCA regulatory structure for the review and possible control of risks posed by biotechnical material?
- Where should the line be drawn between "naturally occurring" life forms, which are not subject to PMN, and "new" life forms, which arguably are?
- How can differences at the DNA level be described (i.e., how would a new life form be characterized for Inventory and PMN purposes)? Can these differences be evaluated in terms of health and environmental concerns?
- Assuming an OTS role in this area, how is the Office going to obtain the necessary expertise to address biotechnology risks? How should it ensure coordination with other regulatory and research agencies?

In reviewing the possibility of a TSCA role in characterizing and controlling risks from genetically engineered material, OTS will be beginning a dialogue with other regulatory or research groups who are now involved in biotechnology or may be in the future (e.g., NIH, FDA, HHS, and NIOSH). Options and recommendations will be prepared for OTS management by the fall of 1983.

II. Existing Chemicals

Initiative 1. Issue triggered §4 rules to require testing of low production/exposure/release chemicals for which existing data indicate a need for testing if production, exposure, or release were to increase.

Discussion. OTS has found that several ITC chemicals do not warrant §4(a) rulemaking because of low production or highly limited exposure and release. In some instances, OTS has developed or is considering the development of §8(a) reporting rules or §5(a)(2) SNUR's to ensure that it is alerted to commercial changes that would warrant OTS reconsidering the need for testing. A possible alternative in such cases is to develop "triggered" §4(a) rules that would take effect only when production volume, exposure, or release criteria contained in the rule were exceeded. These rules could be developed alone or in conjunction with §8(a) or §5(a)(2) rules.

This approach would provide greater assurance that EPA would get the needed test data if production volume, exposure, or release increased. It would also trigger the cost sharing provisions of §4, so that all manufacturers of the substance, rather than simply the manufacturer who exceeded the production volume trigger, would be responsible for funding the testing.

Initiative 2. Issue significant new use rules on §4 chemicals to ensure that production does not increase or new uses develop before testing is completed.

Discussion. Section 4 test rules (and negotiated agreements) generally do not control human or environmental exposure to the substances under test, nor do they prevent further commercial development before the test data are developed. For example, the production volume of a §4 chemical could increase significantly while long-term tests were underway, increasing the extent of human and environmental exposure (and therefore, potentially, risk) and possibly complicating subsequent regulation. One way to prevent this occurrence would be to issue a §5(a)(2) significant new use rule requiring notification of EPA before production volume increased or new uses developed.

Such a rule would effectively set a cap on uncontrolled commercialization of §4 chemicals. Companies would have to stay within the bounds defined by the SNUR until the §4 test data were developed, thereby preventing the chemicals from securing a larger market before data sufficient to assess their risks had been developed.

The simplest triggers for notification in these SNUR's would be production volume limits. While other triggers might in some cases be feasible, they would be difficult to develop, particularly because most chemicals considered for test rule development are already widely used. As a result, new end uses would be relatively unlikely, and therefore a SNUR for such uses would be unnecessary.

Initiative 3: Update the TSCA Chemical Substance Inventory through a §8(a) rule.

Discussion. In compiling the TSCA Chemical Substance Inventory -- a list of chemical substances in U.S. commerce -- EPA collected supplementary data on production volume and site of manufacture. These data are now used for such purposes as conducting preliminary screens of chemicals (e.g., in selecting ITC testing candidates) and identifying manufacturers (e.g., for analyzing the impact of §4 test rules and the §8(a) preliminary assessment rule). In addition, the Inventory is also used by other EPA offices (e.g., the Office of Solid Waste, Office of Emergency Response), EPA regions, and the states as a source of production and plant site information on chemicals of concern. However, Inventory data on production volume and manufacturing sites, which were collected between 1977 and 1979, are becoming obsolete. For this reason, OTS is considering the possibility of updating the Inventory or a subset of chemicals on it.

Toward this end, OTS plans to issue an ANPR, which will solicit public comments on updating information on a subset of the 60,000 chemicals now on the Inventory. The subset could be developed by excluding certain chemicals, such as high-molecular weight polymers or certain inorganic substances generally found to be of low concern. In addition, the rule might be restricted to certain categories, such as chemicals produced at more than a certain production volume, §8(e) chemicals, and former PMN chemicals. In this way, the reporting requirements would be focused on chemicals more likely to be of concern.

Initiative 4: **Select existing chemicals for OTS evaluation through a priority-setting system, which would assign aggregate measures of risk to categories of chemicals with similar uses or structures.**

Discussion: At the present, OTS efforts on existing chemicals are triggered largely by TSCA §8 reporting mechanisms (especially §8(e)) and through literature reviews. A few existing chemical projects result from referrals from other EPA programs and other agencies. As a complement to these procedures, OTS is now exploring the possibility of developing a quantitatively based prioritization system that would indicate the relative hazard posed by different categories of existing chemicals, such as use categories.

Under this prioritization approach -- unlike most earlier OTS approaches -- chemicals would be categorized. The categories (or "clusters") could be based on similarity of use or other characteristics, such as chemical structure. A measure of the degree of risk posed by each cluster would be developed on the basis of parameters such as production volume, number of workers exposed, and toxicity measures for each chemical in the cluster. When total risk values were developed for each cluster, the clusters would be ranked. OTS review would then begin on the chemicals within the highest priority cluster, proceeding to those in the second highest priority cluster, and so on.

The use of cluster analysis to set priorities among existing chemicals has several advantages. First, such a system would be useful in identifying major categories of potential concern, warranting review under the existing chemicals program. Second, the system is essentially quantitative, so that subjectivity is limited. Third, the use of chemical clusters based on use or chemical class permits the evaluation of chemical substitutes at the same time. Fourth, this method tends to increase the efficiency of reviews, because data are gathered and analyses performed on chemicals with similar uses or structure at the same time. If such a system appears feasible, OTS believes that it would provide a useful complement to its current approach identifying candidates for existing chemicals review.