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Priorities for OTS Operation

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Office of Toxic Substances
Office of Pesticides and Toxic Substances
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NOTE

This document was prepared primarily for internal Office of Toxic Substances guidance and planning. It presents the Office Director's current position.

CONTENTS

INTRODUCTION

A. Purpose

The purpose of this report is to provide guidance to Office of Toxic Substances (OTS) staff on priorities for OTS programs over the next few years. This guidance covers both the management and substance of OTS operations. OTS staff should use this guidance in their everyday work. For example, they should expect that:

(1) projects will be approved only if they conform to this guidance and will be disapproved if they do not;

(2) performance standards will be based on outputs that support the goals and objectives given here; and

(3) their working relationships with other OTS staff must support the functional requirements of their position in the proposed organizational structure.

There will be a period of transition from the present to the intended new form of operation. OTS staff should also use this guidance to help themselves and the Office as a whole make this change as smoothly as possible.

B. Background

This report is the result of 100 days of intense activity from September through December 1981. The activity was a means of dealing with a number of problems and concerns identified by the OTS division directors, several branch chiefs and the new Office Director. The Director assigned senior staff to examine OTS goals and objectives, management and organizational issues, and the new chemicals and existing chemicals programs. They in turn selected other OTS staff to work with them on their assigned problems. During and after the 100-day period, the Office Director reviewed their findings and recommendations. The ones that were approved are presented in this report.

In each of the assigned areas, the guidance given here will have associated with it various implementation steps or activities. OTS will, for example, identify specific outputs that relate to its goals and objectives; it will develop steps for moving to and procedures for operating under its new organizational structure; and it will refine the processes used in its new chemicals and existing chemicals programs. As this report demonstrates, these elements are interrelated. The nature and timing of changes in one area will depend on changes being made in another. The Office Director will, however, give OTS staff further guidance in each area as soon as it is possible to do so. The Office Director may also revise this overall guidance from time to time as the Office gains experience in implementation and new information comes to light.

C. Goals and Objectives

The first task that any organization must perform is to define its goals and objectives. The statement presented in Chapter II provides clear priorities for the Office. It is drawn from TSCA and from overall EPA guidance. The three goals are: to provide better guidance for OTS implementation of its new chemicals and existing chemicals programs, to develop more cost-effective means for achieving industry compliance with OTS policies, and to strengthen OTS operations. In Chapter II OTS gives the reasons why these goals and related objectives are important. As indicated above, OTS will identify and set priorities for specific outputs that can be used to measure the attainment of these goals and objectives.

D. Program Guidance

The new chemicals program as presented in Chapter III, is made up of four elements: (i) the review of PMN's, (ii) PMN requirements, (iii) PMN exemptions, and (iv) followup of new chemicals. The overall direction of the existing chemicals program (see Chapter IV) has five parts: (i) focusing on reduction of unreasonable risks, (ii) emphasizing voluntary control by industry and the public, (iii) concentrating evaluation and control efforts on specific problems of chemical activity, (iv) directing those efforts at problems identified through specific TSCA mechanisms, and (v) exchanging technical information with industry, labor groups and others on particular problems.

In these programs, the limited resources of OTS will be focused on problems that pose (or are likely to pose) significant risks to health or the environment. Very minor risks, even if they could be controlled quickly or at little cost, will not be addressed. The new chemicals program is intended by TSCA to be a preventive program. For existing chemicals, in contrast, a preventive focus would have to be at the expense of ameliorating present risks. OTS's existing chemicals program, therefore, will concentrate on solving problems that currently pose a significant health or environmental risk, rather than on attempting to identify and prevent problems that might occur in the future.

A simple 50/50 or other split of OTS resources between the new and existing chemicals programs would belie the more complex balancing needed to achieve the Office's goals and objectives. For example, the Administrator's and the Assistant Administrator's guidance is that activities specifically mandated by statute or court order should take priority over other activities that are discretionary in nature. For OTS this means that, while having an effective PMN process for new chemicals is a very high priority, the Office will not sacrifice meeting statutory and court commitments on existing chemicals to conduct detailed

reviews on a few more PMN's. More generally, high priority existing chemicals projects will not be allowed to slip because of large PMN workloads.

E. Organizational Structure

At the beginning of the 100-day initiative, the existing OTS senior staff strongly expressed the opinion that there were serious problems with the way the Office has been operating over the past few years. By analyzing these problems it was found that they could best be resolved by a change in the organizational structure of the Office. In fact, it became evident that ensuring effective and efficient operation was the single most important issue to be faced. As a result, the Office Director and senior staff spent considerable time in designing the organizational structure that they thought would prove best. This structure is a matrix organization. This proposal is now under consideration by the Administrator. If approved, OTS will try to implement the necessary reorganization as quickly as possible so that OTS staff will not be left in limbo long and the improved management it offers can be instituted soon.

The guidance given in this report represents a commitment by the Office Director to make consistent decisions and to enable OTS staff to work productively toward common ends. OTS's future success depends in large measure on how well this guidance is followed.

CHAPTER II -- GOALS AND OBJECTIVES

No Office can operate effectively without an overall sense of mission that can be translated down to more specific guidance for action. EPA has legislation, the Toxic Substances Control Act (P.L. 94-469) or TSCA, passed in October 1976, that sets forth the overall policy for the Office. TSCA states that "It is the policy of the United States that:

(1) Adequate data should be developed with respect to the effect of chemical substances and mixtures on the health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;

(2) Adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and

(3) Authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."

The law authorizes a number of more specific measures that can be used to implement this policy. It has been the responsibility of EPA, under this law, to develop a program for using these measures. In order to do so, OTS has identified four main categories of activity. These are:

(1) gathering needed information on selected chemicals that are being or may be manufactured or processed for commercial purposes in the United States;

(2) ensuring that industry develops and/or provides information (e.g., testing results and existing health and safety data) on how selected chemicals affect or may affect human health and the environment;

(3) ensuring that chemicals judged to pose unreasonable risks to health and the environment are adequately controlled; and

(4) subjecting new chemicals to a premanufacture review before they are allowed into the United States marketplace.

While these activities sound quite straightforward, the means for implementing them are, in fact, quite complex. After five years of operation, EPA is now attempting to bring more concerted and efficient direction to them. The Office of Toxic Substances has established three goals for improving its operation and under each goal a number of objectives. OTS is already moving ahead to meet these goals and objectives as shown in the following chapters.

GOAL I: To provide better guidance for OTS implementation of Its New Chemicals and Existing Chemicals Programs.

Such guidance is essential for improving the productivity of the Office in order to do more with less and for telling the public what to expect. It provides a framework for even-handed implementation of the law.

OBJECTIVES:

(1) To meet all statutory and court-ordered obligations.

The EPA Administrator and the Assistant Administrator for Pesticides and Toxic Substances both have highlighted this as a major agency objective. It demonstrates a commitment to implement TSCA as Congress intended.

(2) To establish priorities among discretionary TSCA authorities.

Such priorities are needed to focus those OTS resources not committed to meeting statutory and court-ordered obligations on a limited number of activities that will be accomplished.

(3) To adequately articulate the reasons and assumptions for OTS decisions.

Such articulation should increase understanding of OTS's policies by industry and the public, making voluntary actions more likely to be consistent with OTS policies. It should also improve the understanding of those decisions by OTS staff, thereby increasing the focus of their effort in the future.

(4) To improve the scientific basis for OTS decision-making.

Decision-making under TSCA is generally based on the scientific concept of risk, as modified by the judgmental factor of "unreasonableness." OTS's program thus is required to have a scientific base, which must be sound in order to be credible.

GOAL II: To develop more cost-effective means for achieving industry compliance with OTS policies.

OTS must find ways to ensure that the intent of TSCA is carried out by the most efficient and least onerous means.

OBJECTIVES:

(1) To increase voluntary data development and voluntary safe handling of chemicals by industry.

In most cases, voluntary action can be implemented faster and at lower cost to EPA and industry than regulatory proceedings.

(2) To use TSCA authority to control industry behavior where voluntary action is inadequate.

Strong, defensible regulatory action where necessary is essential to motivate voluntary agreement as well as to correct the specific problems at which it is directed and to ensure consistency in toxic chemical control.

(3) To eliminate any unnecessary burdens on industry of TSCA actions.

Industry resources for chemical evaluation and control are limited; they should be devoted to dealing with real problems, not meeting unnecessary requirements. This will promote voluntary cooperation when the "burden" is seen by industry to be necessary and useful.

GOAL III: To strengthen OTS operations.

TSCA implementation is entering its sixth year in a time of dramatic cuts in Federal programs. OTS must strengthen its program to remain viable.

OBJECTIVES:

(1) To improve OTS's organizational maintenance capabilities.

To be an effective force in the future, as well as today, OTS must maintain and strengthen its staff's capabilities and its overall ability to manage its operations.

(2) To improve OTS relationships with other EPA offices and agencies.

TSCA actions must be closely coordinated with other offices and agencies because of potential overlaps of authority. Better coordination can reduce costs and save time for OTS by eliminating duplication of efforts.

(3) To improve OTS relationships with industry, labor and public interest groups.

These relationships are essential to OTS's statutory information gathering and control efforts. Full and frank exchange of information will promote consistency, clarity and voluntary cooperation.

CHAPTER III -- NEW CHEMICALS PROGRAM

A. Introduction

This chapter describes OTS's overall approach under TSCA to new chemicals. In developing this approach, OTS has focused not simply on premanufacture notice (PMN) requirements; it has also considered other elements important in a comprehensive new chemicals program. The program reflects a balancing of the following elements:

(1) Review of PMN's. The review of PMN's will be accorded high priority. Subjecting new chemicals to meaningful review is essential to ensure that risks associated with new chemicals are adequately characterized and, where necessary, controlled.

(2) PMN requirements. PMN submitters will be required to provide only the information specified in the Act. This should be sufficient for review of the vast majority of PMN's. When more information is needed, OTS will seek it on a voluntary basis. If the information is not provided, OTS will issue section 5(e) orders to obtain it. The Office will use section 5(e) flexibly, so that incentives are provided for industry to characterize risks better.

