ASSESSMENT AND CONTROL OF CHEMICAL PROBLEMS

An Approach To Implementing the Toxic Substances Control Act

U.S. Environmental Protection Agency
Washington, D.C.

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PREFACE

This draft document describes a possible approach to the implementation of the Toxic Substances Control Act (TSCA). It represents the first step in the development of an overall strategy for implementation of the new law.

The purpose of this draft document is to stimulate comments from the many parties interested in implementation of the Act. These comments, together with estimates currently being developed concerning the resources required by EPA to carry out alternative levels of TSCA activities, will be considered in preparing a strategy document later this spring.

In an effort to help focus public discussion, the draft document proposes a general goal and two purposes in implementing TSCA. It suggests the initial emphasis and priority to be given to different program activities and addresses some of the major policy issues. The first three years of implementation are highlighted, and timetables for program activities during this period are proposed.

Comments on the draft document are invited. They would be particularly helpful if received by April 15, 1977. They should be sent to Mrs. Vickie Briggs, Environmental Protection Agency, Office of Toxic Substances, Room 715 East Tower (WH-557), 401 "M" Street, SW, Washington, DC, 20460. (To facilitate handling and disposition of comments, please refer to OTS-000002 in the cover letter.)

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EXECUTIVE SUMMARY

The goal of the Toxic Substances Control Act (TSCA) is to protect human health and the environment from unreasonable risks -- now and in future generations. To achieve this goal, TSCA implementation activities will emphasize not only control of specific problems under TSCA regulatory provisions, but also use of TSCA authorities to support other Governmental and non-Governmental programs to control toxic substances. These programs include other activities of EPA and other Federal and State agencies, activities of environmental and public interest groups and of professional societies, policies of the financial and investment communities, and efforts of individual companies and trade associations.

During the first several years, EPA will give top priority to the following implementation activities:

-- *Establishment and Implementation of a Premarket Review System.* The system will emphasize (a) the responsibility of industry to develop adequate data for meaningful chemical assessments, (b) categorization of new chemicals by broad chemical classes and broad uses with particular attention to those categories of greatest environmental concern, and (c) procedures for rapid decisions and adequate documentation of these decisions.

-- *Establishment of Initial Testing Requirements.* Testing will be required in a hierarchical manner on selected categories of both new and existing chemicals. Industry will be required to develop data concerning both toxicity and exposure and to conduct risk assessments of the data. Quality assurance of the data that are developed will be stressed.

-- *Regulatory Actions to Control a Limited Number of Environmental Problems Associated with Existing Chemicals.* In addition to early action on PCB's and selected chlorofluorocarbons, a limited number of serious chemical problems for which adequate data are currently available will be selected for intensive review and for regulatory action as appropriate. Concurrently, a systemmatized approach for identifying, characterizing, and controlling toxic substances under TSCA will be developed and implemented as rapidly as possible.

-- *Assessment and Control of Unanticipated Problems of Urgent Concern.* Unexpected problems will inevitably arise and provisions will be made to respond to such problems without unduly disrupting other priority activities.

In these four priority areas, as well as in other areas, continuing attention will be directed to several overarching concerns. Activities will be oriented to serve the interests of both EPA and other organizations, particularly with regard to data dissemination. Data will be gathered on a highly selective basis to serve specific purposes. Confidentiality aspects will be a major factor influencing data collection, use, and dissemination strategies and activities.

BACKGROUND

The Problem and TSCA

An estimated 1,000 new chemical substances[1] are introduced into commerce each year in addition to the 30,000 or more which are currently used in many ways. The problems posed by the presence of some of these chemicals in the environment are too well known. Assessing and dealing with chemical problems involves the complex tasks of measuring their presence, estimating their effects, and evaluating the economic and social costs and benefits of their use and control. At the same time, there exists a wide variety of often overlapping and uncoordinated regulatory authorities and support activities directed to toxic substances at the national, State, and local levels. TSCA is designed to help reduce scientific uncertainties concerning toxic substances and to add coherence to the national effort to protect man and the environment from unreasonable risks without unnecessarily blunting a dynamic sector of our economy.

The Congressional Interest

Summary of the Legislative Deliberations

Early in 1971, the Administration transmitted to Congress a proposal for toxic substances legislation. The report of the Council on Environmental Quality accompanying the proposal, Toxic Substances, documented some of the environmental problems which such legislation should address. The two Houses of the 92nd Congress passed different versions of the legislation late in the session. However, there was not time to appoint a conference committee to resolve the differences prior to adjournment.

Five different bills were introduced during the 93rd Congress, and by July 1973, the two Houses had passed different versions. However, the conference committee could not resolve several of the key differences between the two bills, including provisions concerning premarket screening and the relationship of TSCA to other laws.

In March 1976, in the 94th Congress, the Senate passed a somewhat revised version of the bill it had considered previously. In August 1976, the House passed still a different version. A conference committee met in early September, and the compromise bill that it developed was passed by both the House and the Senate in September 1976, with an effective date of January 1, 1977. The President signed the legislation on October 11, 1976.

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[1] "Chemicals" and "chemical substances" are used interchangeably in this document in addressing those substances subject to TSCA. In general, pesticides, foods, food additives, drugs, and cosmetics are excluded from TSCA coverage. The problems associated with mixtures and formulations are given special attention in the law.

During the deliberations of both the House and Senate in the 94th Congress, a number of technical aspects of the legislation were considered in detail. Thus, the committee reports of both houses, together with the report of the conference committee, provide considerable guidance concerning Congressional intent.

Findings

In proposing toxic substances legislation, the Congress found that human beings and the environment are exposed to many chemicals, some of which may present unreasonable risks due to their manufacture, processing, distribution, use, or disposal and that to address this problem, regulation of both interstate and intrastate commerce is necessary [2(a)].

Policy and Intent

The Policy of the United States enunciated in the Toxic Substances Control Act is that (a) adequate data on the effects of chemical substances should be developed as the responsibility of those who manufacture and process them; (b) authority should exist to regulate such chemicals which pose unreasonable risks and act on those which are imminent hazards; and (c) exercising this authority should assure that chemical substances will not present unreasonable risks yet not unduly impede technological innovation [2(b)]. The Congress intends that the Act be carried out in a reasonable manner, taking into account the environmental, economic, and social impact of actions taken under the law [2(c)].

Highlights of TSCA

TSCA authorizes EPA to obtain information about existing and new chemicals and take appropriate action against those which may present unreasonable risks. Manufacturers or processors of chemicals may be required to conduct tests and submit to EPA data on the effects and behavior of chemicals. EPA must be notified 90 days in advance of the manufacture of new chemicals and supplied with information necessary to evaluate their effects. When necessary, EPA is authorized to take steps to limit manufacturing, processing, use, or disposal of a chemical substance which may present an unreasonable risk.

TSCA contains several explicit authorities to promote better coordination among Federal agencies in identifying, assessing, and controlling toxic substances. If the Administrator determines that an unreasonable risk may be prevented or sufficiently reduced under a law not administered by EPA, he will request the relevant agency to evaluate the problem and take appropriate action. Similarly, other laws administered by EPA will be used in preference to TSCA when these authorities can adequately address the problems.

OVERALL PROGRAM DIRECTION

General Goal in Implementing TSCA

The general goal in implementing TSCA can be stated as follows:

TO PROTECT HUMAN HEALTH AND THE ENVIRONMENT FROM UNREASONABLE RISKS PRESENTED BY CHEMICAL SUBSTANCES.

The program to be implemented pursuant to TSCA is one of a number of efforts, within and outside Government, directed toward this common goal. These other efforts include not only other programs of EPA and other Federal agencies, but also programs of the States, activities of environmental and public interest groups and of professional societies, policies of the financial and investment communities, and efforts of individual companies and trade associations.

However, the TSCA implementation program is somewhat unique in view of its breadth of coverage and its wide ranging authorities as contrasted to the narrower scope of other programs in the toxic substances area. Thus, there are greater expectations that the program will be able to work toward the common goal on a far broader basis than has been possible in the past.

The number of adverse chemical incidents can and must be reduced. But accidents will continue to occur, and chemicals posing environmental problems will undoubtedly slip through the net of assessment and control. Development of efficient and effective means to minimize the likelihood that such adverse incidents will occur -- now and in the future -- is the challenge of this legislation.

Purposes of TSCA Implementation Activities

The purposes in implementing the regulatory and non-regulatory provisions of TSCA are two-fold, namely

-- TO CONTROL TOXIC SUBSTANCES DIRECTLY, and

-- TO SUPPORT OTHER GOVERNMENTAL AND NON-GOVERNMENTAL PROGRAMS TO CONTROL TOXIC SUBSTANCES.

Inherent in the concept of control is the necessity to match the control requirements with the problems. In many cases, chemicals do not pose a threat to health or the environment, and no control is warranted. At the other extreme, there may be a necessity to ban a chemical altogether. In each case, judicious use of control alternatives must undergird successful implementation.

The dual Purposes of direct control through the regulatory authorities of TSCA on the one hand and, on the other hand, indirect control through the use of TSCA authorities to support the efforts of other

programs in a position to control toxic chemicals reflect the clear intent of Congress. Implementation of this legislation must rely on achieving a "multiplier effect" through the efforts of many organizations if a significant number of commercial chemicals are to be addressed in the near future. Furthermore, the dual Purposes recognize the many common interests among a large variety of public and private organizations and the necessity to share and conserve resources whenever possible in addressing similar problems. Indeed, more than any other environmental legislation, TSCA should be considered as a mechanism to serve the interests of many organizations.

Several principles will guide implementation activities directed to these dual Purposes.

-- The Environmental Protection Agency will assume a position of national leadership in the field of toxic substances control. At the same time, other organizations will be encouraged to utilize the full range of their authorities and capabilities to control toxic substances. In those cases when there are overlapping authorities or capabilities, EPA will encourage the use of the most expeditious and effective approach for addressing urgent environmental problems.

-- Information obtained under the law will be made available as promptly and as widely as feasible to enable the expertise of other Federal, State, and local agencies and of the private sector to be utilized as fully as practical in meeting the purposes of the Act. Similarly, relevant information will be actively solicited from all available sources and used appropriately. International exchange of experiences and of data concerning toxic substances assessment and control will be strongly supported.

-- All interested parties will have adequate opportunity to participate in development of regulatory requirements. The basis for regulatory decisions will be clearly stated at the time the decisions are made. To the extent possible, such statements will distinguish among scientific facts and uncertainties, scientific judgements, and value judgements.

Operationally, it may be desirable to establish formal agreements with other Federal agencies, and perhaps with other Governments and with international organizations. Also, systemmatic approaches to regularly obtaining up-to-date views on the priorities of other organizations will be developed.

Major Functional Areas

The activities to be conducted under TSCA have been divided into four major functional areas and several supporting areas (see Figure 1), recognizing that all of these areas are interrelated as discussed below. In particular, the acquisition and assessment of information provides the basis for regulatory and related decisions by both EPA and other organizations.

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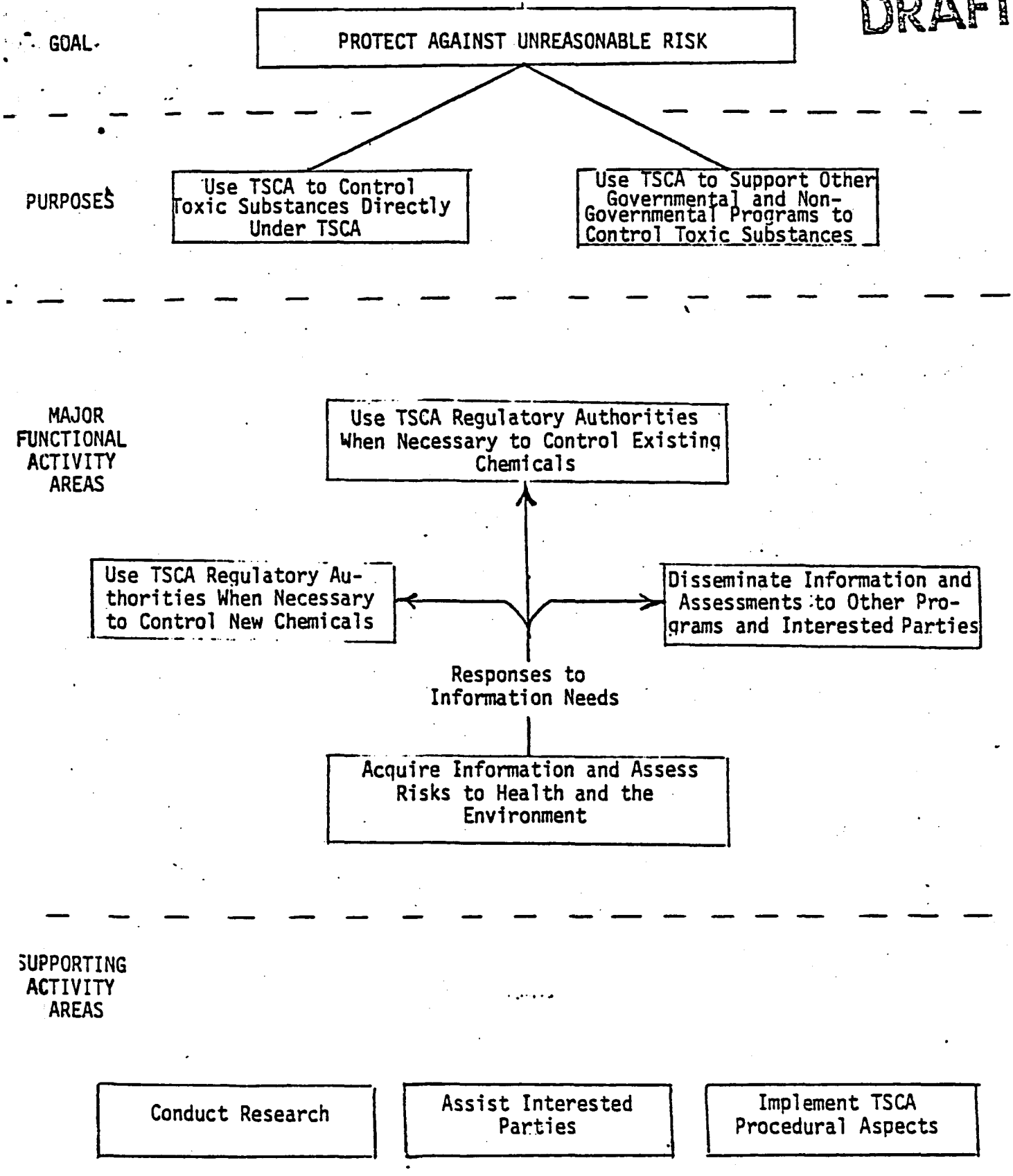

FIGURE 1

Major Functional Area #1: Acquire Information and Assess Risks to Health and the Environment

TSCA provides several new authorities by which EPA may require industry to develop and provide to EPA information concerning chemical substances. These activities include submittal of information concerning the production, by-products of production, uses, and effects of chemicals. In some cases, such data may be readily available to industry. Sometimes, it will be necessary for industry to develop the data.

EPA will obtain information from other sources as well, including other Governmental organizations and private institutions. Also, EPA will, as necessary, carry out laboratory and field studies to supplement or to confirm data available from external sources. However, the emphasis will be on requiring industry to develop data necessary to assess the environmental acceptability of chemicals since TSCA explicitly places this responsibility squarely on industry [2(b)(1)].

The Agency considers that industry has the responsibility not only of gathering and assembling data but also of assessing the data to determine possible environmental risks. This responsibility is particularly important with regard to test data. Industry will be expected to prepare risk assessments in accordance with guidelines issued by EPA on data submitted pursuant to premarket notification and testing requirements. Obviously, the Agency will review such assessments and also conduct independent assessments when necessary.

In some cases when EPA is using TSCA authorities to acquire for other agencies data which are not of priority interest to EPA, the assessment process will be left to the other agencies. More often, there will probably be a congruence among the interests of EPA and other agencies in the same environmental problems and joint risk assessments among agencies will be in order.

Major Functional Area #2: Use of TSCA Regulatory Authorities when Necessary To Control New Chemicals

TSCA calls for establishment from scratch by the end of 1977 of a premarket review system for considering the environmental acceptability of all new commercial chemicals. The system includes (a) final regulations clarifying which chemicals are subject to premarket notification and the notification requirements, (b) an appropriately trained staff to receive and assess the notifications, and (c) an internal EPA policy and procedural framework to help insure consistency, efficiency, and objectivity of the reviews.

The following regulatory mechanisms are available to control new chemicals when appropriate:

-- Premarket notifications will not be accepted by EPA unless they include all information required by regulations [5(a) and 5(b)].

-- If additional information is needed to conduct an adequate assessment, and such information is not available, the manufacture of the chemical will be delayed pending development of the information [5(e)].

-- Should a proposed new chemical be determined to present a significant risk, regulatory steps may be taken to control the manufacture, use, or disposal of the chemical [5(f)].

Major Functional Area #3: Use of TSCA Regulatory Authorities when Necessary To Control Existing Chemicals

Among the types of regulatory actions provided for in TSCA are [6(a) and 6(b)]:

-- banning or limiting manufacture, processing, distribution, or use of a chemical.
-- requiring warning labels.
-- requiring specified disposal methods.
-- requiring specified quality control measures during the manufacturing process.

There are many other statutes available for controlling toxic chemical problems. The rather comprehensive authority of TSCA is intended to be used when necessary to fill the gaps among these other authorities. Thus, the starting point in determining when and how TSCA regulatory authorities are to be used is an overall assessment of environmental problems associated with a chemical or group of chemicals and a determination as to which regulatory approach will most effectively reduce the problems.

If the most appropriate statute is administered by another Agency, EPA may request the other Agency to take action or explain the basis for non-action within a specified period of time [9(a)]. Close collaboration with the other regulatory agencies beginning with the initial discovery of a chemical problem is essential to insure that this system of formal "referrals" does not unnecessarily disrupt the priority activities of these agencies.

Major Functional Area #4: Disseminate Information and Assessments To Other Programs and Interested Parties

A key to achieving "indirect" control of toxic chemicals through other programs is an effective system to aggressively disseminate to the broadest possible audience information obtained through TSCA. To the extent possible the quality and reliability of the data should be clear, and information should be in a format that will be most meaningful to the users [10(b) and 25(b)].

An effective dissemination program is intimately linked to an earlier determination of the information needs of the users and the timing of these needs so that the appropriate data can be generated in the first place. Thus, the first step is a continuing program to assess user interests and needs and, to the extent possible, to shape the data collection efforts to meet their needs.

Much of the data collected for one user, including EPA, will undoubtedly be of interest to many other users as well. Thus, information will be placed in the public domain as rapidly as possible after receipt by EPA.

Some of the data collected under TSCA possibly will be subject to claims of confidentiality. Rapid and efficient mechanisms for segregating data which are confidential from other data are essential if the user community is to be adequately serviced.

Interrelationships Among the Major Functional Areas

As shown in Figure 2, the four major functional areas are integral components of the overall system of assessing and controlling toxic substances. Figure 3 shows in more detail crosswalks among specific provisions of TSCA and indicates the reinforcing character of these provisions.

In general, the information acquisition activities (Area #1) are determined by the needs for data to (a) provide a basis for decisions concerning the control of new or existing chemicals under TSCA (Areas #2 and #3) and (b) service the interests of others (Area #4). In some cases, the data lead directly to risk assessments within EPA; in other cases, the raw data are forwarded for assessment to other programs.

Initial Priorities

During the initial implementation phase, it will be necessary to establish priorities among the many possible TSCA activities. These priorities should reflect continuing concerns of the Congress, the Agency, and the public that there may be a large number of currently unattended environmental problems which should be addressed very promptly. At the same time, early action must be taken to establish the policy and procedural framework for a long-term program, with the groundrules clearly understood by all interested parties. This is particularly true with regard to the premarket review system which should be environmentally meaningful and administratively efficient from the outset. And, of course, the legislative deadlines should be met.

With regard to regulatory activities, newly identified problems that present a significant risk to health or the environment must be dealt with immediately. Also, the chemical problems cited during the five years of legislative hearings should be promptly reviewed to determine whether regulatory action is needed. Finally, selection of early regulatory

INFORMATION
FLOW AMONG FUNCTIONAL AREAS

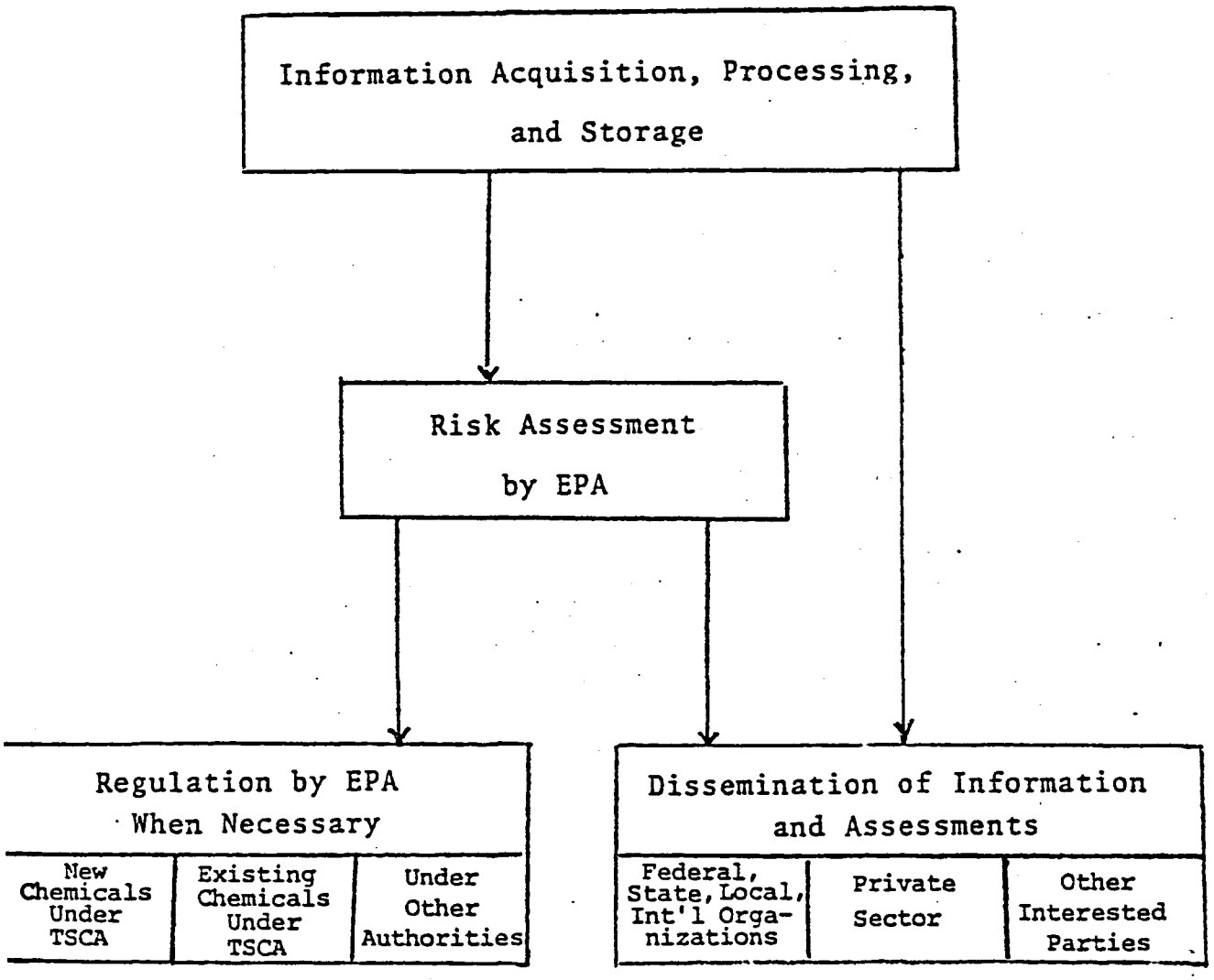

Figure 2

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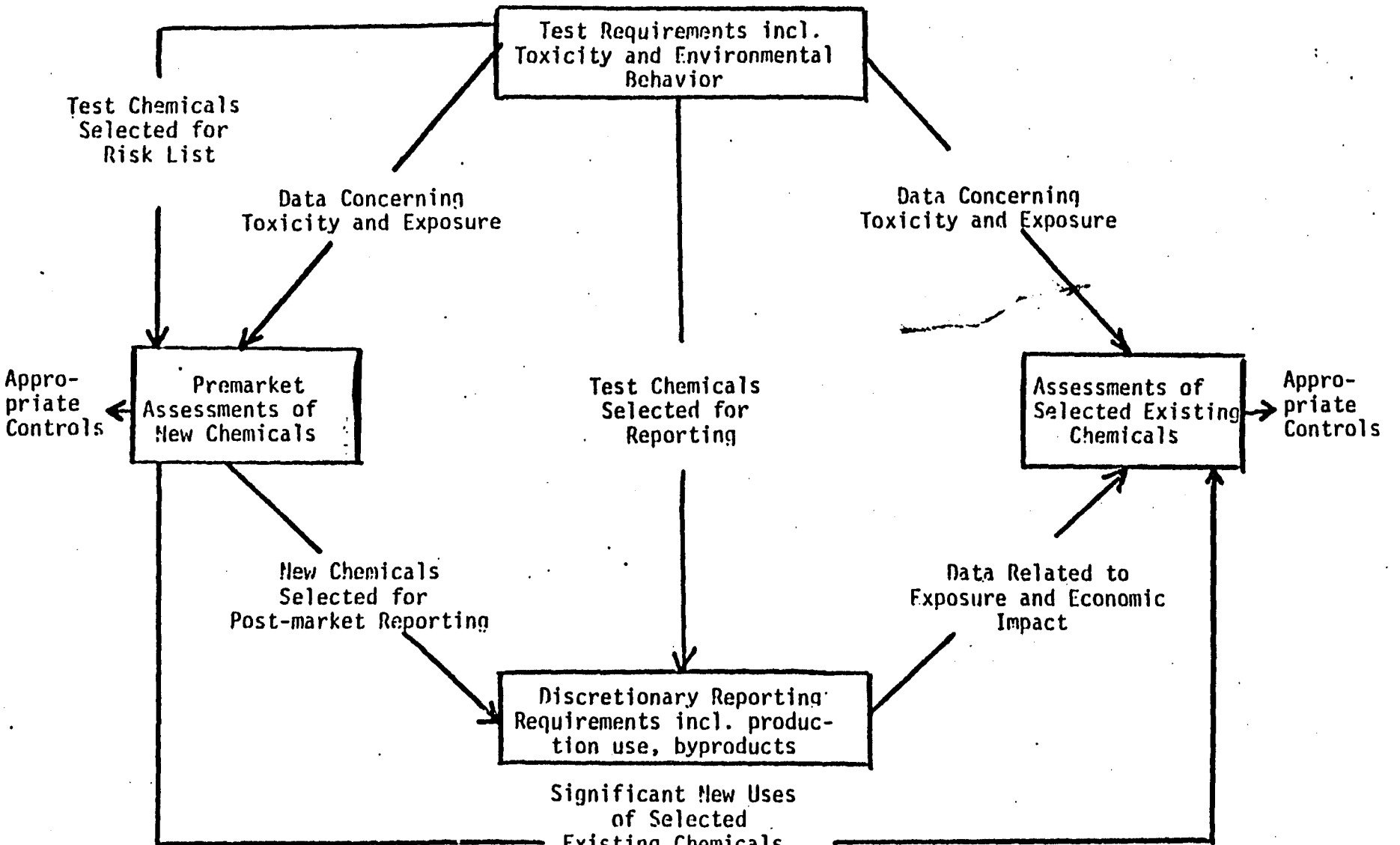
SELECTED CROSSWALKS AMONG PREMARKET TESTING, REPORTING, AND REGULATORY REQUIREMENTS



activities should include consideration of utilizing a variety of approaches that will not only reduce environmental risks but also clarify the dimensions, the strengths, and the weaknesses of TSCA.