(3) Exemptions. By developing exemptions for low risk chemicals from PMN requirements, OTS will minimize PMN costs without significantly increasing risks to health and the environment. Exemptions will also allow EPA to focus its resources on new chemicals of potential concern.

(4) Followup of new chemicals. OTS's followup program will place a bound on the risks associated with new chemicals. Judicious use of section 5(a)(2) significant new use rules supplemented by section 8 information gathering will provide important protection against risks associated with new chemicals after commercialization with minimal burdens on industry.

In implementing an effective new chemicals program, OTS will fully integrate each of these elements into a coordinated overall approach. Any changes in one element of this approach will be examined for potential impacts on other elements.

B. Background

Congress instructed EPA to address risks posed by new chemicals before commercialization and therefore to protect human health and the environment from unreasonable risks before damage occurs. As the TSCA Conference Report states:

> The most desirable time to determine health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs before commercial production begins. Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investment is minimized. (TSCA Legislative History, p. 678).

However, the law also requires that the Agency be careful not to impede innovation and the development of new products unreasonably.

Congress authorized EPA to review new chemicals in section 5 of the Act, which states that manufacturers must notify EPA at least ninety days before they make a new chemical. In EPA's premanufacture review program, which has been in operation since July 1979, the Agency has reviewed over 1,000 PMN's. This program has had some good results: A competent scientific staff has been assembled to review PMN's; methodologies for predicting potential risks, given limited technical data, have been developed, although further refinements are needed; and EPA dealings with industry and other members of the public have been effective -- communications are open and informal rather than highly bureaucratic. The Agency has generally been able to persuade manufacturers to adopt voluntary measures to control exposure when it has identified specific concerns; section 5(e) orders have been issued only when the voluntary approach has failed. Most important, EPA has identified and prevented or reduced risks to health and the environment that might have been posed by a significant number of new chemicals. Several PMN's have been withdrawn during the review period as a result of EPA concerns, and in approximately sixty cases manufacturers have agreed to develop further data or institute exposure controls at EPA's suggestion.

In its experience with the PMN program to date, OTS has been able to make the following observations:

- Relatively few data are submitted on new chemical substances. This is due, in part, to a perception on the part of the regulated community that most PMN chemicals are not intrinsically hazardous. The degree to which this may be an accurate perception is perhaps best addressed in considering an exemptions policy.

- EPA has had some concern about a number of other new chemicals and has successfully negotiated voluntary controls or further data for approximately sixty.

- Only a small number of new chemicals have warranted formal action. Nine PMN's have been subject to section 5(e) orders, and several others were withdrawn before a section 5(e) order was prepared. All of these orders were based primarily on the "may present" rather than the "substantial exposure" finding. No section 5(f) orders have been issued.

- Relatively few PMN chemicals have gone into commerce. (EPA has received Commencement of Manufacture Notices on only about one third of the chemicals that have completed PMN review.)

- New chemical substances are produced in relatively low volumes. Twenty-five percent of PMN chemicals have projected third-year volumes below 11,000 kg. Only 15 percent have projected third-year volumes in excess of 1,000,000 kg.

- PMN's contain only early projections of a chemical's eventual production volume and uses; therefore, they provide limited information concerning the circumstances that will actually develop once the chemical is commercialized.

These facts suggest that, despite its successes, the PMN program as it is now conducted is not completely adjusted to the realities of commercial chemical development. On the one hand many new chemicals of low concern may be subject to notice requirements unnecessarily; on the other hand, new chemicals potentially of concern but not warranting action early in commercial development may now enter commerce without any subsequent EPA review.

To date, OTS has concentrated on developing an effective process for reviewing PMN's. The Office will continue to refine this process, both by focusing the initial information requirements it has proposed for PMN's and by emphasizing voluntary means and the use of section 5(e) to obtain further information, where necessary. OTS will also develop rules under other sections of TSCA to complement the PMN review program and to establish a comprehensive new chemicals program. Specifically, it will exempt certain categories of low risk chemicals under section 5(h)(4), and it will develop followup rules on chemicals of concern under sections 5(a)(2) and 8(a). In this way, OTS will ensure that Agency resources are focused on new chemicals of concern, while burdens on industry are minimized.

The remainder of this chapter describes OTS's overall approach to new chemicals.

C. Review of PMN's

The review of PMN's will continue to be accorded a high priority within OTS. Although industry has made strides in protecting health and the environment, a credible PMN program, subjecting new chemicals to meaningful review, is needed to ensure that risks associated with these chemicals are adequately characterized and, where necessary, controlled.

1. Factors of concern in review. OTS has developed several basic principles in the PMN program for reviewing new chemicals and allocating resources:

- The PMN review addresses the entire life cycle of new chemicals (that is, no part of the life cycle of new chemicals is routinely excluded). Therefore, occupational exposure; releases to air, water, and land; and consumer exposure are reviewed to determine if they raise a potential concern. Congress clearly intended the PMN review to take this broad approach.

- The review focuses on the new chemical itself as it will be manufactured (i.e., including reasonably anticipated impurities). The program provides only a limited evaluation of the byproducts of manufacture and processing and focuses to the greatest extent on byproducts of use.

- The review focuses on chronic or irreversible effects. Such effects may typically manifest themselves even at low exposure; in addition, because there may be a long latency period, such exposures are often not recognized at the time they occur. Acute effects are more immediately obvious and more generally controlled. Nevertheless, acute effects are considered when potential toxicity is severe, particularly if the exposed population is not likely to be aware of potential hazards.

- Both human health and environmental effects are addressed in PMN review. However, the emphasis of the review is on human health risks. OTS has adopted this approach in part because the relatively low production volume and release levels of new chemicals tend to limit environmental concentrations and therefore risk. In addition, environmental assessment methodologies are not as well developed as methodologies for assessing human health risks, and the data base is not as extensive. Nevertheless, in spite of these factors, OTS is continuing to develop its environmental assessment capabilities and will take action where significant environmental risks are identified (such as significant impacts on fish populations).

- Potential risks must be assessed at least in part through structure-activity analyses -- that is, the toxicity of new chemical substances is estimated from their structural similarity to chemicals of known toxicity. This has been necessary in part because of the sparsity of test data on the new chemicals themselves. Although conclusions drawn on the basis of structure-activity analyses must be tentative, there is a great deal of evidence to support the usefulness of this approach when conducted by trained toxicologists and chemists with broad expertise.

2. Data development on new chemicals. Congress did not require testing of new chemicals under section 5. Instead, EPA is given the authority under section 5(e) to require testing of specific new chemicals when it can make the appropriate finding.

OTS's experience with the PMN program indicates that relatively limited health and environmental-effects testing is performed on new chemicals prior to PMN submission. There are several reasons for the sparsity of test data in PMN's. First, many new chemicals do not warrant testing: some belong to chemical classes the biological activity of which is already well characterized; others are produced in low volume or used in ways that lead to limited exposure (e.g., site-limited intermediates). Second, because new chemicals are early in commercialization, they often cannot support the costs of extensive testing. Third, many manufacturers traditionally have not done testing at this stage in a chemical's development, even when it was economically feasible. Finally, manufacturers may be reluctant to create and provide the government with information because of a fear that the government will act precipitously in response to positive data.

Limitations in data, however, in some cases limits EPA's ability to review risks. OTS is structuring the new chemicals program so that essential data can be developed when needed. The Office has two basic tools for achieving this end. The first is the significant new use and section 5(e) authorities. The judicious use of these authorities can allow for the tracking of chemicals of concern so that risks can be managed over the commercial life of the chemical. The second tool is the information-gathering authority of section 8. As described later, these authorities will be used to construct a new chemicals followup program for chemicals of concern that will allow EPA to review data at a later stage of commercialization.

In addition to using these formal mechanisms, OTS will continue to work with individual PMN submitters to encourage the development of needed data on a voluntary basis. In the past, OTS and industry have been able to resolve important uncertainties through such a voluntary approach.

The Organization for Economic Cooperation and Development (OECD), a multinational group including the United States, has adopted a set of uniform guidelines for testing the health and environmental effects of chemicals. Where manufacturers elect to conduct tests on new chemicals, either in support of a PMN or in response to a section 5(e) order, OTS encourages them to consider these guidelines. In addition, the OECD is considering the adoption of a Minimum Premarket Data (MPD) set recommended for new chemicals entering the commercial market. The information provided by this data set is frequently useful in assessing risks posed by such chemicals and in identifying areas where further testing should be conducted. TSCA, however, does not require across-the-board testing of new chemicals. PMN experience confirms that rigid testing schemes for these chemicals are inappropriate -- in some cases, all the MPD data are not necessary; in other cases, other chemical properties should be assessed. Therefore, as the OECD recognizes, manufacturers should use judgment in determining which tests should be conducted on a specific new chemical. They should base this decision on such factors as chemical identity, production volume, intended uses, and likely exposure.

3. Actions under section 5. Although PMN submitters have generally provided relatively limited health and environmental effects data, OTS has taken few actions under section 5(e) to require the development of additional data.* This situation reflects four facts. First, the limited production volume and uses of most new chemicals generally lead to low exposure and consequently low risk. Second, OTS has taken the position that the section 5(e) "may present" finding must at a minimum be supported by test data or by a strong structure-activity case (e.g., that the new chemical is a close analog of substances of known biological activity). Third, OTS has focused primarily on the use of section 5(e) to gather test data rather than to gather other information necessary for a reasoned evaluation of risks posed by a new chemical. Finally, the Office has not considered taking section 5(e) action on new chemicals because of substantial exposure without specific concerns for potential toxicity.

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* Section 5(e) authorizes EPA to regulate a new chemical, pending the development of information, in the absence of information sufficient "to permit a reasoned evaluation of the health and environmental effects" of the substance if it makes the finding that the substance "may present an unreasonable risk of injury to health or the environment," or that the substance "is or will be produced in substantial quantities" and "either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance."