Information is the lifeblood of the overall system. Early development of policies and procedures to establish a broadly based and technically sound data base, drawing on domestic and foreign sources and readily accessible to all interested parties, is essential if future regulatory actions are to be soundly conceived. Given the lead time necessary to develop health and environmental data, steps should be promptly initiated to begin to develop such data on those chemicals which could present serious problems. The information on the health and environmental aspects of commercial chemicals which is currently available only to individual agencies or companies should be promptly made more widely available.

In view of the unusual opportunity provided by TSCA to respond to these general concerns, EPA will give top priority to the following operational activities during the initial three years of TSCA implementation:

-- *Establishment and Implementation of a Premarket Review System.* The system will emphasize the (a) responsibility of industry to develop adequate data for meaningful chemical assessments, (b) categorization of new chemicals by broad chemical classes and broad uses with particular attention to those categories of greatest environmental concern, and (c) procedures for rapid decisions and adequate documentation of these decisions.

-- *Establishment of Initial Testing Requirements.* Testing will be required in a hierarchical manner on selected categories of both new and existing chemicals. Industry will be required to develop data concerning both toxicity and exposure and to conduct risk assessments of the data. Quality assurance of the data that are developed will be stressed.

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-- *Assessment and Control of Unanticipated Problems of Urgent Concern.* Unexpected problems will inevitably arise and provisions will be made to respond to such problems without unduly disrupting other priority programs.

In these four priority activity areas, as well as in other areas, continuing attention will be directed to several overarching concerns. Activities will be oriented to serve the interests of both EPA and other organizations, particularly with regard to data dissemination. Data will

be gathered on a highly selective basis to serve specific purposes. Confidentiality aspects will be a major factor influencing data collection, use, and dissemination strategies and activities.

There are many uncertainties as to the number of chemicals subject to premarket notifications and the availability of data concerning these chemicals, the number and extent of unanticipated problems associated with existing chemicals that will emerge, and the difficulties in gaining a scientific consensus concerning the most appropriate approaches to testing. Thus, there is little basis for estimating at this time the relative emphases that should be placed on each of these four types of activities. However, in setting priorities among the many types of potential environmental problems falling within these activities, the following principles will be considered:

-- Toxic substance problems of national or global dimensions, and particularly those problems affecting many people or extensive ecological resources, will receive priority over localized problems which affect smaller populations.

-- Special attention will be given to the effects of toxic substances on human health, recognizing that ecological impacts can also directly and indirectly affect human health.

-- Toxic chemicals which are discharged into the environment in significant quantities and which persist and/or bioaccumulate will be of particular concern.

Protecting against Unreasonable Risk

The concept of unreasonable risk is the central element in relating TSCA implementation activities to the overall goal of TSCA. This concept recognizes that some level of risk must be accepted in our activities involving chemicals. Also, the welfare of future generations as well as our present population must be of concern.

In general, the most severe risks trigger the imminent hazard provision of TSCA [7(a)], and the possibility of less severe risks may trigger testing or other information gathering activities. In some instances the term "unreasonable risk" is used in the Act, in one case "substantial risk" is used [8(e)], and in other cases elaborations of "unreasonable risk" are presented.

The burden of proof for establishing the degree of risk varies in different sections. For example, the proponent of use must establish that selected new chemicals which are on a "risk" list [5(b))4)(A)] do not present an unreasonable risk. On the other hand, EPA must make explicit findings on risk to take regulatory actions [6(a)]. Meanwhile, there is an overarching requirement on EPA to consider social and economic impacts, as well as environmental impacts, in taking action under any provision of TSCA [2(c)].

The most detailed elaboration in the Act as to the types of considerations involved in assessing risk is set forth in the guidance provided to the Interagency Testing Committee, but this guidance is still very general [4(e)(1)(A)]. Several other provisions of the law, as well as the legislative history, also emphasize the importance of considering carcinogenesis, teratogenesis, and mutagenesis when evaluating risks. While there are no explicit references in the law to acute toxicity concerns, there is no reason for not considering such risks.

Recent court opinions, such as those concerning lead in gasoline and asbestos in drinking water, provide some indication as to the important factors in risk assessment. The 1975 NAS report Decision Making for Regulating Chemicals in the Environment also makes some observations concerning those factors that should be considered in assessing risks and in balancing costs, risks, and benefits in decision-making.

To foster a degree of consistency in the approach to risk assessments, the following steps will be taken:

-- Minimum data requirements for conducting risk assessments will be developed for selected categories of chemicals (e.g., chemical classes, use categories).

-- Guidelines for use by industry and the agency concerning risk assessments and the factors involved in cost-risk-benefit decisions will be developed and used.

-- Risk assessments of the same chemical or same environmental problems by different programs and different agencies will to the extent feasible be consistent even though the determination as to whether regulatory action is warranted may vary depending on the differing requirements of different statutes.

-- Summaries of relevant court opinions related to unreasonable risk will be prepared periodically and made available to risk assessors and decision makers.

-- The feasibility of developing criteria for triggering different types of TSCA actions when the chemicals meet the criteria will be explored in detail.

Supporting Functional Activities

Research

TSCA authorizes a broad range of research activities [10 and 27], and explicitly calls for EPA to direct attention to:

-- development of screening techniques to help assess health and ecological effects [10(c)],

-- development of monitoring techniques and instruments [10(d)],

-- basic research to provide the scientific basis for screening and monitoring developments [10(e)], and

-- training of Federal personnel to utilize the new techniques [10(f)].

HEW and other agencies are expected to intensify their research efforts directed to toxic substances as well.

EPA will be developing a more detailed framework for its initial five-year research program during the next few months. EPA intends to give high priority to research both in its own programs and in encouraging a more broadly based and more effectively coordinated national effort involving research by many organizations. Also, the Agency will encourage efforts to expand the pool of technical manpower needed by many organizations to carry out TSCA requirements.

Assistance to Interested Organizations

Given the limited authorization of $1.5 million for each of the first three years of TSCA for support of a program of state grants (28), the initial grants will be limited to programs in only a few states. The states will be selected on the basis of the likelihood that the proposed programs will significantly upgrade local capabilities to address environmental problems. Should the initial grants prove to be successful in providing an important new dimension to toxic substances control, EPA will consider seeking additional funding in later years and will assess the desirability of incorporating the program into the broader concept of bloc grants.

The Agency will not be in a good position for some time to provide responses to petitions from industry requesting specification of test requirements for individual new chemicals [4(g)]. Within a few years the Agency should have available testing guidelines covering a broad range of chemicals, effects, environmental behavior patterns, and routes of exposure. At that time, authoritative responses to such petitions should be relatively easy to provide. In the interim, heavy reliance will be placed on using, whenever possible, the relevant portions of testing guidelines already prepared by EPA and other agencies for other programs such as those directed to pesticides, food additives, and drugs, taking into account the different types of exposures involved with industrial chemicals.

With regard to EPA assistance in defraying the costs of certain attorneys and witnesses in regulatory proceedings [6(c)(4)(A)], only limited funding will be available in FY 1977, but significant additional funding will be sought in FY 1978. Meanwhile, the criteria for determining eligibility are being developed. Available resources will be distributed on an equitable basis among all bona fide claimants at the end of each fiscal quarter for services rendered during that quarter.

An area of Congressional concern has been the capability of small and medium industrial firms to understand the legal and policy complexities of toxic substances control in relation to specific chemical concerns. Thus, in addition to exempting small business from certain reporting requirements, TSCA calls for an EPA Assistance Office to provide clarification on regulatory and related requirements [26(d)]. The Office has been established. In addition, each of the ten EPA Regional Offices will have an appropriate contact point to help clarify TSCA requirements for the small businessman in particular, and the public in general. The Assistance Office will not be in a position in the near future to provide advice on the environmental acceptability of specific commercial chemicals of interest to individual parties. However, the Office will help identify some of the parameters that should be considered in such assessments and will of course assist in obtaining available information relevant to the particular chemicals of interest.

Procedural Aspects

A number of TSCA provisions call for development of procedural rules. Also, more explicit guidance will help facilitate implementation of other provisions. Some of EPA's earliest activities will be directed to:

-- procedures governing the hearings to be conducted under TSCA and particularly with regard to regulatory actions [6(a)].

-- the requirements for selected EPA and HEW employees to disclose their financial interests [26(e)].

-- clarification of the requirements concerning claims of confidentiality and requests for information under the Freedom of Information Act [14].

-- preemption of State laws [18].

Several TSCA provisions are of special interest to another Federal agency and will receive attention in the near future. For example:

-- national defense waivers (Department of Defense) [22]

-- employee protection (Department of Labor) [23]

-- definition of small manufacturers and processors (Small Business Administration) [8(a)(3)(B)]

-- notice to foreign governments of exports (Department of State) [12]

-- imports (Department of Treasury) [13]

-- reimbursement for use of test data generated by another party (FTC/Department of Justice) [4(b)(3) and 4(c)]

Finally, special studies and reports are called for as follows:

-- study of the indemnification aspects of all laws administered by EPA [25(a)]

-- annual reports to Congress on TSCA actions [30]

ACQUISITION OF INFORMATION AND ASSESSMENT OF RISKS TO HEALTH AND THE ENVIRONMENT

General Policy Framework

The gathering, processing, and storing of information will be designed to support specific requirements of EPA and other organizations and will not be considered an end in itself. Data requirements may be very specific or quite broad. For example, information activities may be oriented to:

-- Development of specific regulations to control new or existing chemicals under TSCA or other EPA authorities;

-- Identification and prioritization of problem chemicals for attention under TSCA or other authorities;

-- Supporting specific activities of other agencies and other organizations to assess and control problem chemicals.

-- Informing the public of chemical activities and associated problems.

The intended use of the information will determine the type and extent of data that are needed, the timing, the sources, and the most appropriate mechanisms for acquiring the data. When appropriate, data already available in Government files will be used. When industrial data are required, data already available to industry should be used to the extent possible. However, in a number of cases, and particularly with regard to new chemicals, additional data must be developed by industry on a routine basis.

Given the interests of many parties in data that can be developed under TSCA, and the multiplicity of data acquisition efforts already in place, the development of new TSCA data requirements will be coordinated widely within and outside the Government. Such coordination should assist in (a) reducing the likelihood of gaps in information needed for regulatory purposes, (b) conserving resources of EPA and other agencies, and (c) limiting the total reporting burden on industry.

Particular attention will be given to assuring that information that is acquired, and particularly industrial data, is accurate, complete, and current. Among the steps to be considered are:

-- Clarity and precision of record keeping and data submission requirements;

-- Procedures for assuring appropriate quality control in the acquisition and reporting of information;

-- Interim reports of progress in fulfilling long-term data requirements to avoid discovery only at a very late date that unacceptable data have been generated;

-- Spot checks and audits of data generation activities conducted in the United States or abroad;

-- Development of confirmatory data to check on accuracy and reliability of submissions;

-- Prompt and vigorious enforcement against violators of data requirements;

-- Encouragement of open communication with industry to discuss implementation problems in satisfying data requirements.

Disclosure of Data

Assertions of trade secrecy and related confidentiality matters could cause many implementation problems and must be addressed promptly. Prior to gathering information which is likely to include confidential data, the need for the information should be very clear. Submitters will be afforded the opportunity to make confidentiality claims at the time of submission. A clear explanation of the consequences of failing to assert confidentiality and the procedure for resolving disputes will be a part of the request for information.

TSCA specifically excludes from claims of confidentiality health and safety studies on chemicals offered for commercial distribution and on chemicals subject to premarket notification and/or testing requirements [14(b)]. Other data which the manufacture, processor, or distributor consider confidential may be so designated but must be segregated from other non-confidential data. Thus, EPA reporting forms will require confidentiality designations for individual items, and a general confidential stamp for an entire form will not be accepted.

If there is a Freedom of Information request or other action concerning release of data designated as confidential, the originator of the data will be given an opportunity to justify the claim of confidentiality in detail prior to the Administrator's decision on the release of the data. Also, he will have an opportunity to seek judicial relief if there is disagreement with the Administrator's determination. However, if the release of data is necessary to protect health or the environment against an imminent, unreasonable risk, the advance notice of release can be as short as 24 hours [14(c)].

The information system for receiving and storing TSCA data will insure appropriate protection of confidential information.