In the future, OTS will use the section 5(e) authority more flexibly. For example, if the circumstances of early commercialization limit the risks from a new chemical, but the standards for section 5(e) actions are otherwise met, the use of a "delayed trigger" section 5(e) order would allow the chemical to enter commerce. Data submission would be required later, either after a certain number of years or after a specified cumulative production volume had been reached. The decision to use a delayed-trigger section 5(e) order or an immediately effective order will depend on the potential risks and the commercial future of the new chemical. Where the magnitude of the potential risk and the level of certainty that such risks will occur is high, OTS will continue to impose immediate controls. However, where the risks are limited or where there is less certainty, it is reasonable to allow limited commercialization and to provide for data submission at a later time, when the costs associated with testing would be less, compared with sales volume, and when manufacturers would have greater certainty of the chemical's commercial potential.

OTS will also use section 5(e) more broadly to obtain exposure and release information (as well as toxicity test data) needed to make a reasoned evaluation of new chemicals. Industry has often suggested that EPA use section 5(e) for this purpose.

Finally, OTS is placing more emphasis on the use of section 5(e) in cases of "substantial exposure" where there is some basis for concern. The Office has adopted the policy that, where production volume and exposure are high, section 5(e) will be invoked if there is significant uncertainty concerning the effects of a chemical; in this way, OTS will use section 5(e) to ensure that risks of new high-volume chemicals are adequately characterized. This approach is especially justified because high volume chemicals are better able to withstand the greater costs of characterizing risks.

After reviewing nearly 1,000 PMN's, OTS has not yet seriously considered issuing a section 5(f) order.* The reason for this is clear: few if any new chemicals are sufficiently characterized to support a finding that they "will present" an unreasonable risk. It is much easier to make the "may present" or "substantial exposure" finding of section 5(e). Therefore, the section 5(e) authority can be more readily used to control risks from new chemicals. Also, where risks are so evident as to warrant action under section 5(f), they will typically be identified by the manufacturer. In this case, the risks will be

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* If EPA finds "that there is a reasonable basis to conclude" that a new chemical substance presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 6 can protect against such risk," the Agency can regulate the substance under Section 5(f).

adequately controlled or no notice will be submitted. For these reasons, it appears that section 5(f) is a practical regulatory tool only in special circumstances. In the event that a section 5(f) issue arises, it would be handled on an ad hoc basis.

4. Relative risk ("me-too" issue). Many new chemical substances present risks comparable to risks presented by structurally similar existing chemicals. In reviewing new chemicals, OTS considers these comparative risks. For example, when a new chemical of concern would substitute for a chemical of greater concern, the Office has generally declined to take action on the theory that it should not do anything to discourage substitutions that would lead to a significant reduction in risk. It has also been argued that EPA should not take action against a new chemical if existing substitutes present comparable risks. OTS has generally rejected this approach: It is Office policy that the Agency should not refrain from regulatory action against a new chemical simply because risks posed by the new chemical were likely to be comparable to risks from similar chemicals already on the market. Thus, OTS has rejected the "me-too" approach to new chemical regulation.

The rationale for OTS's approach is two-fold: (1) Congress intended that EPA subject new chemicals to a higher standard than existing chemicals, and (2) OTS should discourage innovation in classes of chemicals of known concern without the development of adequate data. This policy must be applied flexibly. In circumstances where chemicals provide significant benefits, EPA should not take action in cases of comparable risk. In general, however, the rejection of the "me-too" principle is essential for a viable new chemicals program. Most potential actions under section 5 will raise questions of comparable risk because new chemicals are typically modifications of existing substances. If actions were not taken in such circumstances, EPA's authority under section 5 would be seriously compromised. This would clearly contradict Congress's intent that EPA treat new and existing chemicals differently.

D. PMN Rule

The major purpose of a PMN rule would be to tell the public what information must be submitted as part of a premanufacture notice. The proposed PMN rule and forms, which appeared in the Federal Register of January 10 and October 16, 1979, are controversial. Industry generally views the rule as overly burdensome and argues that submitters would be required to go through the expense of providing information that is generally not needed to review PMN's. In addition, many commenters argued that EPA overreached its authority in interpreting the Act's requirements. On the other hand, some environmental and labor groups have stated that the proposed rule would not provide EPA with enough information to perform an adequate review.

It is clear that the form reproposed on October 16 is imposing, even though it is considerably simpler than the January 10 form. OTS has also learned, after two and a half years of experience with reviewing PMN's, that much of the information required in the latest proposal is not, in fact, needed for the review of most notices. Therefore, OTS now believes that the information requirements should be further focused and that submitters should be required to provide only the minimum specified in section 5(d)(1) of the Act, which references the information required in section 8(a)(2)(A-G) except (E):

(A) The common trade name, chemical identity, and molecular structure

(B) The proposed categories of use

(C) Estimates of the total amount of the substance to be manufactured and of the amount to be manufactured for each proposed category of use

(D) A description of byproducts of manufacture, processing, use, and disposal of the substance

(F) Estimates of the number of individuals who will be exposed in their places of employment, and the duration of such exposure

(G) The manner and method of disposal.

Given this general list of information requirements, two specific questions remain: (1) How should these information requirements be interpreted? (In other words, what information, specifically, should submitters be required to provide?) and (2) Should EPA publish a mandatory form, which submitters would be required to use?

1. Information requirements. As with most statutory provisions, the information requirements listed in section 5(d)(1) are subject to different interpretations. The proposed PMN rule represents an expansive interpretation. OTS is now adopting a narrower interpretation. Information that is clearly specified in section 8(a)(2)(A-G) except (E) must be required. In addition, information that is essential for the review of most PMN's and that reasonably falls within the intent of section 5(d)(1) will also be required. Other information would be optional.

OTS will still have means at its disposal to gather information for the minority of PMN chemicals on which further information is required to make a reasoned evaluation. Informal requests to the PMN submitter have generally in the past proved adequate to secure needed information; OTS will rely increasingly on this mechanism. Nevertheless, there may still be

circumstances under which a submitter refuses essential information. If this occurs, OTS will issue a section 5(e) order if the necessary findings can be made.

2. Mandatory form. OTS intends to require PMN submitters to complete a simplified form. The form will be easy to fill out so that burdens on the submitter are minimized. It will establish a uniform standard providing submitters a clear idea of what is expected of them; it should make it easier to familiarize submitters with PMN data requirements. In addition, the form would facilitate OTS review of PMN's and the computerization of the information submitted in the notices.

E. Exemptions

As previously stated, many new chemicals present little risk and do not warrant full-scale PMN review early in commercialization. Requiring a PMN on these chemicals imposes a burden with relatively few if any health or environmental benefits. A carefully designed exemption policy under section 5(h)(4) will eliminate much of this burden without significantly increasing risk to human health or the environment.

A section 5(h)(4) exemption, to be usable, must be structured so that it exempts categories of chemicals. OTS experience in its section 4 test program and elsewhere indicates that it is a difficult and controversial task to make findings on categories of chemical substances. Defining classes of chemicals that "will not present an unreasonable risk" may be equally difficult. However, OTS does not expect to achieve a fail-safe system; its goal instead is to develop exemptions that will provide reasonable assurances that exempted chemicals will not present such a risk.

In a recent petition, the Chemical Manufacturers Association (CMA) identified polymers, site-limited intermediates, and low-volume chemicals as candidates for a section 5(h)(4) exemption. The CMA approach follows two general lines of reasoning. First, polymers represent a class of substances that have intrinsically low levels of biological activity. Thus, the finding of no unreasonable risk could in this case be made primarily on the basis of inherent toxicological properties; the finding would not depend on conditions of use. As a result, it would not be necessary for EPA to review the specific properties or uses of exempt polymers before they were manufactured. On the other hand, low-volume chemicals and site-limited intermediates are not intrinsically limited in potential toxicity; instead, they are characterized by limited exposure. For this reason, CMA has suggested that chemicals in these classes be eligible for exemption only after a "qualified expert" employed by the manufacturer establishes that the chemical is not hazardous under the conditions of use. In addition, the exemption would provide for an abbreviated OTS review, based on the submission of minimal data.

Review by an industry "qualified expert" may compensate for the absence of toxicity restrictions for these exempt chemicals. However, an acceptable definition of "qualified expert" and standards for a minimal risk assessment will be very difficult to develop. While OTS is making progress in this area, a qualified expert provision is unlikely, by itself, to ensure that no unreasonable risk may occur. Therefore, it is essential that EPA subject each exempt site-limited intermediate and low-volume chemical to an abbreviated review, perhaps before manufacture begins under the exemption.

An important issue to be resolved is the amount of information that would be required in an exemption notice. If exemption notices are burdensome, exemptions will not be used; however, OTS will need enough information to be reasonably sure that a chemical is eligible for the exemption. OTS is considering this fact in defining its information needs.

As a necessary part of the abbreviated review, EPA should have the authority to declare a chemical ineligible for the exemption if it determines that the chemical may present an unreasonable risk. Although industry has expressed concerns that such authority will add considerable uncertainty to the exemption process, manufacturers will in fact have a high degree of certainty that EPA will rarely declare a chemical ineligible. This is because (a) the exemption already defines a low-risk category, (b) the qualified expert will have assessed the chemical and certified that it is eligible for the exemption, and (c) the "may present" standard will ensure that only chemicals of real concern are excluded. CMA originally suggested a very different approach; under the terms of the CMA petition, EPA would be able to act against an exempt chemical only if it could demonstrate an imminent hazard under section 7. Because OTS has not yet seen a new chemical that met the standards for a section 5(f) order, it seems implausible that a new chemical to be manufactured under the terms of the exemption would meet the criteria for action under section 7.