TSCA Information Gathering Authorities

Figure 4 identifies some of the information that will be received as a result of both non-discretionary and discretionary provisions of TSCA. Non-discretionary provisions include:

-- Reporting of chemicals to be included on the initial inventory of existing chemicals [8(a) and 8(b)]
-- Premarket notifications [5(a)]
-- Industrial reporting of substantial risks associated with commercial chemicals [8(e)]
-- Citizen's petitions [21]

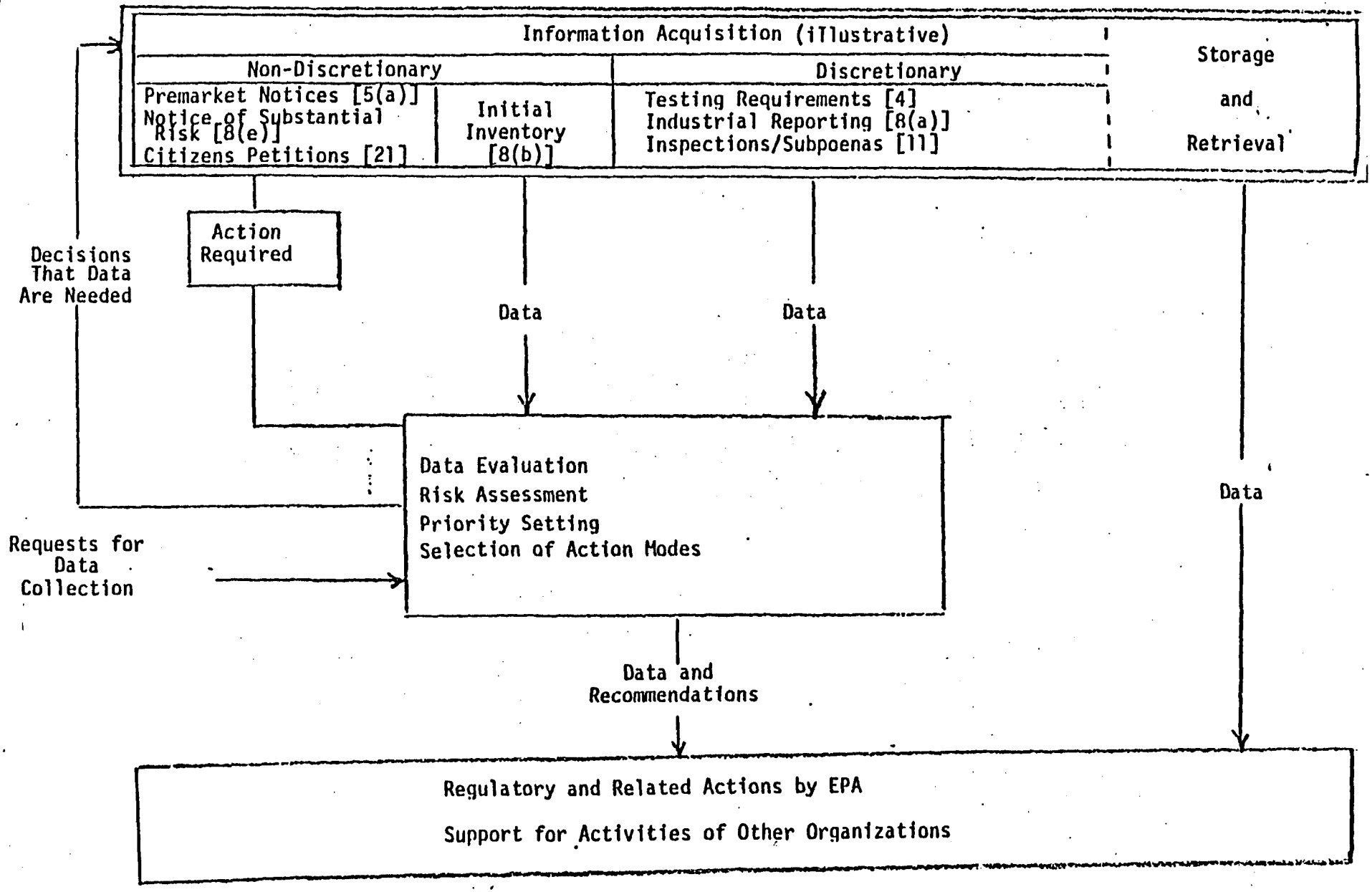

Information Acquisition (Illustrative)
Non-Discretionary
Premarket Notices [5(a)]
Notice of Substantial Risk [8(e)]
Citizens Petitions [21]
Initial Inventory [8(b)]
Discretionary
Testing Requirements [4]
Industrial Reporting [8(a)]
Inspections/Subpoenas [11]
Storage and Retrieval
Action Required
Decisions That Data Are Needed
Data
Data
Data Evaluation
Risk Assessment
Priority Setting
Selection of Action Modes
Requests for Data Collection
Data
Data and Recommendations
Regulatory and Related Actions by EPA
Support for Activities of Other Organizations

FIGURE 4

Some of the provisions to be implemented at the discretion of EPA are:

-- Testing requirements [4(a) and 4(b)]
-- Industrial reporting of production and related activities [8(a)]
-- Industrial submission of records of adverse reactions to health or the environment [8(c)]
-- Industrial submission of health and safety studies [8(d)]
-- Inspections and subpoenas [11]
-- Acquisition of information from other Agencies [10(b)(2)]

Figure 5 sets forth the implementation timetable for the principal activities related to TSCA testing provisions and the provisions concerning industrial recordkeeping and reporting. These activities are also discussed below.

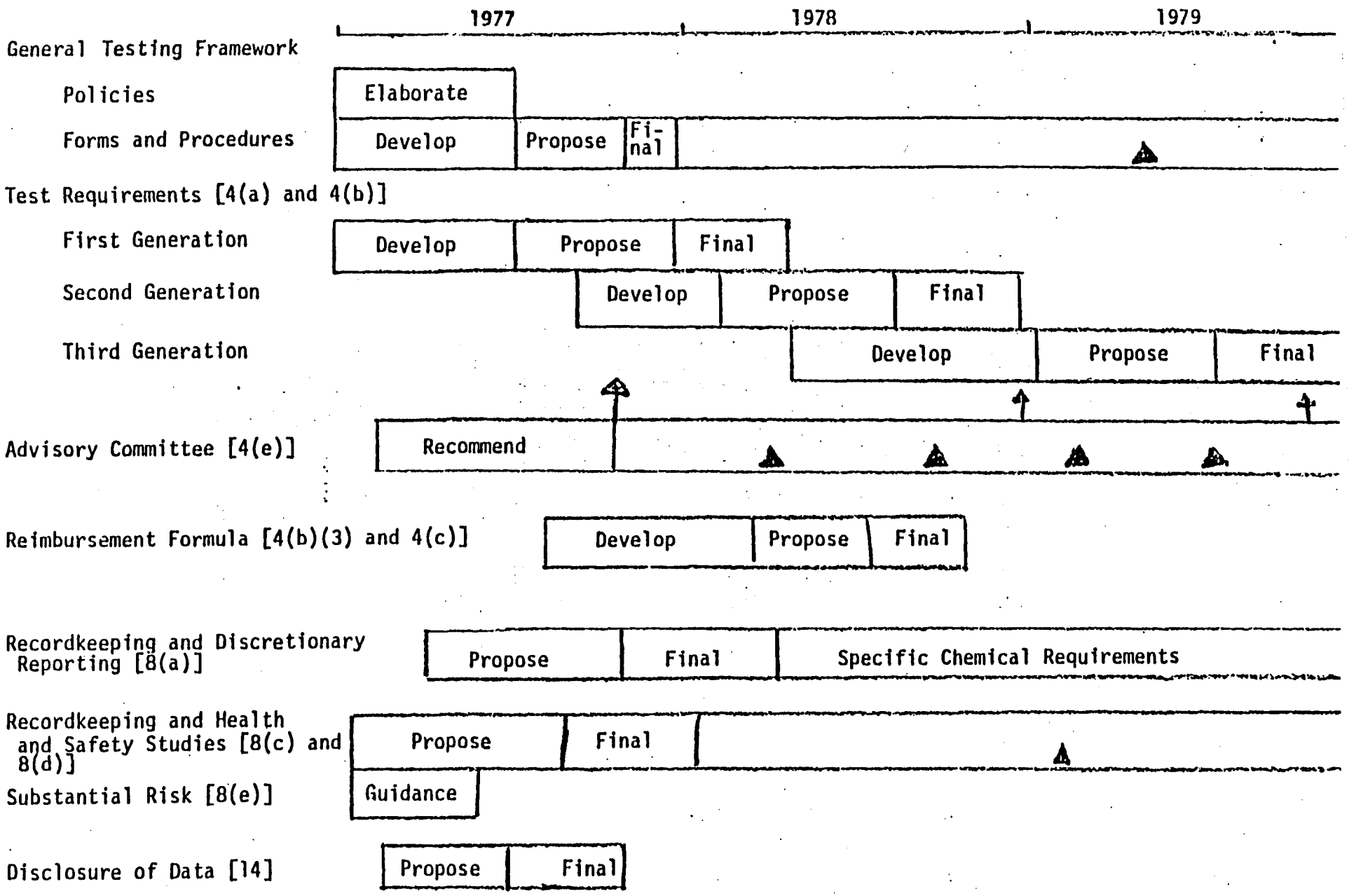
Risk Assessments

Risk assessments are required under a number of TSCA provisions. Risk assessments are inevitably conducted with less than optimal data -- either in terms of quantity or quality. However, a minimum level of data is essential if assessments are to be meaningful, and EPA will develop guidelines concerning such minimum data requirements.

Manufacturers will be expected to conduct and submit risk assessments, prepared in accordance with EPA guidelines, when developing data under TSCA testing regulations and when submitting premarket notices. Also, risk assessments may be required in connection with information provided under other TSCA provisions. The assessments will utilize not only data developed by the manufacturer but also other available data on the chemicals, and when appropriate, on closely related chemicals. In addition to providing a better basis for EPA evaluation of the likely environmental problems associated with toxic substances, this requirement should stimulate a much broader industrial effort to better understand the environmental acceptability of many chemicals being produced and used.

While much remains to be done to clarify, even in a preliminary way, what is involved in risk assessments, the following types of considerations are important:

-- Chemical structure, physical properties, contaminants
-- Source assessment and exposure potential: quantities produced, production processes, uses, reactions involved in uses, and types and frequency of environmental discharges
-- Environmental behavior and fate, including degradation rates and products, chemical reactions in the environment and inadvertent products, bioaccumulation and biomagnification potential, and possible synergistic effects
-- Acute, chronic, and subacute effects on man; absorption, excretion, and metabolism
-- Effects on vertebrates, invertebrates, microorganisms, and plants
-- Effects on inanimate objects and structures



KEY: ▲ - Revise or Update

FIGURE 5

Testing Requirements

Almost all agencies and organizations in a position to assess and control toxic substances have stressed the need for more timely and more reliable test data on a wide range of chemicals. Test data will be used to support specific regulatory actions and to identify problems that need attention. TSCA test requirements that are developed can be pacesetters for the entire field of environmental assessment techniques. Thus, priority will be given to implementation of the testing provisions of TSCA, recognizing that scientific uncertainties and overlapping organizational interests will complicate rapid progress in this area.

The initial implementation activities related to testing will involve (a) establishing the procedures and format for submitting test data under a variety of TSCA provisions, including premarket notifications which will begin to arrive in December 1977, (b) determining general policies which will provide the framework for TSCA test requirements for determining specific effects of specific chemicals, including procedures for assuring the quality of test data, and (c) developing the initial TSCA test requirements for selected categories of both new and existing chemicals.

In view of the number of chemicals of potential interest, test requirements directed to categories of chemicals is the most appropriate approach. The categories will be based on similarities in chemical structure, chemical use, and/or levels and routes of likely exposure, recognizing that production volume may often be an appropriate surrogate for exposure potential. Not only will such an approach simplify the sorting of priorities, but it will also provide a means for anticipating problems with new chemicals and new uses. In general, EPA will develop general testing requirements for each selected category of chemicals and the manufacturer will in turn propose a detailed protocol for each chemical for EPA approval.

Given the current limitations on the availability of testing facilities and personnel and the scientific uncertainties concerning some types of test methods, the testing requirements during the first several years will be developed on a selective basis directed to some of those chemical effects, types of chemical behavior, and routes of exposure of immediate concern. At the same time, a more comprehensive effort will be undertaken to develop testing approaches on a much wider range of chemicals, effects, behavior, and exposure routes. The recommendations of the Interagency Testing Committee and of other interested parties will be considered within this framework. In short, the categorization scheme can be "tuned", in terms of number and breadth of categories and types of effects and exposure, in accordance with the capability to generate sound data and to use the data effectively.

In general, TSCA testing requirements will:

-- require only such data as are necessary to reach regulatory and related decisions.

-- provide the flexibility to enable initial state-of-the-art protocols to be effected immediately while permitting modifications and improvements to be made as the science of testing progresses. EPA will update protocols when appropriate without jeopardizing the acceptability of testing already underway in accordance with earlier protocols.

-- document the laboratory analytical procedures and the requirements for estimating risks so that industry will clearly know what is required and how the information will be assessed. Industry should be able to conduct the same assessments of their data as EPA.

-- provide an approach for developing test protocols in a hierarchical manner so that the degree of testing and evaluation is related to the likely exposure and the projected economic and social benefit.

Consistency of test requirements issued by different programs directed to the same classes of chemicals is important. Also, compatability with recommendations of international organizations and with requirements of other Governments is important. However, two pitfalls must be avoided. First, overstandardization of requirements could stifle advances in the state-of-the-art. Secondly, the types and levels of exposures associated with industrial chemicals usually differ significantly with the exposures associated with drugs, food additives, and pesticides. Therefore, the types and extent of testing of industrial chemicals may differ greatly from the more comprehensive approaches used in these other programs.

In developing the near-term requirements, as well as the more comprehensive long term approach, the Congressional concern with the following aspects will be kept in mind:

-- carcinogenicity, mutagenicity, teratogenicity
-- levels of environmental exposure
-- behavioral effects
-- synergistic and cumulative effects

With regard to assuring the quality of data that are submitted by industry, EPA will explore the feasibility of expanding the FDA laboratory inspection program and the use of the FDA Good Laboratory Practices manual to encompass TSCA concerns. A counterpart system for environmental testing will be explored within EPA. In the longer term, other approaches may be more appropriate to assure that data are obtained and presented in a technically credible manner [3(12)(B)].