CMA has suggested and OTS believes that it is important that exempt chemicals not be placed on the TSCA Inventory. This will go a long way toward solving a major problem with the PMN program as it now operates. Under the current system, EPA receives notices on many new chemicals whose toxicity is sufficiently characterized for their proposed conditions of manufacture and use (e.g., many site-limited intermediates and low-volume chemicals). However, the toxicity of these chemicals may not be sufficiently characterized for uses that involve more exposure. Under the current program, these chemicals are added to the Inventory after commercial production begins. At this point, they may be produced in any volume and for any uses without restriction or prior EPA review. If, on the other hand, these chemicals were exempt from PMN notice for low-exposure uses and were not added to the Inventory, they would be subject to notification before manufacture for nonexempt uses. In this way,

EPA would receive a PMN at a point in the chemical's commercial development when it could expect risks associated with the new chemical to be characterized more fully.

F. Followup*

EPA's review of chemicals at the premanufacture stage must focus on the intended methods of manufacture and use described in the PMN, and it is based on toxicity data that the manufacturer has developed before commercialization. After a new chemical is entered on the Inventory, however, unrestricted commercialization is possible (in the absence of a significant new use rule) without further data development or EPA review. Thus the PMN review addresses an extremely narrow segment of the risks that may eventually be posed by new chemicals. For this reason, a credible followup program is an essential element of the new chemicals review program.

Followup will be based on several principles derived from OTS experience in the PMN review program. These principles are described below.

- Most new chemicals will not be subject to followup rules. Followup will be focused instead on chemicals of concern and substances for which there is significant uncertainty concerning toxic effects. (This is particularly true for followup under significant new use rules.)

- Most new chemicals do not become established in the marketplace and few grow to significant production volume (indeed, the production volume of a high percentage of existing Inventory chemicals is below 50,000 kg a year). Therefore, EPA will complement the PMN review by later review of certain chemicals that achieve commercial success.

- Because of the cost of testing and limited exposure early in commercial development, extensive testing may be more appropriate later in a chemical's commercial development. If EPA does not follow up new chemicals of concern, data necessary to characterize risks posed by these chemicals later in their commercial development in many cases may not be developed.

The followup of new chemicals will rest primarily on sections 5(a)(2) and 8(a). The following sections explain how these authorities will be used.

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* The appendix to this chapter explains in more detail OTS's program for followup of new chemicals.

1. Significant new use rules. OTS will issue SNUR's on new chemicals where it has significant concern about possible new uses of a chemical or class of chemicals, where it believes those uses reasonably may occur, and where review under section 5 is necessary to protect health and the environment against unreasonable risk before it occurs. Examples of a new use might be: (a) reaching a designated production volume, (b) a new consumer exposure, and (c) uses inconsistent with controls required in a section 5(e) order that does not ban production of a new chemical.

2. Section 8(a) information-gathering authority. OTS will also implement the section 8(a) authority to gather information on selected new chemicals after they have entered commercial development. This will allow OTS to identify risks posed by new chemicals of concern after they have entered commercial production but early in their commercial development. Formal action in response to information received under section 8(a) must be taken under other authorities of the act (e.g., sections 5(a)(2), 4 and 6). OTS's priorities for action on chemicals under these authorities will be independent of its priorities for action on fully commercialized chemicals on the Initial Inventory.

To achieve these ends, OTS will issue chemical-specific, volume-triggered section 8(a) reporting rules on new chemicals of significant concern. The Office has rejected a generic approach to section 8(a) followup of new chemicals. It will require followup reporting only where it has identified specific concerns.

Section 8(a) followup rules will focus on gathering information on production volume and use and will be structured so as to impose a minimum reporting burden on submitters. The information reported under this rule will allow OTS to target its resources on recently commercialized chemicals of concern. Since information requirements will be limited, the burden of the rule will not be great. When information is provided, OTS will be in a position to decide whether action is appropriate, such as the encouragement of voluntary testing, requirement of testing under section 4, issuance of a SNUR, referral of the information to another agency for possible action, or regulation of the chemical.

CHAPTER IV -- EXISTING CHEMICALS PROGRAM

A. Introduction

The focus of efforts on existing chemicals during the 100-day initiative was to identify and resolve the primary problems that have led to a sense that the OTS existing chemicals program is misdirected and accomplishing little. OTS identified problems in the following areas:

1. Inadequately defined objectives for the existing chemicals program efforts.

2. Inadequate communication and coordination of efforts with other offices and agencies, industry, and other outside groups.

3. No approved "process" for conducting existing chemicals evaluation and control efforts.

4. Inadequate management to achieve existing chemicals program objectives.

The first two problem areas were addressed in the existing chemicals study whose conclusions are presented in the following sections. The third is addressed through the design of a possible existing chemicals process for OTS that is described in an appendix to this chapter. The fourth problem area is being addressed through a broader reassessment and restructuring of the OTS organizational structure.

B. Objectives

The existing chemicals efforts of OTS generally lack the action-forcing characteristics of the PMN process -- a need to make decisions on specified chemicals within a fixed time period. As a result, OTS's existing chemicals efforts require a clear focusing by management if they are to be effective. One of the primary projects of the 100-day activity has been to define such a management focus to guide OTS existing chemicals efforts. That focus, which draws upon and applies OTS goals to existing chemicals, is presented in this section. Its fundamental directions (and redirections) are:

(1) OTS's primary mission is to bring about reduction of unreasonable existing health and environmental risks to levels where the residual risk is not unreasonable.

(2) OTS's preferred method for achieving such risk reduction is through encouraging voluntary control measures by industry and the public. OTS will

reserve regulatory controls for those instances where conflicting market forces and other factors make voluntary control infeasible.

(3) OTS will redirect its existing chemicals efforts from past attempts to develop comprehensive analyses of all effects and exposures of selected chemicals to focusing on evaluating and achieving any necessary control of specific problems that may be posed by a given activity with the chemical.

(4) OTS will give primary attention to evaluating and controlling existing chemicals problems identified through specific TSCA mechanisms, such as section 8(e) "substantial risk" notices, chemicals found to produce adverse effects in testing performed in response to recommendations of the Interagency Testing Committee, and petitions received under section 21. The ITC will also be involved in priority testing of 8(e) chemicals where the data do not support regulation due to lack of data.

(5) Because much of the information on hazards and exposures of existing chemicals is fragmented, OTS will actively seek exchange of technical information with industry, labor groups, and others early in and throughout its evaluation and decision processes. However, OTS information requests will be focused on particular problems it is concerned about -- OTS will not engage in broad-scale "fishing expeditions" to gather data where it has no specific evidence of a possible problem.

Discussed below in more detail are the principal issues OTS identified for managing its existing chemicals program.

Issue 1 -- Relative Priorities of Various Types of Existing Chemicals Activities

What should be the relative priorities in the OTS Existing Chemicals Program among the following types of activities:

a. Information collection and generation on selected chemicals or classes of chemicals aimed at providing a general data base usable by OTS, other offices and agencies, and the private sector in problem identification, problem evaluation, and possibly control efforts (Toxics Data Base Development);

b. Information collection and generation to support specific problem evaluation and control efforts of other offices or agencies on chemicals or problems

they have identified (Information Gathering Support on Specific Problems Identified by Others);

c. OTS problem identification efforts (and the necessary supporting information collection and generation efforts) focused on identifying serious health or environmental problems irrespective of the organization or statutory authority most likely to be used to correct them (Broadly Focused Problem Identification);

d. OTS problem identification efforts (and the necessary supporting information collection and generation efforts) focused on identifying unreasonable risks likely to warrant TSCA control efforts (Identification of TSCA Control Problems);

e. Encouraging reduction in risks to health and the environment through coordinating control efforts conducted by other offices and agencies (Coordinate Non-TSCA Control Efforts);

f. Encouraging reduction in risks to health and the environment through direct OTS efforts to encourage industry and/or the public to handle chemicals in ways that eliminate unreasonable risk (Work with Industry and Public to Reduce Risk Voluntarily); and

g. Using TSCA control authorities to eliminate unreasonable risk where government regulation is necessary and TSCA provides the most appropriate statutory authority (Regulate Under TSCA to Control Risk)?

Although all of these types of activites could be pursued in a comprehensive OTS existing chemicals program, two factors will limit efforts in the seven areas identified. First, at any given time there may not be suitable projects to carry out in all of these areas. Second, limited resources will require choices among the projects that could otherwise be carried out. The following is the order of relative priority OTS will follow in selecting among existing chemicals projects not specifically mandated by statute, court order, or existing EPA regulations, assuming viable projects are available in all categories.

Priority Rank	Activity	
1	(f)	Work with Industry and the Public to Reduce Risk Voluntarily

2	(g)	Regulate Under TSCA to Control Risk
3	(e)	Coordinate Non-TSCA Control Efforts
4	(d)	Identification of TSCA Control Problems
5	(b)	Information Gathering Support on Specific Problems Identified by Others
6	(c)	Broadly Focused Problem Identification
7	(a)	Toxics Data Base Development

The reasons for this ranking are as follows: First, reducing significant health and environmental risks should be the primary existing chemicals goal. This can be achieved through activities (e), (f), and (g). Among them, direct interaction of OTS with industry and the public in efforts to achieve voluntary risk reduction is likely to have the greatest payoff in reduced risk for a given amount of OTS resources. However, where regulation under TSCA is truly needed to control a significant risk, OTS will devote the effort necessary to develop sound regulations that do not impose unnecessary burdens. Achieving risk reduction indirectly, through coordinating control efforts of other EPA offices or other agencies, is another means of accomplishing the goal of reducing significant risk and OTS will try to assume that role in those instances where it is the most knowledgeable or otherwise the group best suited to do so. However, this is not OTS's primary approach to accomplishing its risk reduction goals.

Before taking actions aimed at reducing risk, OTS must identify and evaluate potential risk problems. TSCA problem identification efforts (d) are ranked next below the control efforts. This does not mean that OTS will spend all of its existing chemicals resources on control efforts and none on problem identification or data gathering, since it must have problem identification and evaluation efforts to set and order its control efforts agenda. However, the problem identification efforts will be subordinate to the control efforts rather than being seen as the primary mission. Among these efforts, OTS will give greatest priority to efforts more likely to identify problems appropriate for OTS control. Although at the earliest stages of problem identification a relatively broad focus may be necessary, OTS's goal is to narrow in on TSCA problems as quickly as possible. Where potential risks are identified that are not clearly the exclusive jurisdiction of a single non-OTS office or

agency, OTS will, as resources permit, pursue their definition to the point where the appropriate role of OTS in further evaluating and/or controlling them can be determined.

The two data gathering activities, (a) and (b), and broadly focused problem identification (c) are ranked lower because the primary focus of OTS efforts will be on TSCA implementation. TSCA does provide information gathering tools that can provide valuable data for other offices and agencies. OTS will take a more aggressive effort to "sell" its information capabilities to others, especially other EPA offices. OTS can make valuable contributions to the programs of those groups at relatively low costs to OTS by combining the needs of others with OTS's in joint information collection efforts. Nevertheless, while OTS should increase its effort in that area, it is not the primary mission OTS will pursue. In supporting the information needs of others, OTS will emphasize meeting their specific current needs, rather than broadly focused problem identification or trying to build general data bases that are likely to require substantial OTS and industry resources to maintain for possible future utility.

This general priority ranking is just that. Specific output commitments identified in annual operating plans will have to take into account other factors, especially the availability and case-by-case importance of specific projects in each area.

Issue 2 -- Priorities Among Different Types of Hazards

What types of risks should OTS concentrate on (acute vs. chronic hazards, environmental vs. human)?

The emphasis of the OTS existing chemicals program will be to correct the most serious health and environmental problems. This means that priority decisions must consider the extent of exposure (and, thereby, risk) as well as the type of hazard involved. Nevertheless, some types of hazards should (given comparable exposure situations) receive priority. Among human health effects, OTS will give priority to life shortening and chronically debilitating types of effects, as contrasted with reversible injuries. By statute (sections 4(e) and 4(f)), particular priority is to be given to cancer, gene mutations, and birth defects. Among environmental effects, OTS will give its greatest emphasis to problems likely to result in serious food or other economic losses.

Issue 3 -- Focus and Priority of OTS Problem Identification Efforts

Should the OTS Existing Chemicals Process include the initiation of information gathering and reviews to identify potential problems or should it respond only to information submitted through statutory mechanisms (section 8(e) notices, ITC list, section 21 petitions, etc.)?

For example, should OTS:

- o Gather and review information on selected industry sectors associated with developing scarcities in natural resources or emerging technologies?

- o Seek out new effects and environmental occurrence data and/or use predictive tools to try to identify chemicals that might pose significant health or environmental problems?

- o Attempt to systematically sort through and evaluate chemicals on the TSCA Inventory not currently identified as potentially posing risks?

OTS will focus its existing chemicals efforts on responding to significant health and environmental problems. The first priority in doing so will be dealing with those problems brought to the attention of OTS through TSCA statutory mechanisms (section 8(e) notices, section 21 petitions, etc.). OTS efforts to identify potential problems not brought to its attention through statutory mechanisms will be of lower priority and their extent will be decided on a year-by-year basis in the approval of the OTS Operating Plan. To the extent resources are available for OTS-initiated problem identification, they will be focused on investigating chemicals or industry sectors where there is good reason to anticipate that significant risks may occur. General screening of high production volume chemicals or of various industry or use categories "to be sure there are no problems there" is not a good use of OTS's limited resources.

Issue 4 -- Comprehensive vs. Problem-Oriented Focus

Should OTS focus its efforts on solving discrete "problems" involving a chemical or should it try to produce a "comprehensive" assessment of each chemical it deals with?

OTS will adopt a "problem-oriented" focus rather than one that attempts to produce a comprehensive evaluation of all aspects of a given chemical, industry or other subject. For example, a properly constituted citizen's petition for adoption of a section 6 rule should specify the nature of the risk to be controlled, including specification of the activity proposed to be regulated, the substance(s) involved, the nature of the adverse effect(s) expected and the population group(s) at risk. Once such a "problem" has been defined, OTS's primary focus will be on evaluating it and determining whether or not action is warranted, not on investigating other possible effects of the substance, other unrelated risks to the population group, or other activities involving the substance that also may give rise to significant risks. The last type of activity is appropriate in the context of OTS problem identification efforts that might be triggered by such a petition, but OTS's response to the "problem" posed by the petition will not be delayed while OTS

seeks to identify additional problems. OTS's own problem identification efforts will be focused on narrowing down the scope of attention as quickly as possible so the Office can concentrate on reaching a conclusion on a few specific problems. While this problem-oriented approach increases the chances that OTS may "miss" a significant problem from time to time, OTS will be more effective overall by narrowing its focus and reaching conclusions than by attempting to study all aspects of a chemical simultaneously.

Issue 5 -- Definition of Unreasonable Risk

Does "unreasonable risk" under section 6 exist when the damage to health or the environment exceeds the costs to society in reducing the risks?

OTS will interpret "unreasonable risk" under TSCA to mean a situation in which a judgment is made that the probability and magnitude of harm to society of the use of a chemical are likely to outweigh the benefits. The benefits will be determined by the uses to which the chemical is put--e.g., by itself or as an intermediate in the production of a compound or material that has valuable applications, as well as by the profits and employment due to its sales. The risks will depend on the certainty that the chemical poses a risk, the nature of the hazard (death or a temporary effect; occurrence after long-term, continued exposure or limited, high exposure; etc.), and the impact (i.e., the probability of risk to a given individual, the number of people exposed, the geographical distribution of the people exposed, etc.). OTS realizes that no formula can be used to determine unreasonable risk, since the amount and nature of the information will differ in each case. It will apply the general approach to benefit-risk analysis described here on a case-by-case basis. This is the type of analysis required of EPA by section 6(c)(1) of TSCA.

Issue 6 -- Establishing Criteria for Choosing Between Voluntary and Regulatory Approaches

Should OTS establish criteria for deciding when to encourage industry to adopt controls voluntarily and when rulemaking under section 6 should be initiated?

OTS will not attempt at this time to establish guidelines or criteria for deciding when to cease voluntary control efforts and initiate rulemaking under TSCA section 6. In all cases, OTS will explore voluntary alternatives before deciding that rulemaking is required (except where rulemaking is required by statute, as for PCB's). The decision to move from a voluntary to a regulatory mode will be made on a case-by-case basis, taking into account all of the relevant factors in the particular case.

Issue 7 -- Relative Priorities of Activities on Specific Types of Problems

What should be the relative priorities in the OTS existing chemicals program of efforts on section 21 petitions, section 8(e) chemicals, ITC chemicals, etc.?

This issue is addressed in two parts, separately considering priorities among problem identification efforts on the one hand and among evaluation and control of specific problems on the other. As indicated in the discussion of Issue 1, control efforts will generally be considered to be of higher priority than problem identification efforts, although a balanced program requires some of the latter.

a. Problem Identification Efforts

OTS will employ the following priorities in planning and carrying out its efforts to identify and define problems that warrant additional OTS evaluation and, possibly, control:

Priority Rank		Activity
1	o	Evaluating ITC chemicals after test data are received to determine what potential problems, if any, warrant further OTS assessment.
2	o	Gathering and evaluating release/exposure information on ITC chemicals before their testing is completed to identify and characterize potential problems that might warrant OTS follow-up if "positive" test data are obtained.
3	o	Preliminary evaluation of section 8(e) "substantial risk" notices to define and characterize any specific "problems" identified by the submitter.
4	o	Gathering and evaluating exposure information to identify and characterize potential problems that might be caused by chemicals reported in scientific journals, section 8(e) notices, or "FYI" notices as capable of causing adverse health and environmental effects.
5	o	Gathering and evaluating information to define and characterize potential problems, other than the specific problem(s) identified by the submitter, that may be caused by a chemical subject to a section 21 petition for control of an existing chemical.

6	o	Problem evaluation of NTP and CIIT test results, FYI notices from industry and other information from outside groups to define and characterize any existing problems.
7	o	Gathering and evaluating information to characterize potential existing chemical problems identified through PMN reviews (e.g., ZDDP's and cutting fluids).

OTS considers ITC chemicals its highest priority source of potential problems among existing chemicals. In descending order of priority, other sources OTS will use (as resources permit) are section 8(e) notices, section 21 petitions, groups outside OTS, and PMN reviews. For each source, OTS will gather and evaluate exposure and other relevant information to identify and characterize the potential problems.

b. Problem Evaluation and Control

OTS priorities for evaluation and control of existing chemical problems are as follows:

Priority Rank		Activity
1	o	Controlling problems believed to pose an imminent hazard.
2	o	Controlling problems for which the Administrator has found section 4(f) applicable.
3	o	Meeting court order on PCB remand.
4	o	Evaluating problems identified by OTS as potentially subject to section 4(f) to determine 4(f) applicability.
5	o	Evaluating problems identified in section 21 petitions to determine whether the petition should be granted or denied.
6	o	Evaluating and responding to requests for exemptions under TSCA control regulations.
7	o	Controlling problems identified and evaluated under TSCA (e.g., ITC chemicals, section 8(e) notices and section 21 petitions).
8	o	Controlling problems on which other offices/ agencies have requested TSCA control.
9	o	Evaluating the need for OTS control efforts on problems identified in Section 8(e) notices.

10 o Evaluating the need for OTS control efforts on ITC chemicals following their testing.

o Evaluating the need for OTS control efforts on non-ITC chemicals whose testing OTS has encouraged or required.

11 o Evaluating the need for OTS control efforts on existing chemical problems associated with PMN actions (e.g., ZDDP's).

12 o Evaluating the need for OTS control efforts on other existing chemical problems identified by OTS.

With one exception, controlling a problem OTS truly believes to pose an "imminent hazard," OTS's highest priorities for existing chemicals evaluation and control are activities with specific statutory or court-ordered time constraints. These activities are meeting EPA's statutory obligations under section 4(f) of TSCA to act within 180 days on any problem that the Administrator has determined to be covered by that section, meeting the court order on PCB's, performing the analysis needed to determine if section 4(f) applied to a problem, and responding to section 21 petitions within the statutory 90-day period. Next in priority below meeting its statutory and court obligations, OTS will process exemption requests under already-promulgated TSCA regulations. Once OTS adopts a rule, OTS has an obligation to promptly process such requests if the rule allows for them.