ORIGIN OF TEST REQUIREMENTS

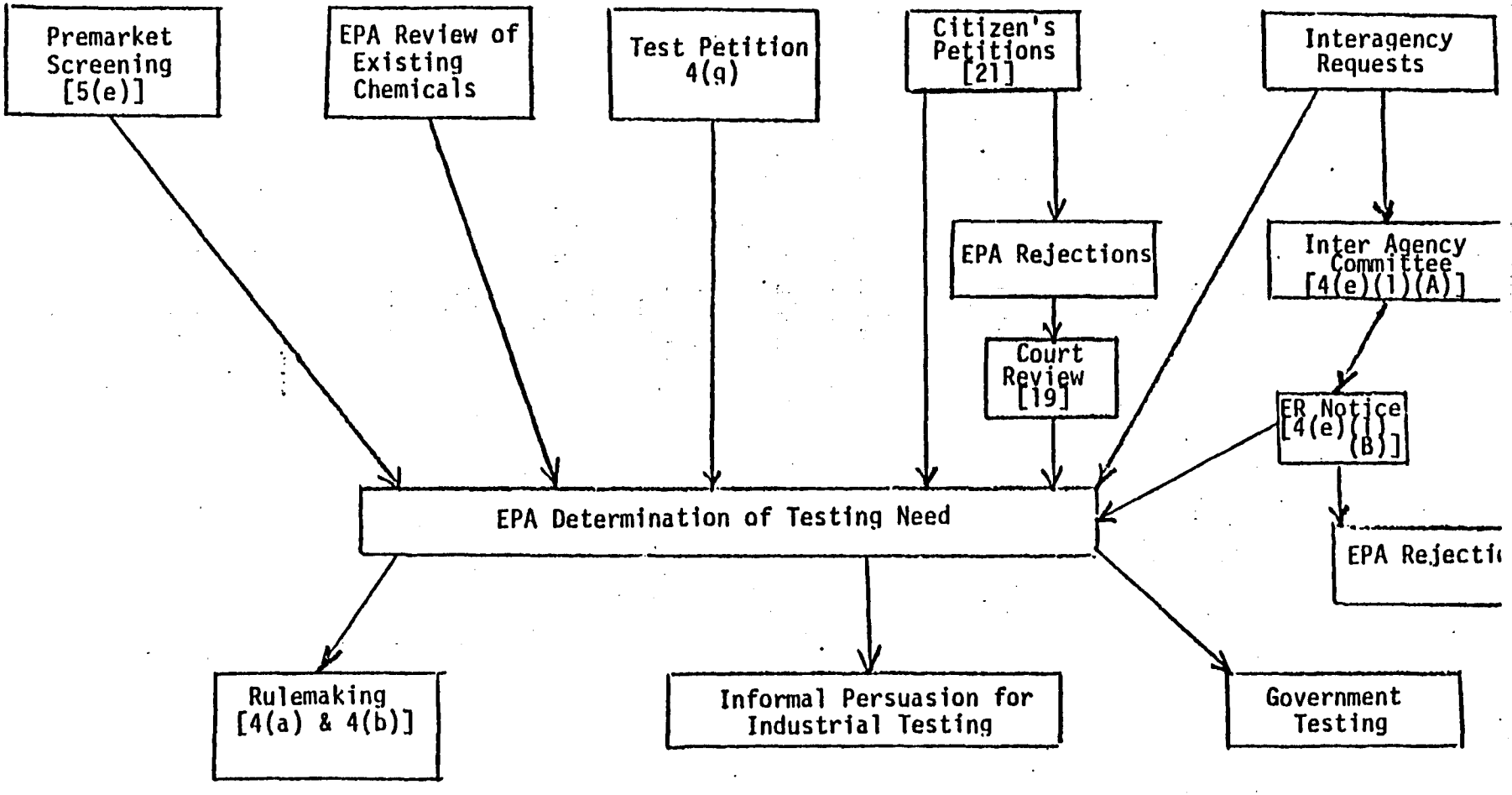


FIGURE 6

During 1977 the Interagency Advisory Committee will designate up to 50 priority chemicals for testing. The Agency will have up to one year to respond to these recommendations [4(e)(1)]. Meanwhile, as indicated in Figure 6, other testing recommendations will be received from a variety of sources. A sorting of the various recommendations, taking into account the availability of testing facilities, will be a major activity during 1977-78. While such prioritizing is important, promulgation of initial test requirements will not be delayed pending development of an elaborate sorting system which may never be feasible. Early EPA action will demonstrate the Agency's intent to consider all suggestions but then to move in the direction of the priorities as viewed by the Agency.

Policies and procedures will be prepared for enabling the developer of test data to receive fair reimbursement from another party who wishes to use the data [4(b)(3) and 4(c)].

Industrial Reporting and Retention of Information

The recordkeeping and reporting provisions of TSCA are illustrated in Figure 7.

Discretionary acquisition of industrial data concerning production, by-products, and uses [8(a)] will be used for a number of purposes, including:

-- to keep track of the commercial development of new chemicals after they have been marketed for the first time. Although the initial production and use patterns might not warrant regulatory intervention in the premarket period, changes in these patterns could become of environmental concern.

-- to provide information related to likely types of exposure on existing chemicals which are subject to testing requirements.

-- to provide data related to exposure and also related to economic impact of controls on those chemicals which are being considered for regulatory action.

-- to provide information on the impact of controls which limit but do not ban chemicals.

-- to help pinpoint the types and locations of exposure potential when unexpected chemical problems of urgent concern arise.

-- to provide trend data concerning newly emerging chemical technologies which should be of special concern.

The initial emphasis will be on requirements for the establishment within individual industrial firms of complete, up-to-date, and easily accessible records concerning each of the individual chemicals which is used by the firm. Such records will include information concerning the chemical identity, production levels, uses, by-products, health and safety studies, alleged adverse reactions, and other factors of environmental significance [8(a) and 8(c)]. These records will be available for on-

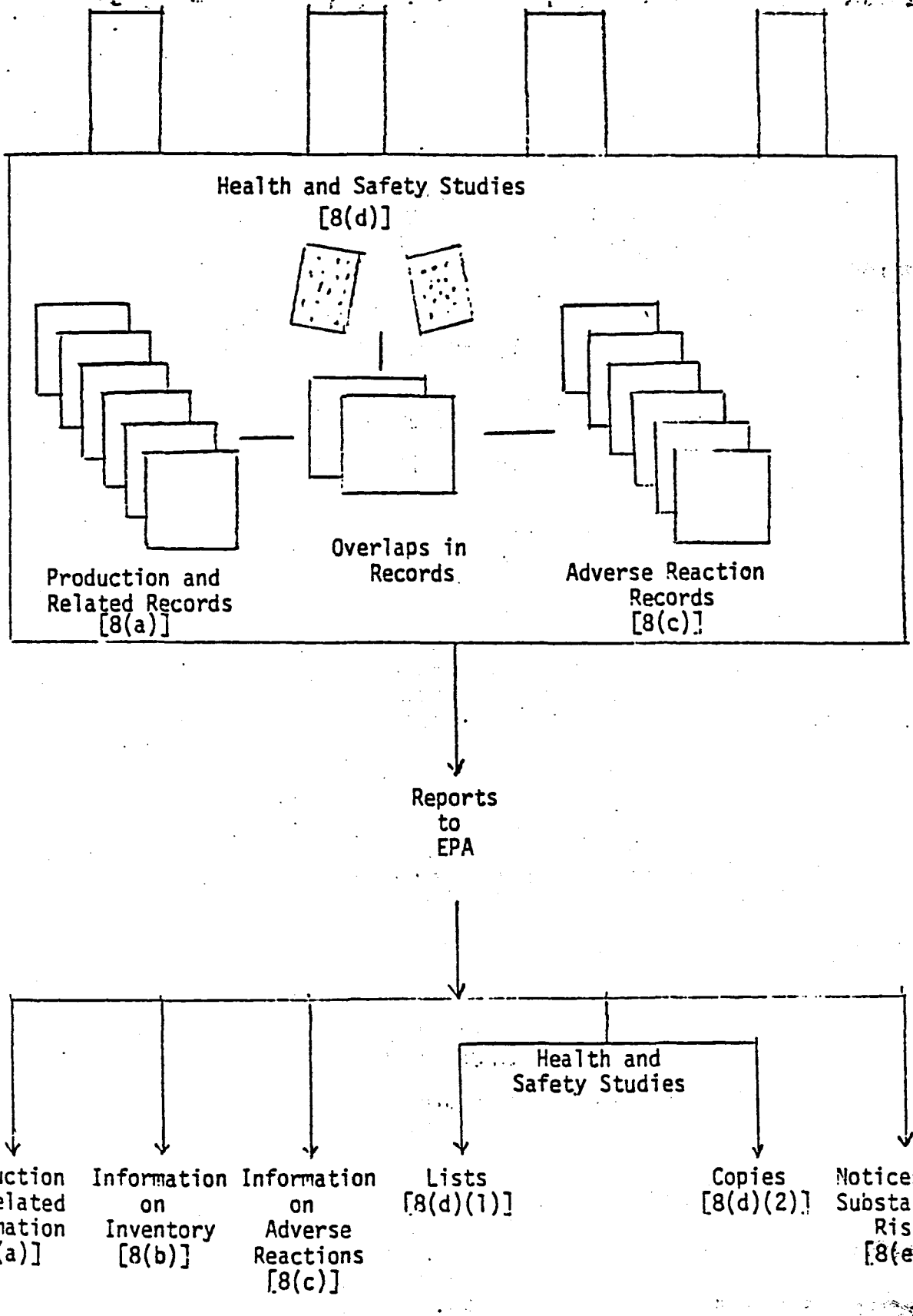


FIGURE 7

site reviews which might trigger requests for the data to be reported to EPA. Also, as individual chemicals are being analyzed in detail by EPA and other agencies, information concerning these chemicals will be requested. In order to know which manufacturers to approach concerning specific chemicals, EPA will require each manufacturer to identify all the chemicals he manufacturers in connection with compiling the initial inventory of existing chemicals [8(b)].

The responsibilities of importers and their suppliers concerning recordkeeping require special attention.

The general procedural requirements for reporting will also be established promptly with the specific chemicals to be subject to reporting identified subsequently [8(a)]. Data on specific chemicals could then be obtained with a minimum of delay. In the early years, this authority will be used selectively to help assess chemical problems under active investigation. At a later date, it may be desirable to build up within EPA a broader base of industrial data. However, before comprehensive reporting requirements are developed, more thorough investigations of the availability of comparable data through other Governmental and non-Governmental mechanisms will be carried out to avoid duplicative reporting.

During the Congressional hearings, concern was repeatedly voiced that considerable amounts of data related to the health and environmental acceptability of commercial chemicals were available in industry files. While the value of such data are unknown, the extent of the backlog of data will be promptly ascertained [8(d)]. Should a manufacturer become aware of data generated by himself or others concerning the likelihood of substantial risks due to chemical exposures [8(e)], notifications to EPA of this data will trigger the activities described under the response section below.

USE OF TSCA REGULATORY AUTHORITIES
WHEN NECESSARY TO CONTROL NEW CHEMICALS

TSCA Authorities To Control New Chemicals

Priority will be given to establishing the program for premarket screening which must be in place by the end of 1977. TSCA requires notification of all new chemicals at least 90 days prior to their manufacture to provide the Agency an opportunity for determining whether such chemicals pose a risk. If the Agency believes that a new chemical poses an unreasonable risk, or if information is lacking to make an evaluation, the Agency may initiate action leading to the following:

-- delay in the manufacture of the new chemical pending development of additional information needed to evaluate the risk [5(e)],

-- ban or marketing limitation on the new chemical to protect against an unreasonable risk [5(f)], or

-- requirements to track the commercial development of the new chemical after initial marketing through periodic reporting by industry of its production levels, uses, by-products, and related aspects [8(a)].

Also linked to the premarket review are several TSCA authorities which can be used to require certain types of information to be submitted at the time of notification, namely:

-- production, use, by-product and related data [5(a)(1)]

-- data required by testing regulations [5(b)(1)]

-- health and environmental data on chemicals on a "risk" list [5(b)(4)]

If required data are not submitted, the notification will not be accepted.

Preparation of the Inventory of Existing Chemicals

The first order of business to implement premarket screening for new chemicals is the compilation of an inventory of existing chemicals. This inventory will be regularly updated and will serve as the baseline for determining which chemicals to be manufactured after publication of the inventory are "new" and, therefore, subject to premarket notification.

Each manufacturer will be required to report for inclusion in the inventory all chemicals produced after January 1, 1977. Manufacturers may report other chemicals produced between July 1, 1974, and January 1, 1977, if they wish to have these chemicals included; chemicals which are not reported will be subject to premarket notification requirements. To

assist in standardizing the nomenclature used in reporting for the inventory, the Agency will publish a candidate list of about 30,000 chemicals, with appropriate names and CAS registry numbers. Also, instructions will be provided for reporting other chemicals not on the candidate list.

The initial inventory will not differentiate among various technical grades of chemicals. The problems related to impurities will be addressed at a later date. The initial inventory will include some categories of chemicals since it is not practical in the short time available, and it may not be desirable, to list every variation of all existing chemicals. Raw agricultural products, for example, will be considered as a single category. Also, minerals will be included on the basis of relatively broad categories.

The exemption from the inventory and from premarket notification of "small" quantities for research purposes will include those amounts no greater than what is reasonably necessary for scientific experimentation, testing, analysis, or research, including such research or analysis necessary for the development of a product [5(h)(3)]. "Test marketing" will be limited to distribution of a chemical to a defined number of potential customers for purposes of evaluating particular uses of that chemical during a predetermined evaluation period [5(h)(1)].

Many intermediate chemicals are often involved in the synthesis of industrial chemicals and are subject to TSCA. Only those intermediate chemicals which cannot be isolated in a practical sense from the immediate vicinity of the reaction process will be exempt from inclusion on the initial inventory and from premarket notification. Thus, for example, those chemicals which normally exist in only a pipeline would be included.

The Agency is considering requiring that all premarket notifications be accompanied by a fee [26(b)]. This requirement would not only help defray costs of administration but would also help insure that Agency efforts are directed to environmental assessments of serious commercial endeavors and are not diverted to address theoretical curiosities submitted by parties who have no intention to manufacture the chemicals commercially. Also, the Agency is considering placing a limit of perhaps one year on the time between premarket notification and initiation of manufacture of the chemical. If the time is exceeded, a second notification would be required.

Data Requirements for the Review of New Chemicals

A meaningful review of new chemicals requires adequate data to review. Thus, EPA reviewers will be provided with internal guidance on minimum data requirements for new chemicals based on chemical categorization considerations. Data requirements will vary among categories. This guidance will be made publicly available.

The guidance for each category will identify the types of data which should normally accompany notification of a new chemical in that category including in some instances data not explicitly required by regulations. A notification submitted without the data will be a candidate for possible action to delay its commercialization. In that event, the Administrator may issue a proposed order to delay manufacture, based on insufficiency of information to "permit a reasoned evaluation of the health and environmental effects" of the new chemical [5(e)]. The guidance will merely serve to alert Agency reviewers to possible problems, and the absence of data will not automatically cause the Agency to issue a proposed order. The Agency is prepared, however, to issue proposed orders when appropriate.