In controlling problems where OTS does not have specific statutory deadlines, the Office will give greater priority to problems identified and evaluated under TSCA than to problems where TSCA control is requested by other offices or agencies. OTS has primary responsibility for implementing TSCA and is likely to be more knowledgeable of and more efficient in dealing with the former type of problems than the latter. Nevertheless, OTS will make every effort to take on serious problems referred to it by other offices and agencies since OTS will be similarly trying to "hand-off" problems to them.

The Office's problem evaluation efforts are, of course, essential for supporting its control efforts. Problem evaluation efforts are ranked below control efforts (except for section 4(f) cases and section 21 petitions, where there are statutory deadlines) to indicate that should the OTS find itself with an overload of control problems at some time, it will focus on concluding the backlog of control problems rather than doing evaluation to develop a still larger backlog. This has not been a problem for OTS to date. Problems identified through TSCA mechanisms (section 8(e), section 4, etc.) will receive greater priority for evaluation.

C. Improving Communication and Coordination with Groups Outside OTS

OTS examined several issues related to how it interacts with outside groups (other offices and agencies, industry, labor and environmental groups, etc.) during the 100-day project. The conclusions that were reached are presented in this section.

Issue 1 -- How Can OTS Obtain Adequate Access to Information Held by Other Government Groups?

In the past, OTS has pursued various mechanisms to obtain access to information held by other EPA offices or other Federal agencies that would be relevant to OTS investigations of existing chemicals problems. In some instances, informal staff-level contacts have been relied upon, while in others more formal management-level requests have been made for information. In a few instances, broad memoranda of understanding (MOU's) have been developed with other agencies to provide a framework for information exchange and joint efforts. Despite these efforts, OTS often is not sure it is aware of relevant information that other government groups may hold.

OTS's primary effort to solve this problem is reflected in the proposed OTS organization, which would create a focal point of contact and responsibility for such coordination. This would help establish OTS's standing as a toxic chemicals information source for EPA and other agencies. Specific approaches to developing better information exchange with other government groups will be developed by as part of the OTS Operating Plan. In general, however, OTS will concentrate on developing action-oriented mechanisms to gather information needed for specific high priority OTS projects, rather than expending resources in developing broad, non-specific MOU's.

Issue 2 -- How can OTS Achieve More Effective Information Exchange with Industry on Existing Chemicals Problems?

In the past, OTS's interactions with industry to exchange information relevant to ongoing existing chemical evaluations often have been characterized by extensive contact by EPA contractors seeking information and generally infrequent contacts by OTS staff who would be in a position to discuss the Office's current perspective on the chemical or problem and to indicate what information OTS has and what additional information it is likely to need. Only as a chemical progressed to a fairly detailed stage of analysis has substantial direct exchange of information between OTS and industry taken place. There have been some notable exceptions to this rule (e.g., evaluation of ITC testing recommendations and certain section 8(e) notice evaluations) but, in general, interaction with industry in evaluating existing chemicals has been much less than for new

chemicals. In part, this may be a result of PMN's typically having an identified, single source of information, the PMN submitter, while multiple and sometimes unknown companies possess the desired information on an existing chemical problem.

To improve its information exchange activities with industry OTS will do the following:

(1) OTS will initiate a formal dialogue with industry earlier in its existing chemicals evaluation process. As a matter of course, OTS will initiate information exchange with industry on each problem that is selected for the detailed evaluation. This exchange will be initiated by OTS staff, employing contacts identified with the help of the Industry Assistance Office, rather than by OTS contractors. OTS may initiate informal information requests to industry at earlier stages in the existing chemicals process where necessary to resolve major uncertainties.

(2) To minimize duplicative information requests to industry, all contractor information gathering contacts with industry will be approved by the contract Task Officer or Project Officer before being made. The Task Officer or Project Officer will be responsible for ensuring that such requests are necessary. In the Detailed Evaluation Stage and later stages of the existing chemicals process, the project manager responsible for the problem will ensure coodination of all information requests to industry.

(3) Before soliciting information from industry, OTS will consult OTS files, search readily accessible data bases, and contact other offices or agencies known or strongly suspected to have the desired data. This will be done to avoid unnecessary requests to industry but should not discourage early contact with industry to obtain information otherwise unavailable to OTS.

(4) Generally, OTS will pursue voluntary submission by industry of needed information before using TSCA reporting requirements. However, in those instances where statutory or court deadlines would be compromised by first seeking data voluntarily or if there is a substantial reason to believe that a TSCA reporting requirement would be more cost-effective than a voluntary approach, OTS may initiate a reporting requirement at the outset. Industry comment on the Advance Notice of Proposed Rulemaking and/or proposed rule will provide a basis for evaluating whether voluntary means can suffice.

Issue 3 -- How Should OTS Make Its Information Available to Outside Requestors?

The Freedom of Information Act (FOIA) imposes a legal obligation to provide non-exempt information to outside requestors, although reasonable charges may be imposed to reflect the costs of file searches and duplication. If OTS is successful in increasing its stature as a primary Federal source of information on toxic substances, outside requests will increase, both from the public and other agencies. In view of increasingly tight budgets, OTS will exlore the feasibility of various user charges that would directly support OTS's information staff.

Issue 4 -- What Existing Chemicals Problems Should OTS Address and Which Should be Handled by Other Groups?

A perennially recurring issue in OTS's existing chemicals efforts has been which problems should be addressed by OTS and which should be "handed-off" to other offices or agencies for action. A related issue has been what level of analysis OTS should devote to a problem before "handing it off."

Strictly speaking, the statutory provisions of TSCA section 9, which provide for consideration of other Federal laws in controlling unreasonable risk, apply only to regulatory actions under TSCA. However, OTS will be guided in its efforts to achieve risk reduction voluntarily by the same principles that would apply in regulatory action on existing chemicals under TSCA.

Specifically, OTS will retain an existing chemical problem for further evaluation, voluntary control efforts, or regulatory control efforts if the available information indicates that the following four conditions are met:

(1) the problem poses a significant health or environmental risk;

(2) there exists a rationale for action under TSCA that is likely to achieve a significant reduction in the health or environmental risk;

(3) control measures that could be mandated under TSCA are likely to be cost-effective and control under other statutes is not likely to be substantially less burdensome; and

(4) the problem currently is not being addressed by another office or agency or that group has requested that OTS take over responsibility for addressing it.

Conversely, OTS will "hand-off" a problem to another office or agency when the available information indicates that these four conditions are met:

(1) the problem poses or is likely to pose a significant health or environmental risk;

(2) there exists a rationale for action under another statute that is likely to achieve a significant reduction in the health or environmental risk;

(3) either there is no appropriate basis for control under TSCA or action under the alternative statute would likely be less burdensome in achieving a substantial risk reduction; and

(4) the other office or agency agrees to accept responsibility for further consideration of the problem.

By including criterion (4) immediately above, the term "hand-off" is limited to those situations where agreement has been established between OTS and the receiving organization concerning the transfer of responsibility for the problem. In cases where OTS evaluation indicates that the problem clearly poses a significant health or environmental risk (criterion (1) is met) OTS will actively pursue such agreement before dropping a problem meeting criterion (3). However, there also will be situations in which preliminary information or evaluation indicates to OTS that <u>if</u> there is a significant risk that risk would likely be more appropriately controlled through the efforts of another office or agency. In such cases, OTS will <u>refer</u> the information or problem to the other organization without either conducting further analysis to determine the risk or attempting to obtain agreement from the receiving organization that they will follow-up. Such referrals will be treated as being on a "for your information" basis.

Some examples of situations in which it may be most appropriate for OTS to retain existing chemicals problems for OTS risk reduction efforts (voluntary first, regulatory if necessary) are discussed below.

(1) <u>Life Cycle Risks</u>

In some instances, the <u>total</u> risk from the manufacture, processing, use, and disposal of a chemical may be sufficient to cause unreasonable risk and justify control action under TSCA, but the risk from each facet viewed independently may not justify action under other narrower statutes. This approach was originally proposed by OTS to control the commercial and industrial uses of asbestos.

(2) Risks that "Fall Between the Cracks"

There may be no alternative legislation that could be used to reduce the risk to large segments of the population. For example, the OSHA Act excludes municipal employees. The asbestos in schools program has been justified, in part, because of the need to protect municipal employees. There may be other such situations. For instance, what legislation should be used to protect people from a toxic dye that may be used in fingerprinting ink?

(3) Need for the Broad Authority of TSCA

TSCA provides broad authority that can provide protection of the public health in ways not afforded by other legislative authorities, such as the authority to control commercial use.

For example, chloromethane is a toxic gas that is odorless. In the past, death and injury occurred as a result of inadvertent exposure from its use as a refrigerant. Under section 6 of TSCA, any manner of commercial use of a substance may be regulated. TSCA could have been used to require manufacturers to add an odorant to the gas so that people would be warned of its presence.

(4) TSCA Provides the Most Cost-Effective Protective Mechanism

The OSHA Act can reduce risk primarily by imposing limits on workplace exposure. On the other hand, the use of a substance can be prohibited or restricted for a specific use with TSCA. Such a use control could be more efficient than workplace controls in certain circumstances. For example, it could be more cost-effective to ban the use of nitrites in cutting fluids to prevent the formation of nitrosamines than it would be to impose stricter limits on workplace exposure. As more states move to implement their own OSHA Acts, industry will be subject to multiple, diverse control requirements that could be more costly than a single control under TSCA. For example, separate labeling requirements for asbestos-containing products by each of the states might be more burdensome than a single labeling requirement imposed under TSCA. If so, the use of TSCA would be consistent with the Administrator's efforts to impose government controls in the least burdensome manner.

(5) Control at the Source Avoids Unmanageable Enforcement

A toxic substance might be much easier to control at the source of supply under TSCA. Once the substance gets out to the multitude of small workplaces, it may be burdensome to small businesses and impossible for government to enforce controls. Workplaces with 10 or fewer people are excluded from OSHA recordkeeping and reporting requirements. Thus, the OSHA Act might not be appropriate to reduce the risk to shoemakers who are exposed to a toxic solvent in a glue used for shoe repair.

(6) TSCA Provides a "Scalpel Rather Than a Sledgehammer"

High human exposure and unreasonable risk may result from one particular use of a toxic substance and that particular use may not be critical to society if there are adequate substitutes. In this case, why impose strict workplace standards and cause high costs to the rest of the industry when TSCA controls could be applied selectively?

Although the above examples are presented in terms of TSCA regulation, OTS will seek to achieve voluntary control of such risks before moving to a regulatory approach. Nevertheless, those situations in which TSCA would be most appropriate *if* regulation were necessary are those on which OTS will concentrate its efforts at voluntary control. To do otherwise would foster situations where OTS responsibilities *vis-a-vis* other offices or agencies are unclear and where inefficient transfers of responsibilities would be required subsequently if voluntary control could not be satisfactorily achieved.

APPENDICES

APPENDIX IIIA: FOLLOWUP OF NEW CHEMICALS

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FOLLOWUP OF NEW CHEMICALS

I. Importance of a New Chemicals Followup Program

The Office of Toxic Substances states in chapter III that a credible followup program is a critical part of any new chemicals program. At the premanufacture stage, EPA's review of chemicals focuses on the intended methods of manufacture and use described in the PMN, and decisions must often be made in the absence of extensive toxicity data. After a new chemical has been entered on the Inventory, however, unrestricted commercialization is possible without further data development or EPA review. Therefore, as a complement to the PMN review program, OTS is instituting a new chemicals followup program designed to reduce possible risks from recently commercialized new chemicals and to encourage data development on these chemicals later in its commercialization.

This followup program will consist of two elements. OTS will develop significant new use rules (SNUR's) under section 5(a)(2) on specific new chemicals when it identifies new uses of sufficient concern. OTS will also use chemical-specific section 8(a) reporting rules to track the commercial growth of selected new chemicals of concern and effectively to place a bound on risks that can occur from these chemicals without Agency knowledge. If judiciously applied, these authorities will impose a minimal burden on industry, while contributing in an important way to the development of data on new chemicals and the reduction of new chemical risk.

OTS's approach is consistent with the general preventive thrust of TSCA, while reflecting the Congressional directive that EPA should not unduly impede or create unnecessary economic barriers to technological innovation. In discussing the case of vinyl chloride, the Senate Commerce Committee Report stated:

> the country has grown extremely reliant on the plastics which are produced from the chemical. In fact, 1 percent of our gross national product is associated with the vinyl chloride industry. Obviously, it is far more difficult to take requlatory action against this chemical now, than it would have been had the dangers been known earlier when alternatives could have been developed and polyvinyl chloride plastics not become such an intrinsic part of our way of life in this country. (TSCA Legislative History, p. 161)

This passage clearly indicates that risks should be characterized early in a chemical's commercialization, before an industry is committed to it and before the costs of regulation would be excessive. The most appropriate time to act to control a hazardous chemical, Congress stated, is before unreasonable risks occur and before heavy costs in jobs and wasted investments would be incurred. This passage does not imply, however, that a chemical must be fully characterized before first manufacture, particularly when the costs of such a characterization would be excessive and exposure would be adequately controlled.

A three-part strategy to promote the development of test data on newly commercialized chemicals is needed. This strategy would modify OTS's current new chemicals program so that it will be closer in line with the realities of new chemicals development.

First, OTS intends to issue a broad section 5(h)(4) rule that will exempt certain low-exposure chemicals from PMN requirements (e.g., low-volume chemicals and site-limited intermediates). If these chemicals were to be commercialized beyond the terms of the exemption, they would be subject to PMN. When PMN's were submitted, OTS would expect data appropriate for the chemicals's potential toxicity, level of commercialization, and uses. Since exempt chemicals would not be placed on the TSCA Chemical Substance Inventory, this approach would in effect institute a followup requirement for new low-volume chemicals and site-limited intermediates. This would eliminate some of the current need for a followup program under sections 5(a)(2) and 8(a).

Second, OTS will continue to rely on section 5(e) during the premanufacture review period to gather data on toxicity and will expand the use of section 5(c) to include information on exposure. In addition, OTS will use "delayed trigger" section 5(e) orders under certain circumstances to promote data development at some later point in a new chemical's commercialization. (See Chapter III for a description of delayed trigger section 5(e) orders.)

With these two policies in place, OTS will receive fewer notices on new chemicals (presumably including more data) and will more frequently request additional data on new chemicals under section 5(e). Even under these circumstances, however, EPA will still receive a number of notices on new chemicals that appear to have potential for significant toxicity, but that do not warrant section 5(e) action because uses and production volume described in the PMN indicate low exposure. In these cases, followup action under section 5(a)(2) or section 8(a) is the most effective way for the Agency to encourage the development of appropriate data later in commercialization, to ensure subsequent Agency review, and to place a bound on risks posed by new chemicals after commercialization.

The use of TSCA authorities to develop such a followup program was clearly anticipated by Congress. Senator Magnuson, Chairman of the Senate Commerce Committee, stated in the Senate consideration of the Conference Report,

> the requirement that manufacturing and processing notices be given for significant new uses of chemical substances is extremely important. As chemical substances frequently are not manufactured in large volumes or for a large number of uses initially, the authority to require notification for these substances as uses mount or as volumes increase is extremely important. (TSCA Legislative History, p. 723)

As Congress recognized, EPA's new chemicals program will be seriously limited without a followup program. Without such a program, EPA's ability to act on new chemicals and to require data development will depend entirely on the accident of how the new chemicals are initially described in the PMN and how the PMN submitters intend to use them. For example, if vinyl chloride -- the example from the Legislative History cited above -- were a new chemical, EPA's review under section 5 would be limited to a consideration of the methods of production and the uses described in the premanufacture notice. If EPA refrained from action in the absence of data during the review period because exposure was low in the uses described in the PMN, the chemical could enter full-scale commercial development without any assurance that its potential hazards would be further characterized. A major goal of the new chemicals followup program will be to reduce this potential problem by making it possible for the Agency to review new chemicals of concern after they had been entered on the Inventory but before significant new exposures occurred. To make the program effective, OTS is committing resources not only to the development of followup rules, but also to the review of followup notices and, where necessary, action on chemicals subject to followup.

OTS recognizes that a new chemicals followup program in some respects treats new chemicals after commercialization as different from existing chemicals already on the TSCA Initial Inventory. This approach is appropriate for several reasons:

- PMN chemicals are in a fundamental sense different from chemicals on the Initial Inventory. Unlike chemicals on the Initial Inventory, they have been subject to EPA review. If a new chemical that has been through PMN review becomes the next PCB or vinyl chloride, this will generally and properly be recognized as a failure of the PMN program. OTS could reduce the possibility of such an occurrence only by

requiring complete toxicological characterization at the PMN stage or by developing a followup program.*

- The new chemicals program properly addresses the full range of risks a new chemical may present as it grows in the marketplace and uses diversify. Because the PMN review addresses only the risks described in the notice, EPA can protect against risks associated with subsequent commercialization only through a carefully focused followup program.

- By its nature, the existing chemicals program generally deals with high-volume, high-concern chemicals. For these chemicals, the costs of regulation may be high. However, recently commercialized new chemicals, which have not yet reached maturity in the marketplace, can be controlled with less cost before high levels of risk occur.

For these reasons, a broader approach to new chemicals, including new chemicals followup, is justified. The following principles will guide OTS's new chemicals followup program:

- EPA will focus its followup activities on chemicals of concern. Followup will not be applied indiscriminately.

- Followup requires a commitment of resources to developing followup rules, reviewing notices when they are submitted, and acting on the chemicals as appropriate after that review.

- Followup reporting requirements will be structured so that notice occurs before significant changes in commercialization of the new chemicals, but after the chemicals have achieved a certain level of commercial success. In this way, EPA can act to require the development of data on a substance or to

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* CMA endorsed the concept of new chemical followup in its recent report, The First Four Years of the Toxic Substances Control Act (1981). According to this report, "CMA agrees that some appropriate mechanism may properly be developed to keep EPA apprised of significant events in the commercial development of [new] chemicals."

control exposure before benefits (e.g., jobs and investments) would make control actions overly burdensome.

- o While the new chemical followup program will be operated separately from the existing chemicals program, it will not proceed in isolation. In some cases, problems identified in the PMN process (or as a result of new chemical followup) will be part of a larger problem that the Agency may address in the context of the existing chemicals program.

II. Implementation of a Followup Program for New Chemicals

There are two basic authorities under which OTS will issue followup requirement: section 5(a)(2) significant new use rules (SNUR's) and the section 8(a) information gathering authority. SNUR's, because they allow review of new uses under section 5, provide a more effective mechanism for preventing risks and encouraging data development. Section 8(a) rules, while easier to develop, do not provide EPA with an effective review mechanism. (Figure 1 summarizes some of the differences between these two authorities.) For this reason, OTS is developing a followup program that relies primarily on SNUR's for situations of high concern supplemented by section 8(a). In this approach, OTS will issue (1) SNUR's on PMN chemicals for which OTS identifies significant new uses of sufficient concern, and (2) 8(a) rules requiring manufacturers to report minimal information on specific PMN chemicals of concern after commercialization. This program is similar to the followup program recommended in July 1980 by the Conservation Foundation, an industry-environmental advisory group.

As explained below, this program will be structured so that it will impose minimal burdens on industry (both because only chemicals of significant concern will be affected and little information would be required). These burdens should be seen as a tradeoff for reduced information requirements at the time of PMN submission.* Because of this, economic and regulatory impacts of this program will be considered within the context of the new chemicals program as a whole.

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* In comments on the proposed PMN forms, CMA couples its argument for a shortened form with a suggested followup program that in many respects would be more extensive than the one suggested here.