In some cases, it may be appropriate to convert portions of the internal guidance into formal testing requirements. In that event, premarket notifications would not be accepted in the absence of such data. As the guidance is developed, the desirability of such testing requirements will be actively explored.

The Agency does not plan to establish a risk list of new chemicals which pose "an unreasonable risk of injury to health or the environment" at the outset [5(b)(4)]. The internal guidance by chemical categories will help insure a meaningful review of premarket notices, and in a sense perform much of the same function as a risk list. Also, the Agency does not plan to activate reporting of significant new uses of existing chemicals in the short term because of the urgency and complexity of the task of instituting premarket notification for new chemicals and the difficulty of preparing a meaningful categorization of uses of environmental significance [5(a)(2)].

Limiting Manufacture or Marketing of New Chemicals

The internal guidance on data needs will also assist in determining the key factors underlying decisions as to whether to restrict new chemicals [5(f)]. However, each regulatory decision must be made on a case-by-case basis, and decision-making criteria beyond a check list of the factors to be considered does not appear feasible at this time.

There are often many uncertainties about the commercial viability of new chemicals. In some cases, the likelihood that the potential environmental problems uncovered during premarket review will become actual problems may be questionnable. Therefore, alternatives to the resource-intensive process of formal rulemaking and, when necessary, court intervention to limit manufacture or marketing will be considered. For example, simply releasing adverse data to interested parties may in certain instances result in limitations on the type of commercialization which poses environmental problems. However, when necessary, EPA will intervene in a regulatory mode. If worker exposure is the principal concern, referral to OSHA might be the most appropriate course [9(a)].

Review Procedures for New Chemicals

As indicated in Figure 8, the Agency will initially determine if the premarket notification contains the information required by regulations. If such information is missing, the notification will not be accepted. An FR notice indicating receipt of a complete notification will be published within five days [5(d)]. The notification will be accepted even if it is not accompanied by the additional data specified in the internal EPA guidance for the new chemical's category.

The internal guidance will also indicate (a) those categories of chemicals which should in all cases be subjected to in-depth reviews, and (b) those categories which should be screened to determine if in-depth reviews are warranted. In the latter case, technical reviewers will identify the specific chemicals for which no action appears warranted and those that deserve in-depth review, along with all the new chemicals in the first group.

The in-depth review will routinely be completed in 30 days and will include consideration of:

-- Physical and chemical properties of the chemical and its byproducts;

-- Health and ecological effects;

-- Environmental behavior and fate including persistence and bioaccumulation;

-- Likely sources of environmental discharges and exposed populations;

-- Technological and economic factors;

-- Industry's risk assessment.

In addition to the data included in the premarket notice, other data on the same chemical and, when appropriate, on chemical relatives which may not have been available to the manufacturer will be reviewed. Criteria will be developed for triggering extensions of up to 90 days of the in-depth review period. These criteria might include the necessity to validate questionable data.

At the completion of the in-depth review, including the supplementary review when appropriate, recommendations will be prepared as to the action that should be taken on each chemical. The recommendations and supporting justification will be concisely summarized in a short decision-making document.

A policy decision body including representatives from appropriate Agency offices will meet on a regular basis and decide the disposition of each of the recommendations of the technical reviewers. The decision will be appropriately documented so that at a later date the basis for the decision is clear. The following types of decisions are envisaged:

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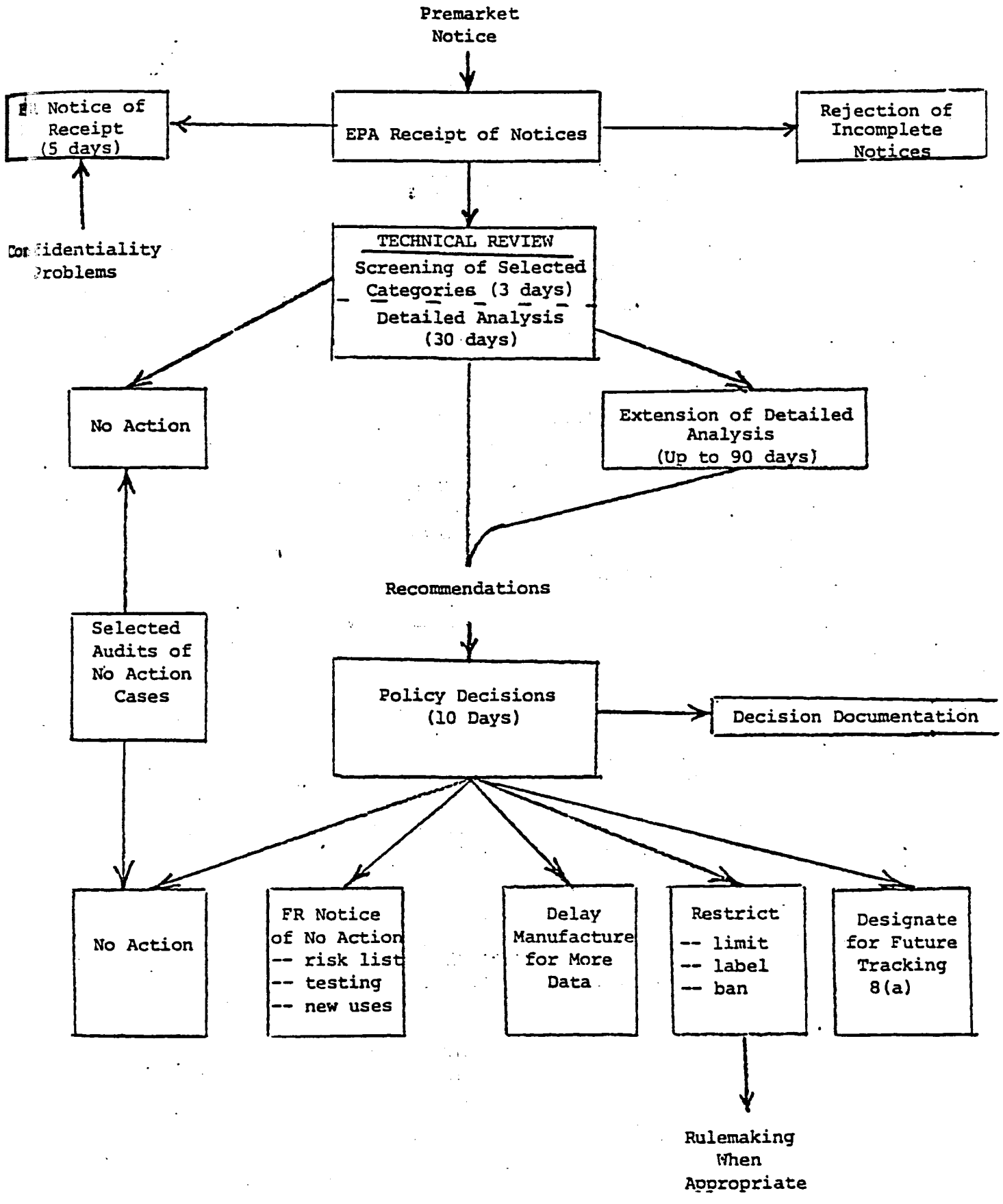


FIGURE 8

1. No action is warranted.

2. No action is warranted but an FR notice of the decision is required if the chemical is subject to testing requirements. Also, at a later date an FR notice will be required if the chemical is on the risk list or is subject to significant new use reporting [5(g)].

3. Manufacture will be delayed pending development of additional data [5(e)].

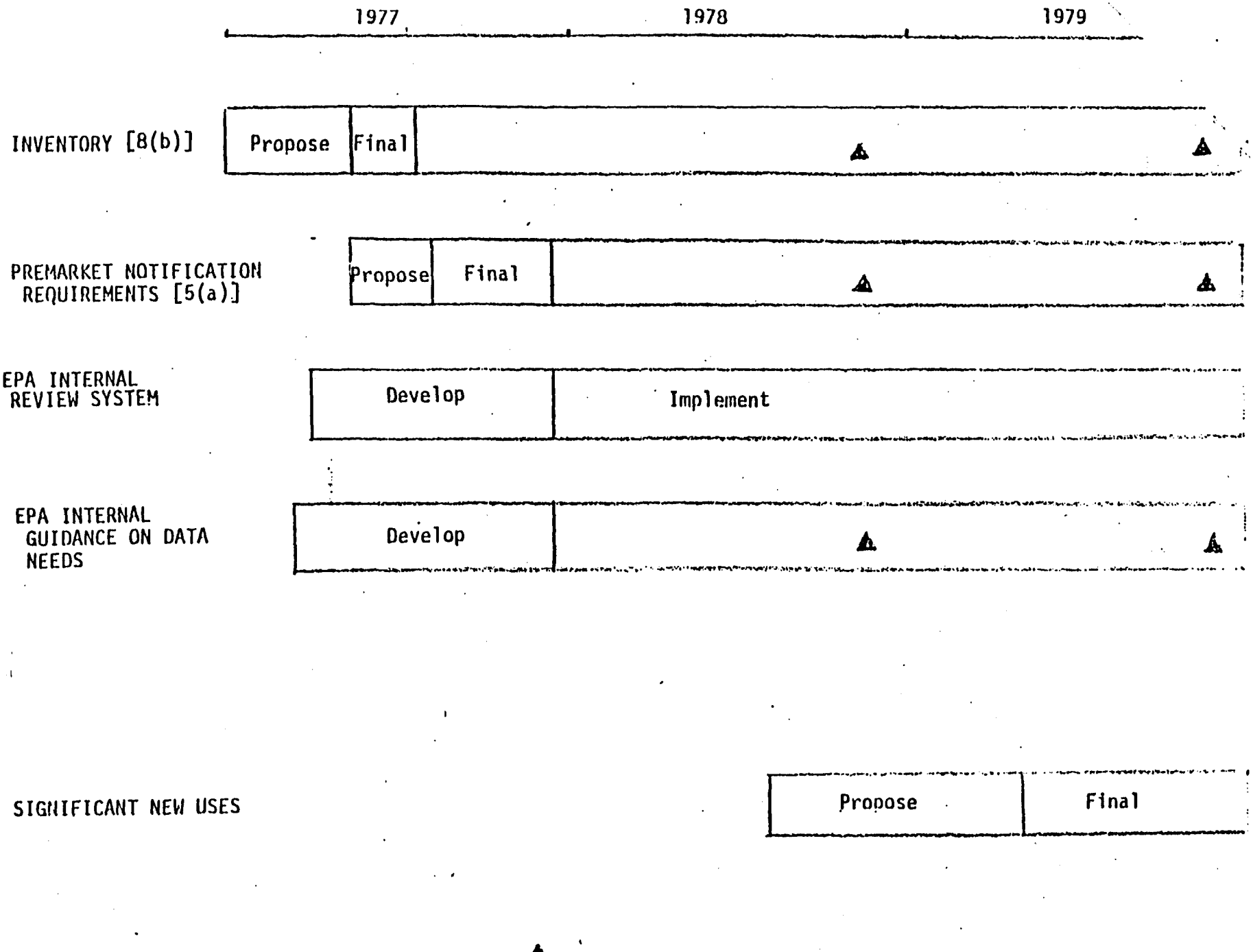
4. Manufacturing and marketing will be regulated [5(f)].

5. While no action is taken during the premarket period, the chemical will be ear-marked for future reporting after it becomes commercialized [8(a)].

"No action" can be decided by technical screeners on chemicals in selected categories and by the policy body on other chemicals. All "no action" decisions will be subject to a later audit on a selective basis to help insure that the necessity to screen out quickly the less worrisome problems does not result in inappropriate chemicals inadvertently slipping through the review process.

The Agency will give prompt attention to development of a data recovery system for premarket submissions. This will allow use of the Agency reviewers' comments and prior analysis of one new chemical when later reviewing a different, although similar new chemical. The data system will also permit use of premarket data for other purposes under TSCA.

The premarket screening implementation timetable is set forth in Figure 9.


1977
1978
1979
INVENTORY [8(b)]
Propose
Final
PREMARKET NOTIFICATION REQUIREMENTS [5(a)]
Propose
Final
EPA INTERNAL REVIEW SYSTEM
Develop
Implement
EPA INTERNAL GUIDANCE ON DATA NEEDS
Develop
SIGNIFICANT NEW USES
Propose
Final
Key: - Revise or Update

USE OF TSCA REGULATORY AUTHORITIES WHEN NECESSARY TO CONTROL EXISTING CHEMICALS

General Regulatory Approach

TSCA is designed to fill the void in the regulatory span of other authorities. It is intended both to prevent problems and to correct problems.

As indicated in Figure 10, EPA plans to initiate a limited number of regulatory actions directed to existing chemicals in the near future. In addition to addressing important environmental problems, such early actions should stimulate a greater degree of introspection within industry concerning preventive and corrective measures in anticipation of future environmental problems or additional regulatory actions. Also, this early attention to specific problem chemicals should enable EPA to play a lead role in establishing regulatory priorities rather than having external developments become the dominant factor in determining the Agency's priorities. Finally, initial actions directed to a variety of environmental situations should help clarify the scope and limitations of TSCA and its interfaces with other regulatory programs.

The regulatory strategy will emphasize overall assessments of the causes of the environmental problems associated with chemicals and the most effective measures to address these underlying causes. A key factor will be a determination of the most effective regulatory approach using TSCA, another statute, or a combination of statutes. In many cases, authorities other than TSCA will provide the appropriate means for reducing the problems. If the most appropriate statute is administered by another Agency, EPA may request the other Agency to take action or explain non-action within a specified time [9(a)]. However, a collaborative rather than adversarial interagency approach is essential, and close interaction with other agencies beginning with the initial discovery of a chemical problem will help insure that this system of formal referrals does not unnecessarily disrupt the priority activities of these agencies.