FIGURE 1

COMPARISON OF FOLLOWUP AUTHORITIES

hority	Rulemaking Standard	Applicability	Reporting Trigger	Information Requirements	Review and Control Authorities
a)	EPA "reasonably requires" information	Manufacturers and processors; small businesses exempt unless chemical is listed under §5(b)(4)	Any appropriate trigger, for example, production volume or specific time after PMN (e.g., 3 years)	Any of the information listed in §8(a)(2); legislative history indicates that this list is illustrative	No mandatory review; control under general TSCA authorities (e.g., §4, §5(a)(2), §6); voluntary controls
a)(2)	New use will be "significant," considering factors listed in §5(a)(2)(A-D)	Manufacturers and processors; no small business exemption	New uses[1]	Same information as PMN: information listed in §8(a)(2), minus (E); test data in possession or control; descriptions of other health and environmental effects data	EPA must review under §5; §5(e) and §5(f) available as well as other TSCA authorities

S has interpreted "uses" broadly. The following are examples of a new use: (1) reaching a designated production ume, (2) a new consumer exposure, (3) uses inconsistent with controls required in a §5(e) order that does not ban production of a chemical. In general, OTS believes that the notification trigger (i.e., the definition of the new should be set at a point where §5(e) action could be possible if a significant new use notice were submitted hout further data

A. Significant New Use Rules

Section 5(a)(2) of TSCA authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule, after considering all relevant factors, including (1) the projected volume of manufacture or processing, (2) the extent to which a use changes the type or form of human or environmental exposure, (3) the extent to which the use will increase the magnitude or duration of human or environmental exposure, and (4) the reasonably anticipated manner or methods of manufacture, processing, distribution in commerce, or disposal. Once a use is determined to be a "significant new use" for a given chemical substance, persons must notify EPA at least 90 days before they manufacture or process the substance for that use. This notice must contain the same information required in a PMN -- i.e., the information listed in section 5(d)(1). (However, OTS would expect that exposure information would relate primarily to exposure associated with the new use.)

The SNUR requirement may involve greater cost and more uncertainty to the manufacturer than does the PMN requirement. A SNUR, in effect, puts the manufacturer or processor on notice that a problem may exist with a particular use of a given chemical and that risks should be adequately characterized before that use occurs. For this reason, TSCA requires under section 5(g) that, if the Agency does not take action on a SNUR notice, it must publish a notice in the Federal Register stating its reasons for not initiating action.

Because of the notification costs associated with SNUR's, these rules might in some cases serve to inhibit the manufacture or processing of chemicals for new uses designated as "significant." Manufacturers and processors would commercialize a chemical for a significant new use only if they determined that the benefits to be derived from commercialization warranted the development of the data necessary to allay concerns (or if they could successfully demonstrate that exposure in the new use would be lower than anticipated). Such an effect is not only acceptable but also appropriate, since SNUR's will be used only when there is a significant level of concern.

OTS intends to issue SNUR's when (1) it believes it would have a reasonable basis for section 5(e) action on a new use if additional data were not provided, (2) new uses involving significant exposure are not unlikely, and (3) EPA review before the new use occurs (including the possibility of action under section 5) is in the public interest. Based on OTS's experience with PMN review, it appears that about ten SNUR's would be written a year on new chemicals if these criteria are applied.

As a first step, OTS will select several candidates for SNUR's from among the chemicals that are currently on the "followup queue." OTS has developed this list of approximately 170 chemicals of potential concern during the past two and a half

years of PMN review. Considerable progress has been made in the past few months identifying reasonable followup candidates from the queue. A few chemical-specific SNUR's, chosen on the basis of the criteria listed above, should allay many concerns industry has expressed about how OTS intends to use SNUR's for new chemical followup,* as well as provide important protection to health and the environment. In developing these rules, OTS will have the opportunity to resolve many specific issues associated with SNUR's (e.g., how confidential information should be handled, how "significant new uses" should be defined, etc.).

Although compliance with SNUR requirements will entail a certain burden, there are several steps OTS will take to ensure that this burden will be reasonable. For example, OTS might require notification for a significant new use only after manufacture or processing for that use had reached a certain volume. The production volume that would trigger a notice requirement could be set at a level at which the costs of developing the data would be reasonable, and at which EPA could reasonably act under section 5(e) if data were insufficient. Also, OTS will clearly state the nature of its concern in each SNUR. Manufacturers and processors could then determine what data EPA would view as necessary to allay its concerns on how exposure might be controlled. This could significantly reduce the uncertainty present in the submission of a SNUR notice.

B. Section 8(a) Information Gathering

Section 8(a) grants the Administrator broad authority to require manufacturers, importers, and processors to provide available information to EPA on any TSCA chemicals. This information can include use information, production volume, descriptions of byproducts, health and environmental effects data, exposure information, and disposal information. In issuing a section 8(a) rule, the Administrator need only find that the information is "reasonably required." While this finding is less stringent than the SNUR finding, EPA must still demonstrate sound reasons for requiring information under section 8(a), and the costs of the requirement must be justified, given the anticipated benefits.

Section 8(a) is particularly appropriate for identifying which PMN chemicals of concern are likely to prove commercial

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* In particular, industry has expressed concern about the SNUR EPA proposed on November 16, 1980, for the new chemical n-methanesulfonyl-p-toluenesulfonamide (PMN 0016). The approach OTS is now taking differs in many respects from the approach taken in this proposed rule -- which defined "significant new uses" very broadly and did not reflect affirmative toxicity concerns.

successes and for tracking specific new chemicals after manufacture begins. Under section 8(a) rules -- which would be applied only to chemicals of concern -- EPA might require minimal information on production volume and use, as well as available health and environmental effects data. Reporting might be required at a specific production volume or after a certain number of years. Although a section 8(a) rule would not afford the protection of a SNUR (because it would not allow review under section 5), it would effectively signal circumstances of major concern before risks became unreasonable and before a new chemical of concern had grown to a point at which control would present significant economic costs.

C. EPA Action on Followup Chemicals

An important distinction between followup under section 5(a)(2) and 8(a) is that, under section 5(a)(2), EPA is required to review the notice, and it has the authorities of sections 5(e) and 5(f) available to require further data on the chemical or to regulate the chemical in its proposed new use. In addition, as mentioned previously, under section 5(g), if EPA does not take action during the review period, it must publish a notice in the Federal Register stating its reasons for not taking action.

Under section 8(a), EPA review is not required, and the Agency does not have the special authorities of sections 5(e) and 5(f). EPA, however, will have the full range of TSCA authorities available to it to control risks identified as a result of section 8(a) followup. These include section 4 test rules (and voluntary approaches to data development in lieu of a section 4 rule), section 5(a)(2) significant new use rules, voluntary controls by the manufacturer or processor, referral to another office or agency, and control under section 6. These authorities should be easier to use as part of a new chemicals followup program than they have proved for fully commercialized chemicals because the chemicals will be relatively early in commercial development. Therefore, costs associated with regulation will be lower, and industry will have greater flexibility in developing controls or in turning to alternative chemicals, if necessary.

Relatively few reports are likely to be received under the new chemicals followup program. Therefore, limited resources will be necessary to ensure an effective program. The Office is also adopting the principle that regulatory or other action against recently commercialized PMN chemicals is appropriate even if similar risks from existing chemicals are not being addressed. In other words, regulatory or other action under the new chemicals followup program will not be driven by the priorities of the existing chemicals program. Instead, where action on chemicals subject to followup would encourage the development of data necessary for an adequate review of risks or would lead to an appropriate reduction in risks, without imposing undue burdens, the Office will not hesitate to act.

APPENDIX IVA: DEFINING A POSSIBLE EXISTING CHEMICALS "PROCESS"

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Lack of an adopted "process" for identifying, evaluating and responding to existing chemical problems has hampered OTS's existing chemicals program since the reorganization of OTS in 1980. The roles and responsibilities of various divisions and branches in dealing with existing chemical problems have been confused and each problem or project has been handled largely in an ad hoc manner. Considerable work was done by OTS during the first half of 1981 to define a suitable process, but final decisions on its implementation were not made. Therefore, during the 100-day initiative OTS took another look at the existing chemicals process in the light of the objectives and directions presented in section B of chapter IV. The highlights of a possible process OTS could use are presented below. This is subject to revision as planning proceeds.

The OTS existing chemicals process must perform three primary functions:

a. Problem Definition -- the process must provide for the timely and efficient gathering and evaluation of information necessary to convert a "cause for concern" about a chemical (e.g., new test results showing adverse effects or new evidence of exposure to a toxic chemical) into one or more discrete potential "problems" on which further evaluation can be focused. A properly defined problem should identify one or more specific chemicals, effects, and exposure situations that may present a significant health or environmental risk.

b. Problem Assessment -- the process must provide for gathering and evaluating the information necessary to determine whether or not potential "problems," whether initially identified by OTS or brought to the Office's attention through such mechanisms as section 8(e) notices or section 21 petitions, actually pose a sufficiently serious risk to warrant control efforts by OTS or some other office or agency.

c. Problem Response -- the process must provide for identifying the most appropriate approach to controlling problems found to be serious and for following through on that approach, whether it be "handing off" the problem for action by another office or agency, initiating OTS efforts to achieve voluntary control, or initiating regulatory action.

The possible OTS existing chemicals process has five stages (see Figure 1). A Problem Identification and Screening Stage and an Initial Assessment Stage would carry out the problem definition function described above. These stages include verification of potential TSCA applicability to the chemical or activity involved, preliminary evaluation of information

triggering the initial concern, and initial gathering and evaluation of complementary effects or exposure information needed to define discrete "problems."

A Detailed Assessment Stage would carry out the problem assessment function. This stage includes in-depth evaluation of the strength of the evidence that the potential problem poses a significant risk, together with further data gathering and data generation as necessary.

A Risk Reduction Analysis Stage and Project Stage of the process would carry out the problem response function, including the evaluation of alternative control measures, the "hand off" of problems identified as posing a significant risk but more appropriately addressed by others than OTS, and all OTS control actions.

These are the elements of a tentative existing chemicals process. OTS will develop and refine these five stages, the steps within each stage and the procedures for carrying them out as it proceeds with implementing its existing chemicals program.