When formally referring chemical problems to other agencies for action, EPA will provide all available information concerning potential risk. While EPA may not have in hand complete documentation concerning all aspects of the risk, there should be a reasonably good indication that preventive or corrective action in the near term deserves serious attention. EPA will follow up with the other agencies. If additional data are subsequently developed, and the follow through by the other agency appears inadequate, EPA will not hesitate to review again the situation and to determine appropriate additional actions.

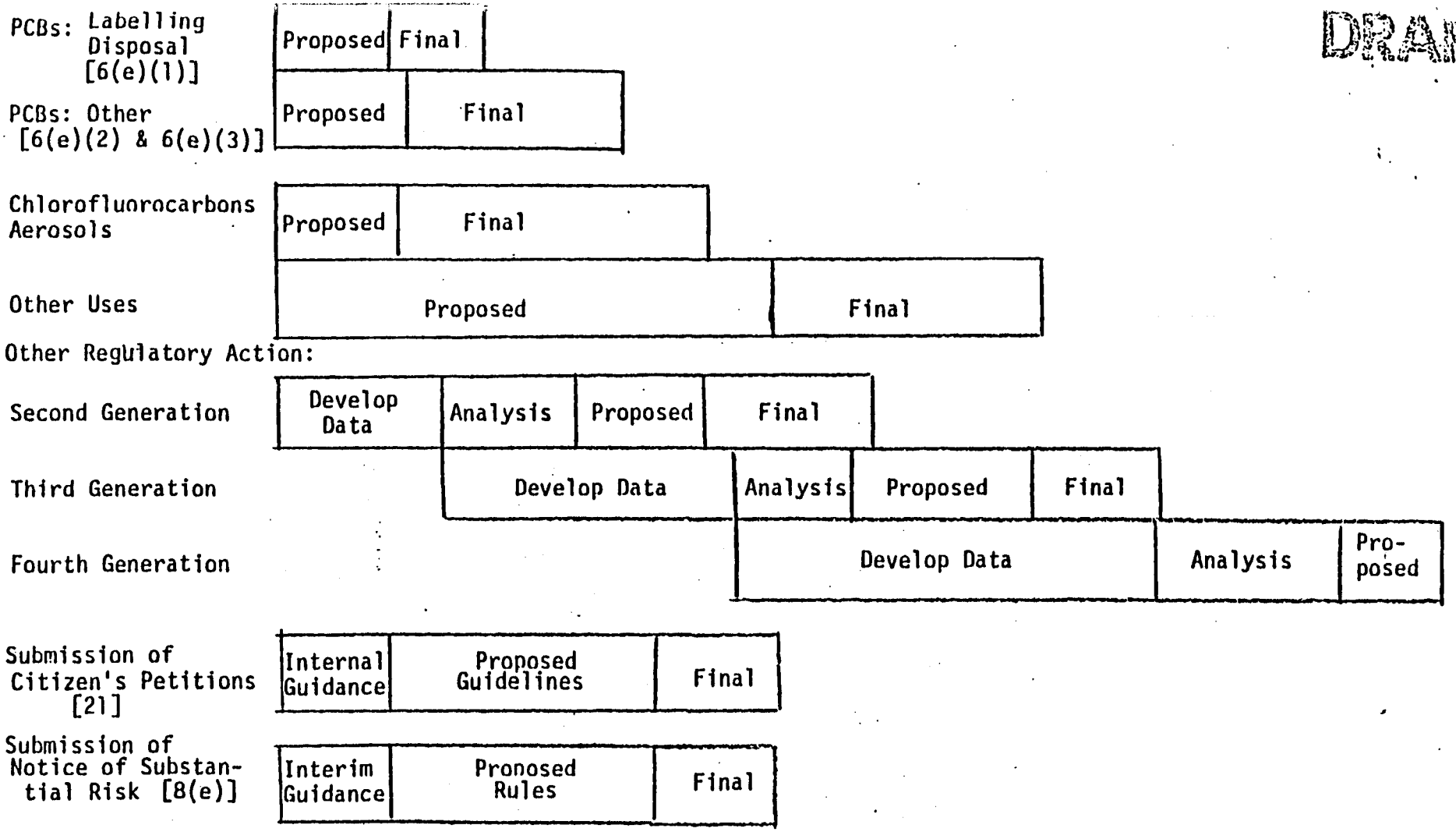


FIGURE 10

Policy Considerations

The basic consideration for all regulatory decisions is the risk to man or the environment of the problems being addressed. The appropriateness and character of the regulation must then take into account the possibility of actions under other laws [6(c) and 9(a)], the least burdensome approach under TSCA [6(a)], and the overarching requirement to take economics and social factors, as well as environmental concerns, into consideration [2(c)]. The environmental acceptability of the substitute chemicals or alternative technologies that are likely to emerge as the result of the regulatory action will be given special attention. Sometimes, the likely alternatives may be less than optimal from the environmental viewpoint and the incremental environmental gains in adopting the substitutes will be considered.

Often the regulatory action taken under TSCA will be in addition to regulatory actions that have been or could be taken by other programs. Different programs must by law give different weights to the economic and to some of the other factors concerning regulations, and there may be some differences in the orientation of the regulatory decisions made by different programs.

Regulatory actions directed to existing chemicals will not be limited only to correcting problems which are known or believed to be having adverse health and ecological effects but will also be directed to preventing such problems in the future. On occasion, TSCA action may address only a portion of the environmental problem posed by a chemical. Nevertheless, such limited steps can be important, and TSCA action to correct a piece of the problem need not be delayed until the entire problem can be effectively addressed.

Orientation of Initial Activities

Polychlorinated biphenyls and selected chlorofluorocarbons have been of special concern to the Congress for several years, and work is well underway to develop appropriate regulations for limiting their discharge into the environment. The other unattended chemical problems cited during the Congressional hearings are also being examined to determine whether additional regulatory actions are needed immediately.

Many agencies already have lengthy lists of chemicals of particular environmental concern. These lists are being reviewed before reaching a judgement as to whether they can provide useful guidance or whether they should be supplemented with still additional lists. Also, the list to be developed by the Interagency Testing Committee on priorities for testing may be useful in determining regulatory priorities as well.

Expanded efforts will be directed to more systemmatic procedures for screening and establishing priorities among chemical problems for regulatory attention. While establishing priorities will inevitably involve a number of judgmental decisions, it may be possible to develop improved techniques for assisting in the setting or priorities. Also, the utilization of chemical classes or categories of chemical use might assist in narrowing the vast array of chemicals to a more manageable number.

Underpinning the entire regulatory effort must be a technically sound program of chemical assessment. Chemical assessments have traditionally involved (a) hazard assessment, (b) source assessment, (c) identification of substitutes and alternative technologies, (d) development of control options, and (e) evaluation of the environmental, economic, and related impacts of controls. In some cases, much of the needed data is at hand; more often, supplementary data must be developed. The assessment program will include anlayses of individual chemicals, categories of chemicals, chemical technologies, and geographic problems.

Responses to Urgent Problems

Response to the uncovering of chemical problems which might pose urgent risks to health or ecological resources will receive the highest priority, and an on-call response capability will help minimize diversion of resources from other priority activities. In the past such problems have usually come to light as the result of new toxicity test results, new monitoring data, or identification of human or ecological victims of chemical exposure. The discovery of real or alleged urgent problems often results from the conduct of Government programs (e.g., PCB's in the milk of nursing mothers), findings of the scientific community (e.g., nitrosamines in the atmosphere), industrial revelations (e.g., worker deaths from vinyl chloride), and press investigations (e.g., cancer death rates in the Little Elk Valley of Maryland).

TSCA provides additional mechanisms for bringing to light urgent problems. Two of these mechanisms -- citizens' petitions [21] and risks uncovered by test data [4(f)] -- require a response within a specified time limit. A third principal TSCA mechanism -- notification by industry of substantial risk [8(e)] -- doesn't have a mandated response time. Regardless of the source of the discovery, the urgency of the problem must drive the response timing.

TSCA also provides several new regulatory mechanisms for limiting chemical exposures quickly if warranted (e.g., imminent hazard [7], regulatory action immediately effective [6(d)(2)], referral to other agency with short deadline for action by the other agency [9(a)]). In the past, local agencies and industry itself have often been willing to take immediate corrective steps in the face of chemical crises. In any event, prompt and effective action to prevent additional damage using TSCA or other programs will be the immediate objective.

The EPA response capability will include available technical specialists to assess the discovery, on-call field and laboratory capability to confirm and supplement the data concerning the discovery, and coordinative and organizational mechanisms -- involving a variety of programs within and outside EPA -- for implementing prompt and effective corrective actions.

While each new problem will have its own pecularities, there are usually some common concerns relating to toxicity, exposure, chemical behavior, related commercial activities, and routes of environmental discharges. Generalized checklists of typical concerns are being developed to help insure that technical and policy analyses do not overlook important factors in the face of tight timetables. Also, steps will be taken to insure that interested parties are continuously informed of developments -- and particularly acquisition of additional data -- in view of the broad political interests in these types of problems.

A very general framework for the response activity is:

(a) Identification of problems associated with chemical activities as the result of

- -- Systemmatic screening of available information
- -- Monitoring, toxicological, and epidemiological screening programs
- -- Ad hoc environmental incidents, research findings, and allegations
- -- Discoveries submitted under TSCA

(b) Characterization of the problems with particular attention to

- -- Health and ecological effects and environmental behavior
- -- Current and projected sources, environmental levels, and exposed population
- -- Substitutes, control technology, and related cost and economic factors
- -- Actions to date and actions underway to clarify and control the problems

(c) Development and stimulation of preventive and corrective approaches including consideration of

- -- Role of relevant authorities of EPA and other agencies
- -- Alternative approaches to voluntary or regulatory redress
- -- Environmental and economic impact of approaches
- -- Implementation of appropriate approach

DISSEMINATION OF INFORMATION AND ASSESSMENTS TO OTHER PROGRAMS AND INTERESTED PARTIES

The Broad Interests in Toxic Substances

Throughout the Congressional consideration of TSCA, there was a recognition of a TSCA role for many of the regulatory and non-regulatory programs of a number of organizations that were in place directed to the assessment and control of toxic substances. Since the enactment of the new law, such programs have already increased in number and in the scope of their interests.

At the Federal level, for example, a large number of chemicals will be explicitly regulated under the Federal Water Pollution Control Act. Many more will be affected by more general standards under that authority and also under the Clean Air Act. The National Academy of Sciences will recommend a large number of chemicals to be considered for possible regulation under the Safe Drinking Water Act. NIOSH has several hundred criteria documents completed or in preparation which will add to the list of chemicals already regulated by OSHA. The Department of Transportation and the Mining Enforcement and Safety Administration similarly have regulations in place or under development affecting many toxic substances. All of these activities must be based on assessments of environmental and related data.

A number of states have taken steps in the toxic substances area. Virginia and Illinois, for example, are particularly interested in data reporting systems. Several states in the Great Lakes area have taken steps concerning PCB's and phosphates. Several states are concerned with chlorofluorocarbons. New Jersey, Texas, and California have very broad concerns over the heavy concentrations of the chemical industry and can be expected to expand efforts in the near future.

Central to the way industry does business are the policies and the attitudes of the financial community concerning investment capital. TSCA, in effect, adds one more risk dimension in the investment world. As this community begins to focus on toxic substances, it needs access to reliable and timely data. The information must be packaged in an understandable and usable form. Meanwhile, the insurance industry is rapidly expanding its interests in toxic substances, particularly with regard to product liability. The issue of substitutes for PCB's also sharpened concern over hazards associated with acceptability of substitutes. Both access to data and early awareness of possible TSCA regulatory actions are important to this side of the commercial community.

Other forces influencing the future directions of the chemical industry are the labor unions, environmental and public interest groups, and the consumer. In all of these cases the specter of possible harmful effects of chemicals can have a direct impact on industrial behavior. TSCA can provide important "early warnings" to these groups who in turn can provide the Government with other early warning signals.

A handful of the larger chemical companies who are responsible for a large proportion of chemical sales have for a number of years conducted sizeable programs to assess the environmental aspects of industrial chemicals. Although there have been many soft spots in these efforts, they nevertheless provide a good foundation for expanded activities. Complimentary efforts have also been supported by industry through a number of trade associations and most recently through the Chemical Industry Institute of Toxicology.

However, relatively few companies have adequate data available to conduct environmental assessments of the chemicals they buy and sell. Despite these shortcomings of the past, the greatest potential impact resulting from TSCA in terms of the number of chemicals that are addressed may lie in the expanded internal assessments and procedures of individual companies, activities that must rest on a solid base of environmental data.

Finally, as the Congress and the courts deepen their involvement in this area, the availability of experts that they can call upon and the credibility of scientific data take on added importance. TSCA will be an important tool for developing the information base which will undergird many major decisions of the future.

Policy Considerations

Several explicit TSCA mechanisms enable interested parties to obtain information. Perhaps the most far-reaching mechanism is the Interagency Testing Committee which provides for seven agencies, in addition to EPA, to set forth the highest priority needs for testing [4(e)]. The provision for citizen's petitions allows any interested party to seek information under the testing and reporting sections of the law [21]. The requirement to place in the Federal Register notices of receipt of premarket data will alert parties concerned with new chemicals reaching the marketplace [5(e)]. The provision concerning disclosure of data clarifies some of the uncertainties concerning the public access to health and safety studies [14(b)]. Of course the overarching requirements of the Freedom of Information Act are designed to enable all interested parties to obtain information collected under TSCA and other laws. All of these explicit provisions of TSCA underscore the clear intent of the Congress that this legislation service the interests of many organizations in a variety of ways, and particularly with regard to acquisition and dissemination of data.

Therefore, EPA will emphasize coordinated approaches with other Federal agencies to the assessment and control of toxic substances, with particular attention to identifying common information requirements that can be best satisfied through TSCA. The Agency will actively solicit the views of other interested parties as well as to information needs. Information

acquired under TSCA will be made available as widely and as promptly as possible. In this regard the interests of the international community are particularly important as we consider the possibility of an international convention to deal on a global basis with the control of toxic substances.

A major effort will be made at the outset to insure that sound procedures are in place which will facilitate a flow of data to all interested parties. Since establishment of these procedural aspects will take priority, it will not be possible to respond to all requests for information to be collected under TSCA until adequate systems are in place to handle the flow. Even in the long run, it will continue to be necessary to prioritize the competing claims from many parties for information services under TSCA.

The Establishment and Operation of Data Systems

System for Receiving and Storing TSCA Data

Data received pursuant to TSCA will be retained in a discrete data system module with entry into and withdrawal from the system controlled, at least initially, by the Office of Toxic Substances. The TSCA data module obviously will be but one additional component to the much larger Governmental data systems covering toxic substances. To the extent feasible, the TSCA module will be made compatible with and linked to the other existing systems. Figure 11 sets forth the implementation timetable for data systems.

While the volume of data received under TSCA may be relatively small at the outset, this volume will probably grow rapidly. Therefore, from the outset the system will incorporate automated components as rapidly as possible. The system will be designed and time-phased so that data received in the initial implementation stages are compatible with data received several years into the future, thus avoiding the potential problem of recoding. Development in sub-modules is envisaged, with components (personnel, hardware, and software) added as implementation progresses and data volumes grow. At the outset, however, methods for coding, cataloging, and retrieving data will be established so that consistent ground rules will guide data requirements resulting from rulemaking activities.

The chemicals included in the initial inventory of existing chemicals [8(b)] will provide a core index for the system which will be expanded as the number of chemicals in the system grows. In general, production and use data obtained pursuant to premarket notification [5(a)] and discretionary reporting [8(a)] requirements will be entered from the outset into an automated system. Initially, test data will be retained

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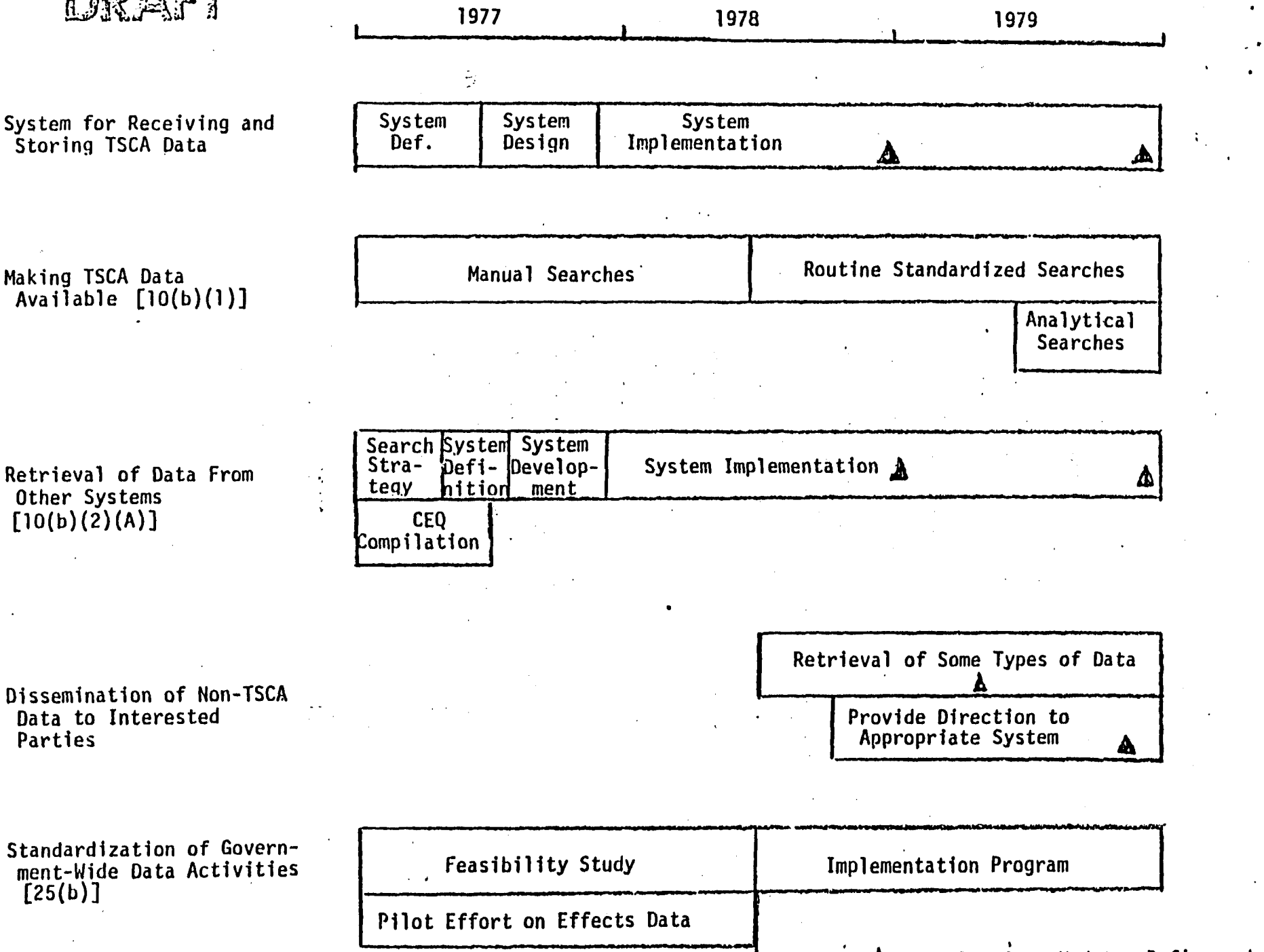
1977
1978
1979
System for Receiving and Storing TSCA Data
System Def.
System Design
System Implementation
Making TSCA Data Available [10(b)(1)]
Manual Searches
Routine Standardized Searches
Analytical Searches
Retrieval of Data From Other Systems [10(b)(2)(A)]
Search Strategy
System Definition
System Development
System Implementation
CEQ Compilation
Dissemination of Non-TSCA Data to Interested Parties
Retrieval of Some Types of Data
Provide Direction to Appropriate System
Standardization of Government-Wide Data Activities [25(b)]
Feasibility Study
Implementation Program
Pilot Effort on Effects Data
KEY = Evaluation, Update, Refinement

in hard copy with a locator tag incorporated into the automated system. A test data summary format which could be automated is currently being explored with the National Library of Medicine.

With regard to coding, CAS numbers and manufacturer identification will provide two keys. A chemical use coding system is currently under development to provide another key.

Access to confidential data will be strictly controlled and initially limited to the examination by authorized officials of available information in situ.

Making TSCA Data Available

EPA plans to aggressively develop and carry out procedures for disseminating to the public information obtained under TSCA. For example, test data will be submitted to EPA in sufficient copies so that one copy can be made publicly available without delay through the National Technical Information Service or other appropriate mechanism. Studies of the feasibility of establishing on-line terminal access to non-confidential data and of periodically publishing such data will be soon initiated.

Retrieval of Data from Other Systems

There are many sources of external technical, scientific, and economic data which should be utilized in implementing TSCA. These sources are located both within and outside the Federal government. CEQ is presently conducting a survey of such data bases. Meanwhile, some states are initiating additional toxic materials data banks. These data activities in particular will be examined in some detail with an eye toward reducing reporting requirements, on the one hand, and avoiding duplicate data searches during examinations of chemical for potential hazards, on the other.

Dissemination of Non-TSCA Data to Interested Parties

Many parties are interested in improved ways for tapping the multiplicity of Governmental data banks concerning chemicals. As part of the overall data system effort, practical means for facilitating such access will be explored. Initially, an inventory of existing data bases is being conducted. Hopefully, meaningful road maps to Governmental data can be provided to all interested users in the future.

Standardization of Government-Wide Data Activities

Data standardization is particularly important when considering interlocking data systems. Data required by TSCA rulemaking should be requested in a format which can be used readily by a multiplicity of interested parties. As an initial step towards improved standardization of Government-wide approaches, emphasis will be given to standardizing

the formatting and dissemination of newly collected data on health and ecological effects. At a later date, the effort will be expanded to include other types of data, and as time and resources permit, efforts will be directed to achieving compatibility of data already in the files of many agencies with the newly collected and standardized data.

TYPES OF ANTICIPATED IMPACTS FROM IMPLEMENTATION ACTIVITIES

The types and extent of the impacts that will result from implementation activities are speculative at best, given the many uncertainties concerning the effects of chemicals and their behavior in the environment, the large number and variety of chemical products, and the continuing rapid growth of the chemical industry. The five years of Congressional testimony included many general statements concerning the environmental benefits that are likely to ensue. A number of unfortunate chemical incidents were cited as examples of the types of problems that can be avoided. On the economic side, the EPA report Draft Economic Assessment of the Impact of the Toxic Substances Control Act of June 1975, as well as economic assessments prepared by industry and by the General Accounting Office, attempted to identify some of the types of direct impact that will undoubtedly occur. However, those discussions were very limited, and little effort was made to address indirect impacts.

The following discussion provides but a very superficial framework for the impact evaluation effort that will accompany implementation activities.

Health and Environment

A primary legislative concern is reducing adverse health effects, and particularly chronic effects. The legislation should offer an opportunity to clarify the health effects of many chemicals and, over time, to reduce the number of deaths and the disease rates attributable to such effects. Also, the possibility of preventing acute effects will be addressed.

Data obtained under TSCA should enhance the capability of OSHA, MESA, and state authorities to reduce the incidence of worker deaths and diseases. Other agencies and organizations which obtain information and support under this legislation should also assist in preventing adverse health impacts at the national and local levels.

The likely impact of TSCA on reducing ecological damage is even more difficult to predict. The early experience in addressing PCB's (i.e., destruction of aquatic resources) and chlorofluorocarbons (i.e., depletion of the ozone layer) clearly demonstrates the importance of the legislation in this regard. A number of toxic chemicals end up in the aquatic environment where ecological damage can be extensive. Prevention of such damage will largely depend on the specific regulatory actions. Ecological test requirements should assist in clarifying the impact of chemicals on the eco-system and in setting quality standards for water and other media under other authorities. This aspect of environmental assessment has been largely neglected by industry in the past.

Commerce and the Economy

Implementation requirements will add a new dimension in financial planning within industry for the development, manufacture, and marketing of chemicals. For example, there will be far greater reluctance to expand commercial investments in chemicals of questionable toxicity, and the search for broader applications of chemicals which are environmentally acceptable will intensify. Some marginal products for which testing is required may give way to substitutes which become commercially competitive. Many firms will be far more cautious in purchasing or selling products of unknown chemical composition. The ripple effect of such adjustments in current marketing practices will impact on a broad range of downstream processors and users.

There will probably be a tendency among some of the larger companies toward greater self reliance on in-house chemical assessments of old and new chemicals and on conducting their own synthesis of small batches of highly reactive chemicals previously purchased from small suppliers. Given the concern over quality control of test data and the shortage of laboratory facilities, in-house toxicological and ecological testing laboratories should become more commonplace. Meanwhile, small firms may tend to move away from product lines that become targets for TSCA attention.

The international development and marketing strategies of multinational firms will also be impacted. Test marketing may be more heavily concentrated in countries where premarket requirements are minimal. Also, there may be a surge of new chemical imports into the United States to establish them as "existing" chemicals and, thus, eliminate the notification period for future imports. In general, more careful planning of international shipment of chemicals will be required.

Industrial Research and Development

Premarket notification requirements and premarket testing requirements will cause some adjustments in the R&D cycle. In a few cases, the testing requirements may in large measure codify existing industrial practices. In most cases, however, the new requirements will alter substantially the time phasing, the types of expertise, and the review processes involved in developing new chemicals. These adjustments will in turn impact on (a) the decisions as to which new chemicals and products should be explored and then developed, (b) the criteria for investing in R&D when there is an increased risk for commercial introductions, and (c) the efforts to "design around" potentially troublesome chemicals from the environmental viewpoint.

The number and quality of environmental assessments conducted by industry should increase markedly. More qualified technical personnel will be attracted to the field, methodological approaches will be significantly

upgraded, and the quality assurance procedures will be improved. However, should Governmental requirements "over-standardize" assessment techniques, there is a danger that industrial creativity in improving the state-of-the-art of environmental assessment could be stifled.

In the early years of implementation, the number of new chemicals reaching the marketplace may decline due to uncertainties as to future regulatory requirements, technical and financial difficulties in adjusting to the new procedural requirements, and the increased R&D costs and lead times for some products with limited market potential. However, in the longer run innovation in introducing new products need not be stifled. More intensive investigations of environmentally acceptable chemicals, coupled with incorporation of premarket requirements into a routine R&D cycle, should continue to allow ever expanding benefits to the consumer from the uses of chemicals.

The Scientific Base

The heavy emphasis in the legislation on improving the scientific methodologies undergirding chemical assessments, and the attendant implications for strengthening the technical manpower base, should have a major impact on the chemical and biological sciences. Not only will the legislation give impetus to the advancement of these individual disciplines, but it should stimulate a closer coupling of these disciplines with engineering, economics, and other areas of imporance to toxic substances control. This general impetus to the broad spectrum of sciences may far overshadow the scientific impact of individual regulatory actions.

The inadequacy of science to provide clear answers for regulatory decisions will probably be subject to frequent criticism by many impatient parties. However, carefully documented scientific investigations will be a key to many actions. There is no doubt that the importance of credible technical data, albeit inconclusive, will be widely recognized.

All should benefit from the expanded sharing of scientific data. The importance of common procedures and common formats in carrying out and reporting scientific investigations will take on added importance as the problems involved in exchanging noncompatible data bases become clear.

Social Concerns

Many of the impacts cited above are tied to social concerns, such as employment effects, increased costs of products, and rights of inspection. However, there are even more fundamental social concerns which will be affected by TSCA implementation such as:

-- How much effort should be directed to protecting the welfare of future generations?

-- To what extent should the public participate in decision-making that has previously been the exclusive domain of private industry?

-- How are health concerns to be balanced with economic costs in determining "unreasonable risk"?

There is little experience in measuring the types of social impact that could far outweigh in importance the other more narrow impacts of this legislation. A continuing effort to identify and understand these impacts is the key to determining the value of TSCA as an instrument of public policy.